Risk Factors Comparison 2024-03-11 to 2023-03-23 Form: 10-K

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Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 1A. " Risk Factors " in this Annual Report. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include the following: ● we have incurred operating losses and may continue to do so for the near- term future, and we cannot assure you that we will be able to generate sufficient revenue to achieve or sustain profitability; ● ~~adverse changes in general domestic and global economic conditions and instability and disruption of credit markets could adversely affect our business, financial condition, results of operations and liquidity; ●~~ we have identified conditions and events that raise substantial doubt regarding our ability to continue as going concern ~~; ● our long- term growth depends on our ability to enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings~~ ; ● the regulatory approval, certification and clearance processes of the FDA and comparable foreign authorities and notified bodies are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval or other marketing authorizations for our products and product candidates, our business will be substantially harmed; ● **we face the** ~~a substantial portion of our net sales is generated through our commercial partners and independent sales agents, which subjects us to various risks~~ **risk** ~~; ● our revenue~~ **of product liability claims** and ~~profitability could~~ **may not** be **able** ~~materially and adversely affected if we fail~~ to **obtain or** maintain **adequate** ~~our relationships with our existing contract manufacturing customers or enter into agreements with new contract manufacturing customers, or if existing contract manufacturing customers reduce purchases of our products~~ **product liability insurance** ~~. Our relationships with these customers also subject us to certain risks~~ ; ● we face significant litigation related to FiberCel **and VBM** ; ● ~~we face the risk of product liability claims and may not be able to obtain or~~ **our long- term** ~~maintain adequate product liability insurance; ● our future~~ growth depends on **our ability to enhance** ~~physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost- effectiveness of~~ our products ~~; ●~~ **, expand** our ~~success depends on the continued and future acceptance of our products~~ **product indications** ~~by the medical community; ● we face significant~~ and **develop** ~~continuing competition from other companies~~ , **acquire and commercialize additional** ~~some of which have longer operating histories, more established products~~ **product offerings** ~~and / or greater resources than we do, which could adversely affect our business, financial condition and results of operations; ● pricing pressure as a result of cost- containment efforts of our customers, purchasing groups, third- party payors and governmental organizations could adversely affect our sales and profitability; ● the processing of human and porcine tissue for our products is technically complex, requiring high levels of quality control and precision, which subjects us to increased production risks~~ ; ● because we depend upon a limited number of third- party suppliers and manufacturers and, in certain cases, exclusive suppliers for products essential to our business, we may incur significant product development costs and experience material delivery delays if we lose any significant supplier, which could materially and adversely affect our business, financial condition and results of operations; **● a substantial portion of our net sales is generated through our commercial partners and independent sales agents, which subjects us to various risks; ● our ability to successfully realize the anticipated benefits of the sale of our Orthobiologics Business; ● 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, most 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;** 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 IItem 1. Business. ~~OverviewWe~~ **OverviewAt** ~~are~~ **Elutia, our mission is to humanize medicine so that patients can thrive without compromise. As** a commercial- stage ~~regenerative medicine~~ company **, we** ~~focused on creating the next generation of differentiated products and improving outcomes in patients undergoing surgery. We~~ seek to leverage our unique understanding of biologics to improve the interaction between **implanted** medical devices and patients **by** ~~, with the goal of~~ reducing complications **associated with** ~~and improving healing. From our proprietary tissue processing platforms, we have developed a portfolio of advanced regenerative medical products that are designed to mimic the~~ **these surgeries** ~~healing response of natural biological material~~ . ~~Our proprietary~~ **These complications include device migration, erosion, non- union of implants as well as implant rejection. In addition, our** products are designed to ~~address~~ **mitigate** the **formation of scar and fibrotic capsule formation that commonly occurs with** device **implants** ~~protection, women' s health, orthobiologics~~ and **is linked** ~~cardiovascular markets, which we believe represent a combined $ 3 billion market opportunity in the United States. To expand our commercial reach, we have commercial relationships~~ with **additional risk factors including infection** ~~major medical device companies, such as Boston Scientific, Biotronik~~ and **capsular contracture** ~~beginning in March 2023, Sientra, to promote and sell some of our products~~ . We ~~believe our~~ **are dedicated to supporting patients by providing physicians with a consistent product of uniform material, thus enabling surgeons to** focus on **achieving** ~~our unique regenerative medicine platforms will ultimately maximize our probability of continued clinical and commercial success~~ **successful outcomes** ~~and will create a long- term competitive advantage~~ for ~~us~~ **complex procedures** . We estimate that, over the past two years, ~~approximately two million patients~~ **more than 600, 000 surgical procedures were performed** per year in the United States

~~were~~ **in which the patient was** implanted with ~~either~~ medical devices ~~,~~ such as pacemakers, defibrillators, neuro- stimulators ~~, spinal fusion and trauma fracture hardware~~ or tissue expanders for breast reconstruction. This number has been driven by advances in medical device technologies, reimbursement models focused on patient outcomes, and an aging population with a growing incidence of comorbidities, including diabetes, obesity and cardiovascular and peripheral vascular diseases. These comorbidities can exacerbate various immune responses and contribute to other complications upon device implant. ~~3Our~~ **Our** products are targeted to address unmet clinical needs with the goal of promoting healthy tissue formation and avoiding complications associated with medical device implants, such as ~~infection,~~ scar ~~-~~ tissue formation, capsular contraction, erosion, migration ~~, non- union of implants~~ and implant rejection. **These** ~~We have~~ products **currently focus on** ~~in each of our four~~ **our** priority markets ~~: – device~~ **Device** ~~protection~~ **Protection** ~~, cardiovascular, orthobiologies~~ and ~~women~~ **Women** ' s ~~health~~ **Health** . In ~~device~~ **Device** ~~protection~~ **Protection** , we sell ~~the only~~ **CanGaroo, a " first- to- market "** biological envelope, protected by a global patent portfolio, that **is indicated** ~~forms a natural, systemically vascularized pocket~~ for ~~holding~~ **use with** ~~implanted~~ **implantable** electronic devices **including cardiac and neurostimulator devices. CanGaroo is designed to create a secure pocket to hold the device and mitigate complications such as device migration and erosion. The CanGaroo product is a biomatrix comprised of extracellular matrix (" ECM "), which has been shown to 3support healthy wound healing. Because of this inherent ECM trait, CanGaroo may facilitate re- operative procedures by mitigating scar formation and fibrosis** . In **addition, the CanGaroo envelope is the only envelope designed for subcutaneous implantable cardiac defibrillators, a growing market. In Women' s Health, we have developed both patented and proprietary technologies, culminating in the creation of SimpliDerm — a novel biological matrix designed to leverage the inherent science of natural healing processes. SimpliDerm' s design uses human acellular dermal matrices with heightened structural integrity and superior handling capabilities, which may mitigate inflammation and tissue incorporation, leading to a better healing experience. We believe that these acellular dermal matrices represent an optimal choice for tissue repair and reconstruction, finding applications in fields such as sports medicine, hernia repair, and trauma reconstruction. These matrices are also useable in breast reconstruction surgeries, particularly for women undergoing mastectomy as part of cancer treatment. With respect to pipeline products, we are seeking to pioneer drug- eluting biomatrices (" DEB "), to help solve problems unaddressed by currently available options. One such product is a version of CanGaroo currently known as CanGarooRM, a first- in- class biomatrix that combines the CanGaroo envelope with antibiotics. These antibiotics, rifampin and minocycline, have been shown to reduce the risk of infection following surgical implantation of an electronic device. CanGarooRM will require clearance of an FDA 510 (k) submission to be marketed in the United States. If approved, we anticipate CanGarooRM will be the only drug- eluting biomatrix approved for use with implantable electronic devices, and the first envelope that helps protect against infection, erosion, migration and complications associated with fibrotic tissue formation providing both acute and long- term benefits to the patient. We also intend to leverage our DEB platform technology by developing and commercializing products for markets with similar unmet needs, such as neurostimulation and breast reconstruction. We also sell legacy products into the** ~~cardiovascular~~ **Cardiovascular market. In Cardiovascular** , we sell our specialized porcine small intestine submucosa ~~(" SIS ECM ")~~ **, which is also the tissue used to make CanGaroo,** for use as an intracardiac and vascular patch **as well as for pericardial reconstruction** . In ~~orthobiologies~~ **addition** , **our TYKE product is designed** ~~we have a proprietary processing technology~~ for ~~manufacturing a comprehensive portfolio of bone regenerative~~ **use in the neonatal patient population. These cardiovascular** products ~~designed to promote~~ **are sold in** the **United States through an exclusive agreement** ~~body' s ability to regenerate healthy bone, osteogenesis, while decreasing cell apoptosis, or programmed cell death. In women' s health, we have a patented cell removal technology that produces undamaged extracellular dermal matrices~~ with ~~superior handling~~ **LeMaitre Vascular** , ~~designed to promote faster healing and reduce inflammation. In~~ **Inc** ~~pre- clinical and clinical studies, our products have supported and, in some cases, accelerated tissue healing, which has contributed to improved patient outcomes~~ . **(" LeMaitre Vascular ")** ~~We operate in four segments that align with our major product groupings – Device Protection, Women' s Health, Orthobiologics~~ and ~~Cardiovascular~~ **internationally through distributors** . Our ~~product portfolio and contract manufacturing capabilities within each of these segments are highlighted in the table below. 4Our~~ growth strategy is focused on increasing penetration in ~~each of~~ the ~~device~~ **Device** ~~protection~~ **Protection** , ~~and~~ ~~women~~ **Women** ' s ~~health~~ **Health** , ~~orthobiologies and cardiovascular~~ markets. We believe we can grow our business by increasing our commercial footprint, developing clinically exceptional products and, when possible and appropriate, through inorganic opportunities. ~~5Our~~ **Our** go- to- market strategy includes a ~~hybrid~~ **combination** of a direct sales force, commercial partners and independent sales agents. **CanGaroo is sold through both our internal sales force and independent sales agents and our commercial partner, Boston Scientific.** As of December 31, ~~2022~~ **2023** , we had ~~24~~ **12** direct sales representatives who focus on gaining additional market access and driving market penetration **for CanGaroo** , not only by selling ~~our~~ **such** ~~products~~ **product** , but also, where appropriate, by managing our commercial ~~partners~~ **partner** and providing technical assistance for selling our products. **SimpliDerm is sold through both independent sales agents and our distributor, Sientra Inc. (" Sientra ").** Through our direct sales force and leveraging our existing commercial partners **and sales agents** , we believe we can expand our customer base and further strengthen our existing customer relationships and increase penetration in our priority markets. We have a well- established and scalable **internal** manufacturing ~~platform, consisting of two facilities~~ **facility along with** ~~that are supported by~~ our corporate headquarters and other administrative location ~~. Our Silver Spring, Maryland location is our headquarters and functions as a research and development and corporate support center~~ . Our Roswell, Georgia location is our processing, production and distribution facility for all of our implantable electronic device protection and cardiovascular products. Our ~~Richmond~~ **Silver Spring** , ~~California~~ **Maryland** location is our **headquarters** ~~human tissue processing~~ and **functions as a research** ~~distribution facility for our orthobiologics~~ and ~~soft tissue reconstruction products~~ **development and corporate support center** . Our San Diego, California location provides additional administrative oversight and support. ~~We believe~~ **With**

the sale of our Orthobiologics Business in November 2023 to Berkeley (as described in further detail below), we **no longer operate our former Richmond, California human tissue processing and distribution facility; however, we continue to** have ~~sufficient~~ **a contract manufacturing relationship with Berkeley under which we receive SimpliDerm. 4Sale of Orthobiologics BusinessOn November 8, 2023, we completed the sale to Berkeley of substantially all of the assets of our Orthobiologics segment (the " Orthobiologics Business "), which were comprised of assets related to our business of (i) researching, developing, administering, insuring,** operating ~~capacity at both~~ **, commercializing, manufacturing, selling and marketing** our ~~Roswell~~ **Orthobiologics products, and (ii) contract manufacturing of particulate bone, precision milled bone, cellular bone matrix, acellular dermis, soft tissue and other products. In the sale, we received approximately $ 14. 6 million, and we may earn up to an additional $ 20 million, in the aggregate, in the form of earn- out payments. The earn- out payments are equal to 10 % of the actual revenue earned by Berkeley in each of the five years after the closing of the sale from sales of specified Orthobiologics products under the purchase agreement (including improvements, modifications, derivatives and enhancements related to those products). The purchase agreement contains customary representations, warranties and covenants of the parties, and we, on the one** ~~and~~ **hand** ~~Richmond~~ **, and Berkeley, on the other hand, agreed to customary indemnification provisions for breaches of representations, warranties and covenants, as well as assumed and excluded** ~~facilities~~ **liabilities** ~~to support future growth~~ **and pre- closing items** . Our Competitive ~~StrengthsOur~~ --- **Strengths Our** mission is to provide advanced regenerative care products that improve the outcomes in patients primarily undergoing implantable device- related surgery. To accomplish this mission, we intend to establish our products as the standard of care for treating patients undergoing such procedures. We believe our key competitive strengths position us well to execute on our growth strategy. Our key competitive strengths are: Our Integrated Company. Our end- to- end capabilities spanning research and development (**"** R & D **"**), manufacturing and commercialization ~~enables~~ **enable** us to continually advance our product portfolio and drive commercial growth. For example, our integrated structure allows us to receive market feedback from our sales team on unmet physician and patient needs, providing us with invaluable direction on our innovation priorities. It is this feedback **, for example,** that allowed us to refine our SimpliDerm product to **have,** what we believe to ~~have~~ **be,** industry- leading handling properties. ~~Our integrated structure also allows us to leverage our R & D capabilities to continually improve our manufacturing processes to lower our production costs.~~ Well- positioned in Large, Attractive and Growing Markets. We believe that the device protection, women' s health ~~,~~ ~~orthobiologics~~ and cardiovascular markets, which we believe **currently** represent a combined ~~$ 3 billion~~ market opportunity **of greater than $ 1 billion** in the United States, will continue to experience ~~accelerated~~ **significant** growth, given advancements in implantable medical device technologies and surgical techniques; shifting global demographics that include an aging population with a greater incidence of comorbidities, and increasing procedure volumes. We believe there is growing adoption of regenerative medicine products by the medical community as physicians become aware of the benefits of natural products, including improved healing and reduced inflammation, scar- tissue formation and foreign body response. ~~Regenerative Medicine Technology Focus. Our scientific expertise, commercial- scale manufacturing and know- how in regenerative medicine technology has allowed us to develop and process our proprietary platforms to create differentiated biomaterials, including our CanGaroo, ProxiCor, Tyke, VasCure, Fiber VBM, ViBone, OsteGro V and SimpliDerm product lines. These types of products, which are designed to more closely resemble natural products than highly processed or synthetic substitutes, have enabled us to advance the science of regenerative medicine as well as to process tissue and produce products at commercial scale. Broad Portfolio of Regenerative Medicine Products to Address the Needs of Physicians, Patients and Providers. Physicians use our broad portfolio of regenerative medicine products to meet the needs of individual patients. The breadth of our current portfolio, which includes products used in device protection, women' s health, orthobiologics and cardiovascular markets, gives us the flexibility to target a broad set of procedures, each with a full suite of products to accommodate both the clinical and economic factors that may affect purchasing decisions. Our experienced contracting and direct sales force teams are highly trained to assist clinicians in effectively selecting and using the full complement of our products. 6Large~~ - **Large** and Growing Body of Clinical Data. We have and continue to develop a body of pre- clinical, clinical and patient outcomes data, including third- party publications and patient registries that provide evidence supporting the technical and clinical attributes of our products. We believe that our extensive in vivo and clinical data give us a competitive advantage. Commercial Relationships with Major Medical Device Companies. We have commercial agreements with major medical device companies, including our strategic relationships with Boston Scientific, ~~Biotronik and beginning in March 2023,~~ Sientra **and LeMaitre Vascular** , which, along with others, we collectively refer to as our commercial partners, to promote or commercialize some of our products. These commercial partners use their own network of **approximately** ~~more than~~ 1, ~~400~~ **100** sales representatives, clinical specialists and independent sales agents, including approximately 1, ~~200~~ **000** of which are focused on our CanGaroo product. We leverage this additional presence in targeted markets to significantly increase our opportunity to cost- effectively penetrate these large markets. ~~Established and Scalable Manufacturing and Commercial Infrastructure. We have well- established relationships to obtain the human and animal tissues, which we need to manufacture our products, in the quantity needed and in a manner that preserves their integrity. We have sufficient capacity to increase the scale of our manufacturing, and the required quality control and regulatory capabilities to ensure that our products meet established specifications. We have developed rigorous medical, clinical, manufacturing, distribution and logistics capabilities designed to comply with FDA requirements. We pair our operational capabilities with a strong commercial team of sales, marketing and contracting professionals. Our established regulatory, operational and commercial infrastructure provides a firm foundation for growth as we continue to scale our business.~~ Executive Management Team with Extensive Experience in Regenerative Medicine. Our executive management team has extensive experience in the regenerative medicine and medical device industries, spanning R & D, operations, manufacturing and commercial. This experience allows us to operate with a deep understanding of the ~~underlying~~ **5underlying** 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 StrategyThe 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 **, Boston Scientific, Sientra and LeMaitre Vascular** that have well- established and significant ~~cardiac rhythm and orthopedic / spinal sales~~ infrastructure and experience in our target markets. **Pipeline** ~~We believe the breadth and flexibility~~ of **Innovative Drug- Eluting Biologics Products. In December 2023, we submitted a 510 (k) premarket notification to the FDA for** our ~~current portfolio of~~ **next- generation DEB** ~~products~~ **product** ~~provides~~ **, CanGarooRM. CanGarooRM is tailored for** ~~us~~ **use** with **cardiac** ~~the capability to address a wider variety of~~ implantable **electronic** ~~device~~ **devices** ~~procedures and soft tissue reconstructions~~ **(" CIED ")** , **such as pacemakers** ~~all of which should offer significant new growth opportunities. Robust Pipeline of Innovative Core Products from Our Proven Research~~ and ~~Development Capabilities~~ **internal defibrillators, currently served by only one competitor** . **CanGarooRM will require** ~~We have brought to market two commercial products in the past three years. We intend to continue to pursue~~ FDA clearance **of the 510 (k) submission to be marketed in the United States. The Company anticipates an approval decision in the first half of 2024 and is now preparing** for **commercial** ~~the next- generation of our flagship CanGaroo product, the CanGaroo RM. CanGaroo RM is a device- protection pouch designed to combine the regenerative properties of biological materials with the antibacterial effects of two antibiotics. If cleared by the FDA, we plan to~~ launch ~~CanGaroo RM in collaboration with our commercial partners and maximize market penetration~~ . **Furthermore** ~~In addition to our current commercial products and our intended path involving CanGaroo RM~~ , we intend to **leverage our DEB platform technology by** ~~develop~~ **developing** ~~additional~~ **and commercializing** ~~product~~ **products** ~~candidates~~ for ~~the device protection, women' s health and orthobiologics~~ markets ~~. We will continue to conduct pre- clinical and clinical studies, gather patient data and perform other research to support the further adoption of our products in the marketplace. 7Additional 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~~ -- **similar unmet needs** , ~~in 2017~~ **including neurostimulation** , **wound care** ~~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 **breast reconstruction** ~~expanded our clinical and commercial teams, which provided us with the opportunity to form new partnerships and commercialize CanGaroo. As a result, we again accelerated the growth of our revenue stream. We will continue to evaluate possible acquisitions that complement our existing portfolio and leverage our established commercial and manufacturing infrastructure~~ . Our Proprietary Products / SolutionsOur portfolio of regenerative medicine products has been developed to address the following specific markets: **Device** ~~WOMEN' S HEALTH RECONSTRUCTIONORTHOBIOLOGICSDevice~~ Protection and Cardiovascular MarketsMarket ~~Opportunity~~**In OpportunityWe** ~~2019, we~~ estimate, based on industry sources and other third- party estimates, that there were more than 600, 000 procedures in the United States to install or replace implantable electronic devices (" IED "), such as pacemakers, pulse generators and defibrillators, as well as spinal cord neuromodulators and vagus nerve, deep brain and sacral nerve stimulators, which represents an estimated $ 600 million opportunity. Limitations of Existing SolutionsIEDs are now the standard of care for patients suffering from cardiac arrhythmias and heart failure. Such devices, ~~cardiac implantable electronic devices (" CIED~~ **CIEDs** ~~")~~, are implanted in soft tissue, which is not heavily vascularized, and its implantation may trigger a biologic response that results in inflammation and fibrosis, leading to the device and its wire leads being encased in dense or calcified fibrous material. In 2015, a group of third- party researchers published a systematic review and meta- analysis of 60 published reports, consisting of 21 prospective, nine case- control and 30 retrospective cohort studies published between 1981 and 2013, each of which examined the rate of infection associated with the implantation of electronic devices. The average rate of infection was between 1. 0 and 1. 3 % and the reported rates of infection ranged from 0. 3 % to 16. 4 %. In 2019, a different group of third- party researchers published the results of a global, prospective randomized clinical study focused on infection complications of implantable electronic cardiovascular devices which identified a 1. 2 % infection rate during 12- month follow- up in the control arm (3, 488 patients), and this was later reported by other third- party researchers in 2020 to rise to 1. 9 % at the 36 months follow- up. However, infection is not the only significant complication associated with implantation. Data from third- party studies published in 2011 and 2016 indicated that migration occurred in 0. 5 % to 10. 9 % ~~8of~~ **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~~ **6with** 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~~ **released the antibiotics rifampin and minocycline** over a period of **approximately one** ~~seven to ten days, during which time the antibiotics rifampicin and minocycline were~~ **week** ~~released~~. In 2013, TyRx replaced the original product with AIGISRXR, a comparable product with the same two intended uses, but ~~totally~~ **fully** bioresorbable. In 2014, Medtronic acquired TyRx and now sells this ~~totally~~ **fully** bioresorbable synthetic product under the name TYRX. **The utilization of** TYRX ~~is~~ **,** a ~~relatively stiff~~ synthetic mesh ~~with rough edges~~ **employed as an envelope to deliver antibiotics in surgical procedures, presents several challenges. Notably, the material' s rigidity and limited** ~~available~~ **availability** in only two sizes ~~, which may~~ require ~~the surgeon to make a~~ larger ~~incision~~ **incisions during implantation** ~~than is needed only to implant the electronic device~~. ~~The~~ **These characteristics** ~~larger incision~~ can **potentially** lead to ~~longer~~ **extended** surgery times and complications **during subsequent** ~~at the time of replacement or upgrade of the implantable~~ device **replacements or upgrades** . **Furthermore** ~~Third- party studies have shown that the synthetic TYRX mesh is broken down and reabsorbed within approximately nine weeks. According to published literature~~ , ~~synthetic mesh, unlike biological mesh, does not promote biological signaling needed to mitigate~~ the ~~anticipated and well- documented~~ foreign body response ~~that results in~~ **, which can lead to** the ~~production~~ **formation** of **fibrous capsules around synthetic material, poses significant hurdles. Excessive** scar tissue ~~to~~ **resulting** ~~form~~ **from this response may complicate** ~~a capsule surrounding an implantable~~ device **replacement and revision surgeries, highlighting potential issues with long- term outcomes** . ~~TYRX' s primary benefit~~ **Our SolutionWe estimate that there** is **currently a 7** to **11 % complication** ~~dispense antibiotics to reduce the~~ rate ~~of infection associated~~ with ~~device implantation~~ **CIED placement** . **CanGaroo** ~~Our SolutionCanGaroo~~ 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 **small intestine submucosa (“** 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 **all CIED** ~~various sized electronic~~ devices **commercially available** , 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 ~~9risk~~ **risk** of **thick** ~~capsular~~ **capsule** 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. ~~ProductDescriptionRegulatory PathwayCanGaroo 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 Device510 (k) Development~~ **7Development** PipelineWe **have developed** ~~are currently developing~~ a version of the CanGaroo Envelope, ~~the~~ **called** ~~CanGaroo~~ **CanGarooRM** ~~RM~~ , that combines the envelope with antibiotics **. These antibiotics, rifampin** and ~~is designed~~ **minocycline, have been shown** to reduce the risk of infection following surgical implantation of an electronic device. ~~Based on feedback from the FDA~~ **We refer to this combination of biologics with antibiotics as drug- eluting biomatrix** , **or DEB.** ~~CanGaroo~~ **CanGarooRM** ~~RM~~ will require clearance of ~~a~~ **an FDA** 510 (k) submission to be marketed in the United States. We submitted the required 510 (k) in April 2022 and, in March 2023, received a Not Substantially Equivalent ~~(“ NSE ”)~~ letter from FDA requiring us to address questions relating to drug testing, primarily a request by FDA to modify an in vitro drug release assay employed as a manufacturing control. **In December 2023, we submitted a** ~~We intend to address the questions raised in the NSE letter and continue to work with FDA for potential clearance via the~~ 510 (k) ~~pathway~~ **premarket notification to the FDA for our next- generation DEB product, CanGarooRM. The Company anticipates an approval decision in the first half of 2024 and is now preparing for commercial launch. If approved, we anticipate CanGarooRM will be the only drug- eluting biomatrix approved for use with implantable electronic devices, providing both acute and long- term benefits to the patient** . Commercial ApproachWe sell CanGaroo in the United States and globally using our direct sales force and our commercial ~~partners~~ **partner** , Boston Scientific ~~and Biotronik~~ , which ~~act~~ **acts** as **a** sales ~~agents~~ **agent** and ~~give~~ **gives** us access to approximately 1, ~~200~~ **000** sales representatives and clinical specialists to further expand our footprint and accelerate our sales. Our primary customers are electrophysiologists, cardiac surgeons and neurosurgeons. Our direct sales force is focused on gaining additional market access and driving market penetration, not only by selling our products, but also, where appropriate, by managing our commercial partners and providing technical assistance for selling our products. Our sales team provides the critical knowledge of the advantages that CanGaroo provides for patients over those of our competitors. We ship the product directly to hospitals. Cardiovascular **ProductsWe** ~~ProductsThrough 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 **for Cardiac Tissue Repair (“ CTR ”)** is cleared for use as an intracardiac

patch ~~or pledget~~ for ~~tissue repair~~ **repairs such as** ~~, i. e.,~~ atrial **and** ~~septal defect,~~ ventricular septal ~~defect~~ **defects** and suture- line buttressing, as well as for **pledgets** ~~the repair and reconstruction of the pericardium~~. ProxiCor **CTR** 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~~ **tissue** layer **versus** ~~. Typically, the absence of~~ a **synthetic patch which may calcify over time** ~~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~~ **Pericardial** ~~repair potentially avoids adverse events~~ **Closure (" PC ") is used to reconstruct the pericardium after heart surgery. Data shows that post- operative complications** associated with **open- heart surgery are reduced in patients who have had** ~~the~~ **their pericardium reconstructed. By providing a protective covering over** ~~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~~ **heart, ProxiCor PC may help protect the heart during repeat sternotomies**. ● 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 ~~10repaired~~ -- **repaired** cardiac structures; and as a patch material for intracardiac defects, septal defect and annulus repair, suture- line buttressing and cardiac repair. ~~We believe that~~ Tyke is the only extracellular material that has been specifically cleared for use in neonates and infants to repair ~~pericardial~~ **cardiac** structures. ● VasCure is cleared for use, and is used by, cardiovascular, vascular and general surgeons as, a patch material to repair or reconstruct the peripheral vasculature, including the carotid, renal, iliac, femoral and tibial blood vessels, by modeling into site- specific tissue and conforming to repair defects easily. VasCure is also cleared and is used for the closure of vessels, as a pledget, or for suture line buttressing when repairing vessels. ~~It is designed to prevent and stop bleeding, resulting in minimal bleeding at suture lines.~~ Unlike synthetic or cross- linked materials, VasCure approximates normal tissue and, we believe, is, therefore, less likely to provoke an immune response. ~~Women' s Health MarketMarket OpportunityAccording~~ **8In April 2023, we entered into an agreement with LeMaitre Vascular, a provider of vascular devices, implants and services, granting LeMaitre Vascular the exclusive U. S. distribution rights for the products within our cardiovascular segment: ProxiCor PC, ProxiCor CTR, Tyke and VasCure. The term of the collaboration is three years, and LeMaitre Vascular has the exclusive option** to **acquire the product line following the first year or under** certain third- party estimates, there were..... 2023, no biologic matrix or any other **circumstances** soft tissue reinforcement material, including our..... membrane as finished product for select customers. Clinical DataWe have accumulated a substantial body of clinical and pre- clinical data for our ~~proprietary~~ **device protection** products. We believe that the reported outcomes from our studies help to differentiate our products in the marketplace. **Pre** ~~Device ProtectionPre~~ - clinical **StudiesPublished** ~~StudiesRecently published~~ pre- clinical data from a rabbit model showed that the CanGaroo Envelope was more successful in providing a barrier surrounding a CIED compared to a pacemaker canister alone. When implanted with a pacemaker, CanGaroo Envelopes ~~were observed to promote~~ **promoted** significantly greater stabilization of the device and more vascularized tissue ingrowth within the pocket compared to implantation with only standard fixation methods, such as ~~14sutures~~ -- **sutures** through the CIED header or no fixation at all. These data were initially presented as a live podium presentation at the **American Society for Artificial Internal Organs (" ASAIO ")** 2022 annual conference and published in abstract form in ASAIO Journal. Clinical StudiesTo evaluate our CanGaroo Envelope, we have conducted multiple post- market studies and are currently conducting ~~retrospective~~ **prospective** studies ~~including~~ **that comprise** over 2, 000 patients in total. We believe the results from the completed studies provide evidence supporting the safety of the CanGaroo Envelope when used for the implantation of CIEDs in humans. CARE Study and SECURE StudyThe CARE Study ~~was~~ **,** a retrospective, post **-** market ~~study.~~ **investigation, gathered** ~~Data~~ **data** from 96 consecutive patients who underwent simultaneous **implantation of** CIED and CanGaroo Envelope ~~implantation~~ at a single institution ~~were retrospectively reviewed for the occurrence of CIED- related complications and infection~~. The SECURE Study ~~was~~ **,** a prospective, single **-** arm, observational, post- market study ~~assessing~~ **, included** 1, 026 patients **from** ~~enrolled at~~ 39 centers who underwent ~~the~~ **CIED** implantation **within** ~~of a CIED in~~ a CanGaroo Envelope. ~~The endpoints of the~~ **Combining data from both** studies **resulted in** ~~were to evaluate: (~~ a ~~) the proportion~~ **comprehensive analysis involving a total** of **1, 102** patients ~~with CanGaroo- related adverse events and (b) the incidence of major infections observed in the pocket. Data from these two studies were combined to determine overall clinical outcomes and adverse events, and resulted in a large dataset~~ from 40 centers ~~throughout~~ **across** the United States ~~of 1~~ **. The dataset** , ~~102 total patients~~ with an average ~~number~~ of 2. 3 infection risk factors **per patient** and **a** mean follow **-** up time of 223 days **, was utilized to evaluate overall clinical outcomes and adverse events**. ~~The most common~~ **Common** risk factors among **the** enrolled patients ~~included~~ **encompassed** oral systemic anticoagulants, obesity, diabetes, congestive heart failure, device replacement / revision, and renal insufficiency. This real- world dataset revealed physician practice patterns for usage of the CanGaroo Envelope, and the type of hydration solutions that were chosen by the treating physician. Physicians demonstrated a preference for usage of an antibiotic hydration solution in higher infection risk patients ($p <. 05$), particularly gentamicin, and those patients had an equivalent major infection rate to lower risk patients receiving a saline soaked CanGaroo ($p = NS$). Of the total sample population, 14 patients (1. 3 %) developed hematoma requiring intervention, and 12 patients (1. 1 %) developed a pocket infection- 10 of which (0. 9 %) came from the antibiotic without gentamicin hydration group. The use of gentamicin was associated with a threefold reduction in infection risk (OR 3. 0, 95 % CI, 1. 0 – 10. 0). A major contributing factor to pocket infection rate was whether the site also employed guideline recommended preoperative intravenous antibiotics (IV ABX) alongside use of an antibacterial envelope; sites utilizing IV ABX on ≥ 80 % of their patients had significantly lower infection rates than sites that used it on < 80 % of their patients (0. 8 % vs. 5. 6 %, $p =. 008$). There were no reports of device migration in the total dataset. These results were presented and published as separate sub- analyses of the dataset at multiple national conferences between 2017 – 2022, and collectively in a recent

publication, and highlight the importance of evaluating real world evidence for CIED envelopes, and conjunctive use alongside other guideline recommendations for high infection risk patients. We believe the low rates of CanGaroo Envelope complications observed in the CARE and SECURE Studies support the safety of the product when used clinically in human CIED implantation. ~~CARE~~ **9CARE** Plus StudyThe CARE Plus Study ~~was~~ **,** a single- center, post- market, retrospective cohort study ~~to evaluate~~ **, assessed** outcomes in patients ~~who received~~ **undergoing CIED implantation with either** a biologic CanGaroo Envelope, Medtronic' s non- biologic TYRX envelope, or no envelope ~~during CIED implantation. Adverse patient outcomes and any adverse events that occurred following implantation out to 12 months were analyzed~~ . The **study, published in Cureus in May 2022, included** results ~~of~~ **from** 455 patients (165 CanGaroo, 219 TYRX **,** and 71 no envelope) ~~were published in Cureus in May 2022~~ . ~~The results indicated~~ **Analysis of adverse patient outcomes and events occurring up to 12 months post- implantation revealed** that most patients with at least two infection risk ~~factors~~ - **factor** received an antibacterial envelope (77. 9 % any envelope vs. 52. 1 % no envelope, p <. 001). The overall rate of adverse events was 9. 2 % (n = 42) ~~.~~ **, with low** ~~Rates~~ **rates** of pocket infection (0. 4 %) and hematoma (2. 6 %) ~~were low~~ , ~~with~~ **and** no significant differences between groups in overall or individual adverse event rates. ~~We believe~~ **The findings suggest** ~~these~~ -- **the potential benefit** ~~data support the use~~ of antibiotic **-** eluting CIED envelopes ~~to limit~~ **in reducing** infection risk ~~in~~ **for** high- risk patients. ~~A~~ **The study also presented a** decision tree **to** ~~was proposed by the author based on their patient selection criteria for real world envelope usage and other supporting data that may~~ aid clinical decision- making **regarding** ~~when considering~~ CIED envelope usage. ~~15HEAL~~ -- **HEAL** StudyThe HEAL Study **was a** ~~is an ongoing~~ retrospective cohort study of CIED patients who ~~are~~ **were** presenting for ~~their latest~~ reoperation after a ~~previous~~ **prior** implantation ~~that is~~ **. The study was** designed to ~~identify and~~ compare the characteristics of soft tissue healing surrounding **CIED** ~~cardiovascular implantable electronic device~~ implants **with or without an envelope** . ~~As~~ **A total** of **46 patients** ~~December 31, 2022 there~~ were ~~45 patients~~ enrolled **, categorized into** ~~. Patients evaluated in the study will be from one of~~ three cohorts based on whether a biologic CanGaroo Envelope, Medtronic' s non- biologic TYRX Envelope, or no envelope was ~~used~~ **employed** during ~~the~~ **their** prior implantation. ~~At~~ **During** reoperation, the current implant pockets of the patients **were** ~~will be~~ examined and compared ~~by~~ **using both** a blinded histological biopsy and ~~visually~~ -- **visual** ~~using~~ **assessment through** photographs. ~~An~~ **Positive outcomes from the HEAL Study, were presented at Heart Rhythm Society (HRS 2023). The study assessed patients who underwent CIED implantation with CanGaroo Envelope, Medtronic' s TYRX non- biologic envelope, or no envelope, returning for a revision procedure at least four months post- implantation. In the** interim analysis **of 43** ~~was performed in May 2022 on 21~~ patients **,** ~~that were enrolled at the time (9~~ CanGaroo **demonstrated statistically significant advantages** ~~and 12 no envelope) as of a cutoff date of April 25~~ , **with reoperations scoring 46** ~~2022, and the results were presented as a poster at the American Heart Association (AHA) Conference in November 2022 and published in Circulation. The CanGaroo cohort required 63~~ % **easier in generator mobilization** ~~fewer capsulectomies, and treating physicians scored capsular lead adhesion classification as significantly less severe than the no envelope cohort~~ (p =. 02) ~~. On a 10- point scale~~ , **41** ~~physicians scored CanGaroo reoperations as significantly less difficult in generator mobilization (39~~ % easier **in** ~~, p =. 04),~~ lead mobilization (**p =. 01), and** 43 % **less** ~~easier, p =. 01), and~~ overall procedural difficulty (~~45 % easier,~~ p =. ~~01~~ **04**) **compared to the no- envelope group** . ~~On average,~~ CanGaroo ~~capsules were found via blinded~~ **required significantly fewer capsulectomy procedures (83 % less, p =. 04), and** histologic **evaluation revealed 30** ~~assessment to have a 39~~ % thinner ~~fibrotic capsule~~ **capsules** compared to ~~the~~ no envelope ~~capsules~~ (p = **0** . ~~05~~ **12**) **and 32 % thinner capsules compared to TYRX (p =** . ~~Although the~~ **09). The** study **findings underscore** ~~is ongoing, we believe these~~ -- **the potential** ~~interim results suggest that use~~ of ~~a biologic~~ CanGaroo **to enhance** ~~Envelope at initial~~ CIED implantation **outcomes and streamline subsequent** ~~has the potential to prevent operative complications, facilitate~~ reoperative procedures ~~,~~ **. Final analysis is underway** and ~~enhance clinical outcomes~~ **will be reported upon completion** . CanGaroo S- ICD Pilot StudyA retrospective, single- center, post- market pilot study was designed to evaluate whether low voltage lead impedance (**"** LVZ **"**), as routinely measured by subcutaneous implantable cardioverter defibrillators (**"** S- ICDs **"**), could be a clinically relevant assessment. These devices sense changes in impedance, which could be influenced by fibrotic tissue surrounding the S- ICD. Such encapsulation could complicate future procedures for patients. LVZ changes from 0 to 4 years post implantation of ~~a~~ **an** S- ICD were analyzed in 24 patients, half of whom received CanGaroo Envelope and half received no envelope. LVZ measurements reliably detected changes in impedance over time and between groups. After an initial decrease in both groups in the first month, impedance changes appeared to increase more slowly in the CanGaroo cohort compared to patients in the no envelope cohort out to 30 months. The data, presented at the European Society of Cardiology 2022 Congress and published in European Heart Journal, suggest that LVZ may provide a non- invasive assessment of surrounding tissue quality. Further study is needed to determine whether use of a CanGaroo Envelope may stabilize impedance changes long- term. CanGaroo Registry StudyThe CanGaroo Registry Study is a prospective, multi- center registry ~~with~~ **that completed enrollment at** 500 patients ~~enrolled~~ (329 CanGaroo and 171 no envelope) **in** ~~as of~~ December ~~31~~ , 2022. The objective is to explore clinical profiles, procedural details, and post- implant outcomes of patients who received the CanGaroo Envelope or no envelope at time of initial (de novo) CIED implantation. All patients will be followed for three months postoperatively, and a subgroup of patients aged 65 years or younger at time of enrollment will undergo extended follow- up for up to five years. ~~breast construction surgery~~ **third- party estimates,there were more than 100,000 procedures** in the United States ~~grew 29 %~~ in ~~2022 versus 2020,with such~~ **2019 using biologic matrices for plastic and reconstructive** ~~surgeries~~ **surgery** ~~now~~ **,which** ~~constituting~~ **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** ~~appearing restoration~~ of the affected anatomical structure.Clinical practice of plastic and reconstructive surgery includes excision of tumors of the skin,vasculature,chest,oral and oropharyngeal cavities and extremities and reconstructions of the same;debridement,skin grafting and skin flaps for burn reconstructions;trauma surgery for the

hands,upper and lower limbs and facial region;congenital or acquired malformations related to the hands,face,skull and jaw;surgical removal of vascular abnormalities;a range of aesthetic surgeries;and reconstructions of the breast.One of the most common applications of biologic matrices in plastic and reconstructive surgery is breast reconstruction surgery **during or** after mastectomy.Mastectomy is a method of tumor removal for breast cancer in which all breast tissue,including the cancerous cells,is surgically removed. ~~It is estimated that~~ **In the United States in 2020,there were** more than ~~10~~ **100** ~~% of women will develop invasive breast cancer in their lifetimes,which in 2022,lead to approximately 150~~ ,000 post- mastectomy breast reconstructions ~~in the U.S.~~ ,of which approximately 66 % were **bilateral** operations ~~where~~ **,that is,** both breasts were reconstructed.Breast reconstruction surgery is a surgical procedure generally used to restore a breast to near normal shape and appearance and can be performed using either a prosthetic breast implant,referred to as implant- based reconstruction,or the patient' s own tissue,referred to as autologous reconstruction.Additional reconstructive surgeries may be required following the initial breast reconstruction,including breast lift,also known as mastopexy,or breast revision surgery,in which the surgeon adjusts the position and shape of the breast.In ~~2022~~ **2020** ,plastic surgeons used human acellular dermal matrices (" HADMs ") in approximately ~~76~~ **59** ,000 women (approximately ~~125~~ **98** ,000 breasts).The use of these materials is well- characterized in the clinical literature and recommended by recent U.S.and European consensus guidelines for certain surgical techniques.However,as of March **6,** ~~2024~~ **2023** ,no biologic **matrix or any** ~~Soft~~ **soft** ~~soft~~ tissue reinforcement material,including our product,had been approved or cleared by the FDA specifically for use in breast reconstruction surgery.Limitations of Existing SolutionsAutologous 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 ~~11and~~ -- **and lead to capsular contracture which occurs when scar tissue,or capsule,around the device tightens and squeezes the implant.This can** cause **both visible deformity as well as severe** pain ~~or other complications~~ .Other major issues are damage to the surrounding soft tissue,altering of the mechanical properties or appearance of the original tissue and increased risk of infection.HADM products offer an " off the shelf " biologic choice for reconstructive procedures,but they have their own limitations.The use of harsh chemicals to remove the cells can damage the extracellular matrix.The products can lack uniformity as determined by pliability in each direction,elasticity and non- uniform thickness.Such issues can affect how rapidly,and the extent to which the implant is integrated,as well as the resulting tissue strength.In addition,there is a limited availability in larger sizes for some of these products. ~~Our~~ **11Our SolutionWe** ~~SolutionSimpliDerm was~~ designed **SimpliDerm** to offer improved biocompatibility and better ~~functioning~~ **tissue integration** in the patient.It is marketed for use for the repair or replacement of damaged or insufficient integumental tissue or for the repair,reinforcement or supplemental support of soft tissue defects or any other homologous use of human integument.SimpliDerm is a pre- hydrated,HADM manufactured with our patented cell removal technology,a process that maintains the biological and structural integrity of the tissue' s extracellular matrix components and is designed to allow for rapid integration,cellular repopulation and revascularization at the surgical site.Its structurally intact extracellular matrix is designed to closely resemble natural,healthy tissue. ~~ProductDescriptionRegulatory PathwaySimpliDermHydrated human acellular dermis~~ **Development PipelineThe clinical literature suggests that greater than 10 % of breast reconstruction patients experience a post- operative infection and the treatment for many of these infections will require reoperation to explant the implant.To address this surgical complication,we are leveraging the technology used in CanGarooRM to develop a DEB version of SimpliDerm (currently called SimpliDermRM)** designed to **prevent** ~~be used for repair or replacement of damaged or inadequate integumental tissueHCT / PsDevelopment PipelineBreast implants are generally placed below the pectoral muscle,known as subpectoral positioning.This~~ **this serious** ~~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 ") Tissue~~ **issue. When developed, SimpliDermRM will require clearance of an FDA premarket approval (" PMA ") submission to be marketed in the United States. Commercial ApproachSince its launch in 2019, SimpliDerm has been sold through independent sales agents to plastic and** ~~ReconstructionPre~~ **reconstructive surgeons. In March 2023, we entered into an agreement with Sientra, a medical aesthetics company uniquely focused on plastic surgery, to expand the distribution of SimpliDerm. Under the agreement terms, Elutia has granted Sientra certain non- exclusive rights in the United States to market, sell and distribute SimpliDerm. This agreement with Sientra gives us access to approximately 50 sales representatives to further expand our footprint and accelerate our sales. On February 13, 2024, Sientra reported that it had filed for chapter 11 bankruptcy protection in the Bankruptcy Court for the District of Delaware, and that it received a debtor- in- possession financing from Deerfield Partners. Sientra also reported that it will seek a sale of its business under Section 363 of the Bankruptcy Code. While Sientra continues to operate as a debtor- in- possession and we continue to ship product with Sientra as our distribution partner, there can be no assurance that Sientra will be successful in its sale of business transaction or that the potential purchaser of the Sientra business will agree to assume our contracts with Sientra. Clinical DataWe have accumulated a substantial body of clinical and pre- clinical data for our women' s health products. We believe that the reported outcomes from our studies help to differentiate our products in the marketplace. Pre** - clinical StudiesIn vitro studies were conducted to evaluate and compare SimpliDerm to native human dermis and two other commercially available HADMs, in terms of morphological structure, composition, physical characteristics and chemical and thermal stability. Histology slides of SimpliDerm and native dermal matrix were examined microscopically, using three different stains. Stained samples of SimpliDerm retained the collagen

structure (density and orientation), elastin, blood vessels and basement membrane complex that was observed in the native dermal matrix. Transmission electron microscopy demonstrated intact collagen fibril structures in native dermis and SimpliDerm, supporting the conclusion that ~~16the~~ -- **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~~ **dermis** . These tests included glycosaminoglycan content, matrix protein stability and differential scanning calorimetry. The glycosaminoglycan content of SimpliDerm and ~~Alloderm~~ **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~~ **12to** 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 StudiesA retrospective, multi- center study evaluating patients who have undergone breast reconstruction post- mastectomy with SimpliDerm and patients receiving other HADMs ~~was~~ **has been** published. A total of 107 patients (181 breasts) who underwent immediate, 2- stage breast reconstruction with tissue expanders and either SimpliDerm (n = 38) or AlloDerm RTU (n = 69) after mastectomy, were followed to exchange to permanent implant (s) or tissue expander (s) explant. Reconstructions were predominantly prepectoral (82. 3 %). Patients were followed for a median of 134 days. A total of 35 adverse events (AEs) occurred in 27 (25. 2 %) patients, with no difference in AE type or rates between ADM groups, and no AEs deemed related. The observed AE profiles and rates were similar to those published for other ADMs in breast reconstruction. These results demonstrate comparable clinical outcomes of SimpliDerm and AlloDerm RTU following 2- stage breast reconstruction. ~~OrthobiologiesPre- clinical StudiesIn vitro and in vivo characterization studies were conducted to compare whether the manufacturing processes for our viable bone matrices improve certain product characteristics versus traditional viable bone matrix manufacturing processes. The characteristics evaluated addressed the three key elements for bone formation: osteogenesis, osteoconduction and osteoinduction. The assays included those for apoptosis, cell proliferation, osteogenic potential and osteoinduction, as well as for specific bone morphogenic proteins, bone formation factors, alkaline phosphatase and chemotaxis. Compared to viable bone matrices prepared with traditional processing methods, our viable bone matrices were superior in all of the characteristics examined, including less cell death. For example, our viable bone matrix formulations exhibited 58 % less apoptosis and had a two- fold greater cell proliferation capability as compared to allografts processed by traditional methods, suggesting greater osteogenic potential. One particular viable bone matrix formulation was tested for osteoinductive properties and was observed to have at least four- fold higher levels of bone morphogenic protein- 2 and bone morphogenic protein- 7 than traditionally processed allografts. An alkaline phosphatase (“ ALP ”) assay 17was used as an indicator to determine cellular activity after exposure to C2C12 cells, which are model cells used for evaluating differentiation to bone forming cells. The ALP activity of cells exposed to this viable bone matrix formulation was 6- fold greater than traditionally processed allografts. Clinical StudiesA prospective, multi- center, post- market clinical study was conducted to evaluate outcomes in 95 patients undergoing 1 – 3 level cervical (n = 48) or lumbar (n = 47) interbody fusion surgery using ViBone. Patients were evaluated clinically and radiographically at baseline, 6- and 12- months. Clinical assessment included Visual Analog Scale for pain (VAS- pain), the Neck Disability Index (NDI) for patients with cervical pathologies, and the Oswestry Disability Index (ODI) for patients with lumbar pathologies. Fusion success defined by an independent radiologist was determined radiographically by plain films. All patients reached the minimum clinically significant mean reduction in subjective pain and disability scores at 12 months. Spinal fusion rates as measured by independent radiologic evaluation were found to be comparable to the published rates of iliac crest bone autograft and other viable bone matrix grafts: at 12 months, the fusion rate per patient averaged 88. 1 % in cervical and 97. 6 % in lumbar patients, while per- level fusion was 98. 5 % for cervical and 100 % for lumbar segments.~~ CompetitionWe operate in highly competitive markets that are subject to rapid technological change. Success in these markets depends on product efficacy, ease of product use, product price, availability of payor coverage and adequate third- party reimbursement, customer support services for technical, clinical and reimbursement support and customer preference for, and loyalty to, the products. We believe that the demonstrated clinical efficacy of our products, the breadth of our product portfolio, our in- house customer support services, our customer relationships and our reputation offer us advantages over our competitors. Our products compete primarily with implantable electronic device envelopes and other cardiovascular repair ~~products, other orthobiologics~~ and human- derived acellular dermis products. The CanGaroo Envelope competes with the synthetic envelope TYRX from Medtronic. ProxiCor, Tyke and VasCure compete with bovine pericardium **and synthetic patch materials** produced by numerous companies, including Gore’ s ~~Goretex~~ **Gore- tex** 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 Biologies' VIA Graft and LifeNet Health' s ViviGen~~ . SimpliDerm competes primarily against human- derived acellular dermis matrix meshes, including AbbVie' s AlloDerm, **MTF' s FlexHD,** Stryker' s DermACELL and ~~MTF~~ **RTI Surgical** ' s ~~FlexHD~~ **Cortiva** . 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~~ **13Our** competitors' products in the soft tissue repair market have been ~~approved or certified and~~ available for use for multiple years. During this time, private payors have developed policies for coverage based on available data and literature. Third- party payors generally do not currently cover SimpliDerm or procedures using SimpliDerm. We are aware of several companies that compete, or are developing technologies, in our current and future product areas. As a result, we expect competition to remain intense. Our ability to compete successfully will depend primarily on our ability to develop proprietary products that reach the market in a timely manner, are used in procedures that receive adequate payor coverage and reimbursement, are cost- effective, and are safe and effective, as well as our reputation in the market and success of our sales strategy. See Part I, Item 1A. " Risk Factors- Risks Related to Our Business- We face significant and continuing competition from other companies, some of which have longer operating histories, more established products and / or greater resources than we do, which could adversely affect our business, financial condition and results of operations. " ~~18Sales~~ -- **Sales** and MarketingWe 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 **, which as of December 31, 2023, totaled 12 sales representatives,** and **through** our commercial ~~partners~~ - **partner** , Boston Scientific ~~and Biotronik~~ **Corporation (" Boston Scientific ")** , which ~~act~~ **acts** as **a** sales ~~agents~~ - **agent** , marketing CanGaroo and obtaining orders, and ~~give~~ **gives** us access to approximately 1, ~~200~~ **000** sales representatives and clinical specialists ~~to further expand our footprint and accelerate our sales~~ . Under the terms of ~~these~~ **this** ~~agreements~~ - **agreement** , Boston Scientific ~~and Biotronik receive~~ **receives** 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 **representatives** ~~force and other independent sales agents. Our commercial approach to the orthobiologics market has been to leverage commercial partners with existing sales and marketing infrastructure in these areas, while we~~ focus on ~~research~~ **gaining additional market access** and ~~development and the manufacturing of~~ **driving market penetration, not only by selling our** products ~~. We currently have an agreement~~ **, but also, by managing our commercial partnership** with ~~many commercial partners~~ **Boston Scientific and providing technical assistance** for **selling** ~~the sale of~~ our ~~viable bone matrix~~ products. ~~Under the terms of those agreements, these~~ **These sales representatives** ~~commercial partners purchase products from us at specified prices~~ and **agents** ~~resell such products in the United States to the primary customers, which~~ are **supported** ~~hospitals and other healthcare facilities. We fulfill most orders from our commercial partners~~ by ~~shipping these products directly to these hospitals~~ **teams of professionals focused on sales management, sales operations, ongoing training, analytics** and **marketing** ~~other healthcare facilities~~ . SimpliDerm, our women' s health product, is sold using independent sales agents **and** ~~which beginning in March 2023, includes~~ Sientra ~~. We may also explore additional~~ **, who Elutia has granted certain non- exclusive rights in the United States to market, sell and** ~~distribution~~ **distribute** ~~partnerships across our other product categories~~ **SimpliDerm for select use in reconstruction surgery** . **This agreement with Sientra gives us access to approximately 50** ~~As of December 31, 2022, we had 24 direct~~ sales representatives **to further expand our footprint** ~~who focus on gaining additional market access~~ and ~~driving market penetration~~ **accelerate our sales. Under the terms of this agreement** , ~~not only by selling~~ **Sientra purchases SimpliDerm through a transfer fee and sells it to the end user hospital** ~~our~~ - **or healthcare facility. On February 13, 2024, Sientra reported that it had filed for chapter 11 bankruptcy protection in the Bankruptcy Court for the District of Delaware, and that it received a debtor- in- possession financing from Deerfield Partners. Sientra also reported that it will seek a sale of its business under Section 363 of the Bankruptcy Code. While Sientra continues to operate as a debtor- in- possession and we continue to ship product with Sientra as our distribution partner, there can be no assurance that Sientra will be successful in its sale of business transaction or that the potential purchaser of the Sientra business will agree to assume our contracts with Sientra. Our cardiovascular** products, **ProxiCor** ~~but also~~ , ~~where appropriate~~ **Tyke and VasCure** , ~~by managing our commercial partners~~ **are sold in the U. S. through LeMaitre Vascular. In April 2023, we entered into** ~~and~~ - **an** ~~providing technical assistance~~ **agreement with LeMaitre Vascular granting them the exclusive U. S. distribution rights** for ~~selling~~ our **cardiovascular** products. ~~These~~ -- **The term** ~~sales representatives are supported by teams~~ of ~~professionals focused on sales management~~ **the collaboration is three years** , ~~sales~~ **and LeMaitre Vascular has the exclusive** ~~operations~~ ---- **option** ~~, ongoing training, analytics and marketing~~ **to acquire the product line following the first year or under certain other circumstances** . We have historically focused our market development and commercial activities primarily in the United States. However, we have obtained marketing registrations, developed commercial and distribution capabilities and are currently selling CanGaroo and cardiovascular products in several countries outside of the United States. Independent sales agents in Argentina, Australia, the European Economic Area, the European Union, Latin America and Mexico sell our products. Sales generated in the United States represented greater than ~~98~~ **97** % of our net sales in ~~2022~~ **2023 and sales of these products outside of the United States will largely cease after May 2024 due to changes in certain international regulatory rules which require investment by us not warranted by the current level of sales in these markets** . ~~Research~~ **14Research** and DevelopmentOur research and development team has extensive experience in developing regenerative medicine **and DEB** products and works to design products that are intended to improve patient outcomes, simplify techniques, shorten procedures, reduce hospitalization and rehabilitation times, and, as a result, reduce costs. We have recruited and retained staff with significant experience and skills, gained through both industry experience and training at leading colleges and universities. In addition to our internal staff, our external network of development laboratories, testing laboratories and physicians aids us in our

research and development process. Manufacturing and ~~SuppliersWe~~ -- **Suppliers** ~~manufacture our orthobiologies 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 **Incorporated (" Cook Biotech ")** as our sole porcine tissue supplier for these products. We have significant expansion capabilities in our in- house manufacturing ~~facilities~~ **facility** . 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 **. In February 2024, it was announced that Cook Biotech Inc. was acquired by RTI Surgical. We do not expect the acquisition to affect our supply agreement with Cook Biotech, which we understand will continue as a subsidiary of RTI Surgical** . 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~~ **facility** ~~are~~ **is** registered with the FDA as **a** medical device ~~and human cell and tissue~~ manufacturing ~~establishments~~ - **establishment** ~~, respectively~~ . **In addition to Cook Biotech, we** ~~We are also accredited by the American Association of Tissue Banks (" AATB ") and are licensed with several states per their tissue bank regulations. 19We~~ use **other** 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. **With** ~~Manufacture of all of our products is dependent on~~ the ~~availability~~ **sale** of ~~sufficient quantities of source tissue, which is the primary component of~~ our ~~products. Source tissue includes porcine tissue and donated~~ **Orthobiologics Business in November 2023 to Berkeley, we no longer operate our former Richmond, California** human tissue **processing and distribution facility; however** ~~. We acquire donated human tissue directly through tissue procurement firms engaged by us. Cook Biotech~~ , ~~our sole porcine tissue supplier~~ **we continue to have a contract manufacturing relationship with Berkeley under which we receive SimpliDerm. At present** , **Berkeley** is ~~registered~~ **our single source of supply for SimpliDerm, but we are evaluating additional options for supply redundancy. No contracted minimum purchase commitments are defined in the agreement and Berkeley must comply** 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 ~~"~~) **, American Association of Tissue Banks Standards and all applicable state and local** regulations ~~, AATB standards, international standards and U. S. Department of Agriculture (" USDA ") requirements~~ . Intellectual PropertyWe rely on a combination of patents, trademarks, confidentiality agreements and security procedures to protect our proprietary products, preservation technology, trade secrets and know- how. We believe that our patents, trade secrets, trademarks and technology licensing rights provide us with important competitive advantages. We have also obtained additional rights through license agreements for additional products and technologies. As of December 31, ~~2022~~ **2023** , we owned approximately 15 U. S. patents, seven U. S. patent applications, six foreign patents (in Australia, Germany, Spain, France, Great Britain and Italy), and four foreign patent applications (in Australia, Canada, and Europe ~~, as well as applications with the World Intellectual Property Organization~~); and we in- licensed three U. S. patents, 12 foreign patents (in Australia, Canada, Japan, Denmark, Germany, Great Britain, Ireland, Italy and the Netherlands), and two U. S. and five foreign patent applications (in Brazil China, Japan as well as an application with the European Patent Office). Our owned patent portfolio includes 14 U. S. patents and six U. S. patent applications that relate to our technology for CanGaroo, including issued claims covering biological envelopes and pending claims covering their use. In addition, we own one **U. S.** patent that relates to our technology for SimpliDerm that claims a method of preparing an acellular dermal matrix. Excluding any patent term extension, our issued patents relating to our technology for CanGaroo are anticipated to expire starting in 2027, and our issued patent that relates to our technology for SimpliDerm is anticipated to expire in 2033. There can be no assurance that any pending patent applications will ultimately be issued as patents. We do not own or in- license any patents or patent applications covering our other products. ~~As~~ **15As** 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 ~~20of~~ **of** any of our patents. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. For more information, see Part I, Item 1A. " Risk Factors- Risks Related to Intellectual Property. " As of December 31, ~~2022~~ **2023**, we had ~~17~~ **11** registered trademarks and ~~one~~ **two** pending trademark ~~application~~ **applications** worldwide, including trademark registrations for " Aziyo, " " CanGaroo, " " ProxiCor, " " Tyke, " " VasCure, " " ~~ViBone~~ **SimpliDerm**, ~~" " OsteGro~~ " and " SimpliDerm **Ellipse,** " in **the United States, trademark applications for " Elutia, " in Jamaica and** the United States, and trademark registrations for CanGaroo in the European Union, United Kingdom and Japan. We have confidentiality agreements with our employees, consultants, independent sales agents and third- party vendors to maintain the confidentiality of our trade secrets and proprietary information. There can be no assurance that the obligations of our employees, consultants, independent sales agents and third parties, with whom we have entered into confidentiality agreements, will effectively prevent disclosure of our confidential information or provide meaningful protection for our confidential information if there is unauthorized use or disclosure, or that our trade secrets or proprietary information will not be independently developed by our competitors. See Part I, Item 1A. " Risk Factors- Risks Related to Intellectual Property " for additional information regarding these and other risks related to our intellectual property portfolio and their potential effect on us. License Agreement with Cook BiotechOn 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~~ **16Under** the Cook License Agreement, we agree to use commercially reasonable efforts to promote, solicit and expand the licensed products in certain fields of use. We are subject to a minimum purchase requirement for the SIS ECM for the fields of use added in connection with the December 21, 2017 amendment, or the Subfields, and certain diligence obligations for commercial sales in the Subfields. The license requires that we order and pay for a minimum of at least $ 500, 000 of SIS ECM per calendar year for use in the Subfields. Cook Biotech has the right to terminate the license granted to us in the Subfields or convert such license to a non- exclusive license, if we fail to comply with such minimum purchase requirement or diligence obligations. We have the first right, but not the obligation to initiate legal proceedings against any patent infringement in our fields of use by a third- party product that is the same as one of the licensed products. Under the Cook License Agreement and SIS Material Supply Agreement, Cook Biotech is the exclusive supplier of the SIS ECM used in the licensed products. Under certain circumstances we will have the right to manufacture the SIS ECM used in the licensed products, provided that in such cases we are required to pay Cook Biotech a low single digit royalty on net sales of the licensed products that include the SIS ECM material manufactured by us and that are covered by a valid enforceable claim of a licensed patent. As consideration for the license, we paid Cook Biotech a $ 200, 000 license fee in 2018 and a $ 100, 000 license fee in years 2019 through 2022, and are responsible for a yearly license fee of $ 100, 000 until 2026. Upon a change in control transaction, which includes an acquisition of 50 % or more of our then outstanding capital stock, we will be obligated to pay Cook Biotech the total amount of all license fees that have not yet been paid within a specified period after the consummation of such change in control transaction. ~~21The~~ -- **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. **In February 2024, it was announced that Cook Biotech Inc. was acquired by RTI Surgical. We do not expect the acquisition to affect our supply agreement with Cook Biotech, which we understand will continue as a subsidiary of RTI Surgical.** Regulatory MattersGovernment RegulationOur 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, **they fall** ~~our products are subject to regulation as medical devices~~ under **the regulations of** the Federal Food, Drug, and Cosmetic Act (~~the~~ " FDCA ") **as medical devices** 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 ~~RequirementsUnless~~ ---- **RequirementsIn** ~~an exemption applies, each medical device commercially distributed in~~ the United States ~~requires either~~ **, medical devices fall under the regulatory purview of the** ~~FDA~~ **FDCA** ~~clearance of a~~ **with**

classification into three categories based on risk. Class I devices, considered low- risk, are usually exempt from the 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 **devices,** ~~or Class III- depending on the degree~~ of **moderate** risk **, require** ~~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~~ **clearance through a 510 (k) submission** , **involving** ~~which include~~ compliance with ~~the applicable portions~~ **general controls and potential imposition** of ~~the~~ **special controls, such as performance standards and post- market surveillance. The** Quality System Regulation (~~the~~ " QSR ") **is a key aspect** ~~facility registration and product listing, reporting~~ of **general controls** ~~adverse medical events~~, ~~and truthful and non~~ **ensuring adherence to quality standards in 17manufacturing processes. For the highest** - **risk** ~~misleading labeling, advertising, and promotional materials.~~ Class ~~II~~ **III** devices ~~are subject to the FDA' s General Controls~~, **PMA is required** ~~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~~ **encompassing life** - **sustaining** ~~market surveillance, patient registries and FDA guidance documents. While most Class I~~ devices **,** ~~are exempt from the~~ **those with** ~~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~~ **uses** , or ~~use~~ **utilizing** advanced technology ~~that is~~ not substantially equivalent to ~~that~~ **existing devices. This comprehensive regulatory framework aims to ensure safety and effectiveness based on the specific risk levels** of **each** ~~a legally marketed~~ device ~~, are placed in Class~~ **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 PathwayCertain of our ECM products are subject to premarket notification and clearance under ~~section~~ **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 ~~22Class~~ -- **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** ~~" de novo~~ **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. **Following** ~~After a device receives~~ 510 (k) marketing clearance, ~~any~~ **significant** ~~modification~~ **modifications** ~~that could significantly affect its~~ **to a device, impacting** safety or effectiveness ~~,~~ or ~~that would constitute~~ **constituting** a major change ~~or modification~~ in ~~its~~ intended use, **necessitate** ~~will require~~ a new 510 (k) clearance ~~or, depending on the modification~~ , PMA approval **,** or de novo reclassification. ~~The FDA requires each manufacturer~~ **Manufacturers** ~~to~~ **initially** determine ~~whether~~ the ~~proposed change requires~~ submission **pathway** ~~of a 510 (k), de novo request or a PMA in the first instance~~ , but the FDA can ~~review any such decision and~~ disagree **and enforce** ~~with a manufacturer' s determination. If the FDA disagrees with a manufacturer' s determination, the FDA can require the manufacturer to cease~~ marketing **cessation** ~~and /~~ or **device** ~~request the~~ recall ~~of the modified device~~ until **proper** ~~510 (k) marketing~~ clearance or ~~until PMA~~ approval is obtained ~~or a de novo request is granted~~ . **Non- compliance** ~~Also, in these circumstances, the manufacturer~~ may **lead** ~~be subject~~ to ~~significant~~ regulatory fines or penalties. PMA Approval PathwayClass III devices ~~require~~ **necessitate** PMA approval before **marketing** ~~they can be marketed~~ , although ~~some~~ **certain** pre- amendment Class III devices **without mandated** ~~for which FDA has not yet required a PMA~~ **PMAs** are cleared through the 510 (k) process. The PMA process ~~is~~ **,** more ~~demanding~~ **rigorous** than ~~the~~ 510 (k) ~~premarket notification process. In a PMA~~ , ~~the~~ **requires** ~~manufacturer~~ **manufacturers** ~~must~~ **to** demonstrate ~~that the device is safe~~ **safety** and **efficacy with** ~~effective, and the PMA must be supported by~~ extensive ~~data, including data from~~ pre- clinical ~~studies~~ and human clinical **data,** ~~studies. The PMA must also contain~~ a full **device** description ~~of the device and its components~~ , ~~a full description of the methods, facilities, and controls used for~~ manufacturing **details** , 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 **for PMA** ~~under the FDCA to complete its~~ review ~~of a PMA~~ , ~~although in practice, the FDA' s review~~ often **extending beyond** ~~takes significantly longer~~ , **with the possibility of convening** ~~and~~ - **an expert** ~~can take up to several years. An~~ advisory panel **for** ~~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~~ . **A** ~~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~~ **ensures** compliance with the QSR. ~~The~~ FDA ~~will approve~~ **approves** the ~~new~~ device for commercial distribution if it **deems PMA** ~~determines that the~~ data **as** ~~and information in the PMA constitute~~ valid scientific evidence **, ensuring** ~~and that there is~~ reasonable assurance **of** ~~that the device is safe~~ **safety** and ~~effective~~ **effectiveness** ~~for its intended use (s)~~ . ~~The FDA may approve a PMA with post~~ **Post** - approval conditions ~~intended to ensure the safety and effectiveness of the device~~ , including **labeling** ~~, among other things,~~ restrictions ~~on labeling~~ ,

promotion, sale and distribution, and collection of long- term follow- up data **collection, and** from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies **,** post- approval. The FDA may condition **accompany** PMA approval **.** on some form of post **Post** - market surveillance **may** 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 **as well.** to follow certain patient groups for a number of years and to make periodic reports to the FDA on **Non - compliance** the clinical status of those patients. Failure to comply with the **approval** conditions **may lead to** of approval can result in material adverse enforcement action **actions** , including **such as** withdrawal of the approval. Certain changes to an approved device, such as changes in **affecting safety or effectiveness, necessitate a PMA supplement. This includes modifications to** 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 **typically** require submission of the same type of information as **similar to** a **full** PMA **but are specific** , 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 . **Some** Certain other changes **, like alterations leading** to an approved device require the **a new intended use or significant design changes, mandate** submission of a new PMA , such as when the design change causes a different 23intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness . None of our products are currently marketed pursuant to a PMA. Clinical StudiesClinical studies are **typically** almost always required to support a PMA and **may be necessary for** are sometimes required to support a 510 (k) submission. All **In the United States, all device- related** clinical investigations in the United States of devices to determine safety and effectiveness must **adhere to** be conducted in accordance with the FDA ' **'** s investigational device exemption (**“** IDE **”**) regulations which **. IDE regulations** govern investigational device labeling, prohibit **restrict** promotion **18promotion** of the investigational device , and specify an **and outline** array of recordkeeping, reporting **,** and monitoring responsibilities **for** of study sponsors and study investigators. If the **a** 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 **be** 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 **submitted** an **and approved** 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 **relevant** data, such as animal and laboratory test results, **demonstrating** showing that it is safe **safety for** to test the device in humans - **human** and that the testing protocol is **and a** scientifically sound **protocol** . 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 **. The IDE becomes effective 30 days after FDA receipt unless modifications are required. Regardless** of **the device' s risk level,** clinical studies **require approval and oversight from an Institutional Review Board (“ IRB ”) at each site** . An **The IRB conducts initial and ongoing reviews of the** IDE supplement must be submitted to , and approved by, the **setting additional study requirements. If** FDA before a sponsor or investigator **and IRBs approve the IDE application, human clinical studies** may **commence** 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 **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 RegulationAfter a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include: 24 ● 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 **and promotional** 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 **mandate** ~~require that a manufacturer~~ **manufacturers to** report to the FDA if a **marketed** device ~~it markets~~ may have caused or contributed to a death or serious injury, or **if it** has malfunctioned and the device or a similar ~~device that it~~ **one in the** ~~markets~~ **market** ~~would~~ **could** ~~be~~ likely ~~to~~ cause ~~or contribute to a death or~~ serious **harm** ~~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; **19** ● 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. ~~25FDA~~ ~~--~~ **FDA** Regulation of Combination ProductsCertain 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 **. In** ~~and provide more certainty to the regulatory review~~ **reviewing the application** ~~process. That office serves as a focal point~~ for **a** 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 / PsCertain of our products **fall under** ~~, including certain of our spinal and orthopedic products are regulated by the~~ FDA **regulation** as **Human Cells, Tissues, and Cellular and Tissue- Based Products (“** HCT / Ps ~~, which~~ **”) and** may be ~~regulated~~ **categorized** under Section 361 of the PHSA **. This section allows** ~~, which among other things, authorizes~~ the FDA to issue regulations ~~to prevent~~ **preventing** the ~~introduction, transmission or~~ spread of communicable ~~disease~~ **diseases** . **These** HCT / Ps **must comply with various** ~~regulated as " 361 " HCT / Ps are subject to~~ requirements ~~relating to~~ **, including facility** ~~registering~~ ~~--~~ **registration** ~~facilities and~~ **, product** listing ~~products with the FDA~~ , ~~screening and testing for tissue~~ donor eligibility **screening** , and Good Tissue Practice ~~when~~ **for** processing, ~~storing~~ **storage** , labeling **,** and ~~distributing~~ ~~-~~ **distribution** ~~HCT / Ps, including required labeling information, stringent record keeping and adverse event reporting, among other applicable requirements and laws~~ . ~~Section 361 HCT / Ps~~ **These products, considered" minimally manipulated" and intended for" homologous use,"** do not require ~~510 (k) clearance, PMA approval, Biologics License Application (" BLA ") submissions, or other~~ premarket authorization from the FDA **for** ~~to be legally~~ ~~--~~ **legal** ~~marketed~~ **marketing** in ~~the United States. However, to be regulated as a Section 361 HCT / P, the product must, among other~~ ~~--~~ **the** ~~things, be~~ **U. S.** " **Homologous use** ~~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~~ ~~---~~ **depend** 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 **failing to** ~~that do not~~ meet ~~the criteria of~~ Section 361 **criteria** are regulated under Section 351 of the PHSA ~~. Unlike 361 HCT / Ps~~ , **requiring FDA** ~~HCT / Ps regulated as " 351 " HCT / Ps are subject to~~ premarket review and approval ~~by the FDA~~ . International RequirementsSales 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. ~~26Regulation~~ -- **Regulation** of Medical Devices in the European UnionThe European Union (" EU ") has adopted specific directives and regulations regulating the design, manufacture, clinical investigation, conformity assessment, labeling and adverse event reporting for medical devices. ~~Until May 25, 2021, medical devices were regulated by Council Directive 93 / 42 / EEC (the " EU Medical Devices Directive "), which has been repealed and replaced by Regulation (EU) No 2017 / 745 (the " EU Medical Devices Regulation ").~~ We have CE mark ~~for~~ **20for** four of our cardiovascular products and ~~in January 2021,~~ we ~~obtained~~ **have had** certification for updated labeling of our CanGaroo Envelope to allow for the addition of the antibiotic gentamicin **since 2021** . ~~Our current~~ **After expiration of our** CE **mark on certificates have been granted under the Medical Devices Directive whose regime is described below. However, as of** May ~~26~~ **23** , ~~2021~~ **2024** , ~~some of~~ **we no longer intend to maintain our CE mark and will not continue to market our products in** the EU **. We will maintain compliance with the transitional** Medical Devices Regulation **, or MDR,** requirements **as applicable apply in place of the corresponding requirements of the EU Medical Devices Directive with regard to registration of economic operators and of devices** , **including** post- market surveillance and vigilance requirements. **Regulation** ~~Pursuing marketing~~ of ~~medical devices in the EU will notably require that our devices be certified under the new regime set forth in the EU~~ Medical Devices ~~Regulation when our current certificates expire. Medical Devices DirectiveUnder the Medical Devices Directive, all medical devices placed on the market in the EU must meet the relevant essential requirements laid down in Annex I to the EU Medical Devices Directive, including the requirement that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performance intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter as it creates a rebuttable presumption that the device satisfies that essential requirement. To demonstrate compliance with the essential requirements laid down in Annex I to the EU Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. Except for low- risk medical devices (Class I non- sterile, non- measuring devices), where the manufacturer can self- assess the conformity of its products with the essential requirements (except for any parts which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A notified body would typically audit and examine a product' s technical dossiers and the manufacturer' s quality system (the notified body must presume that quality systems which implement the relevant harmonized standards – which is ISO 13485: 2016 for Medical Devices Quality Management Systems – conform to these requirements). If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. Throughout the term of the certificate of conformity, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the notified body before it will renew the relevant certificate (s). Medical Devices Regulation27The regulatory landscape related to medical devices in the EU recently evolved. On April 5, 2017, the EU Medical Devices Regulation was adopted with the aim of ensuring better protection of public health and patient safety. The EU Medical Devices Regulation establishes a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensures a high level of safety and health while supporting innovation. Unlike the EU Medical Devices Directive, the EU Medical Devices Regulation is directly applicable in EU member states without the need for member states to implement into national law. The EU Medical Devices Regulation became effective on May 26, 2021. Devices lawfully placed on the market pursuant to the Medical Devices Directive prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid and no substantial modification must be made to the device. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the EU Medical Devices Regulation, in particular the obligations described below. Recently, the European Parliament voted to extend the Medical Devices Regulation (MDR) transition period. The conformity assessment process for MDR needs to be completed by the end of 2027 for high- risk devices and the end of 2028 for lower- risk devices. Our products for implantation would be in the category of high- risk devices. The EU Medical Devices Regulation requires that before placing a device, other than a custom- made device, on the market, manufacturers (as well as other economic operators such as authorized representatives and importers) must register by submitting identification information to the electronic system (Eudamed), unless they have already registered. The information to be submitted by manufacturers (and authorized representatives) also includes the name, address and contact details of the person or persons responsible for regulatory compliance. The EU Medical Devices Regulation also requires that before placing a device, other than a custom- made device, on the market, manufacturers must~~

assign a unique identifier to the device and provide it along with other core data to the unique device identifier (“ UDI ”) database. These new requirements aim at ensuring better identification and traceability of the devices. Each device – and as applicable, each package – will have a UDI composed of two parts: a device identifier (“ UDI- DI ”) specific to a device, and a production identifier (“ UDI- PI ”) to identify the unit producing the device. Manufacturers are also notably responsible for entering the necessary data on Eudamed, which includes the UDI database, and for keeping it up to date. The obligations for registration in Eudamed will become applicable at a later date (as Eudamed is not yet fully functional). Until Eudamed is fully functional, the corresponding provisions of the EU Medical Devices Directive continue to apply for the purpose of meeting the obligations laid down in the provisions regarding exchange of information, including, and in particular, information regarding registration of devices and economic operators. All manufacturers placing medical devices on the market in the EU must comply with the EU medical device vigilance system which has been reinforced by the EU Medical Devices Regulation. Under this system, serious incidents and Field Safety Corrective Actions (“ FSCAs ”) must be reported to the relevant authorities of the EU member states. These reports will have to be submitted through Eudamed – once functional – and aim to ensure that, in addition to reporting to the relevant authorities of the EU member states, other actors such as the economic operators in the supply chain will also be informed. Until Eudamed is fully functional, the corresponding provisions of the EU Medical Devices Directive continue to apply. Manufacturers are required to take FSCAs, which are defined as any corrective action for technical or medical reasons to prevent or reduce a risk of a serious incident associated with the use of a medical device that is made available on the market. A serious incident is any malfunction or deterioration in the characteristics or performance of a device on the market (e. g., inadequacy in the information supplied by the manufacturer, undesirable side- effect), which, directly or indirectly, might lead to either the death or serious deterioration of the health of a patient, user, or other persons, or to a serious public health threat. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and / or to the end users of the device through Field Safety Notices. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a FSCA implemented or where the incidents are common and well documented, manufacturers may provide periodic summary reports instead of individual serious incident reports. The advertising and promotion of medical devices is subject to some general principles set forth in EU legislation. According to the EU Medical Devices Regulation, only devices that are CE marked may be marketed and advertised in the EU in accordance with their intended purpose. Directive 2006 / 114 / EC concerning misleading and comparative 28advertising and Directive 2005 / 29 / EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example, requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at a national level. EU member states’ laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals. Many EU member states have adopted specific anti- gift statutes that further limit commercial practices for medical devices, in particular vis- à- vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national “ Sunshine Acts ” which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs. In the EU, regulatory authorities have the power to carry out announced and, if necessary, unannounced inspections of companies, as well as suppliers and / or sub- contractors and, where necessary, the facilities of professional users. Failure to comply with regulatory requirements (as applicable) could require time and resources to respond to the regulatory authorities’ observations and to implement corrective and preventive actions, as appropriate. Regulatory authorities have broad compliance and enforcement powers and if such issues cannot be resolved to their satisfaction can take a variety of actions, including untitled or warning letters, fines, consent decrees, injunctions, or civil or criminal penaltiesThe aforementioned EU rules are generally applicable in the European Economic Area (“ EEA ”) which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland. Regulation of Medical Devices in the United Kingdom The **In the aftermath of Brexit, the** Medicines and Healthcare products Regulatory Agency (" **“** MHRA "), is now the standalone regulator in the United Kingdom (“ UK ”) . Although the UK and EU have now reached an agreement on its future trading relationship (implemented in the EU- UK Trade and Cooperation Agreement from January 1, 2021, (" TCA")), the agreement does not cover all regulatory areas regarding medical devices, which may be subject to future bilateral discussions going forward and could further change the relationship between the UK and the EU in this regard. EU laws which were directly applicable before the end of the transitional period or have been transposed into UK law through secondary legislation continue to be applicable as" retained EU law." However, under the Retained EU Law (Revocation and Reform) Bill 2022, which is currently before the UK parliament, any retained EU law not expressly preserved and “ assimilated ” into domestic law or extended by ministerial regulations (to no later than June 23, 2026) will automatically expire and be revoked by December 31, 2023. In addition, new legislation such as the EU Medical Devices Regulation is not applicable. The UK government has **become the sole** introduced a new Medicines and Medical Devices Act which seeks to address regulatory – **regulator** gaps through implementing regulations and delegated powers covering the fields of human medicines, clinical studies of human medicines, and medical devices. Significantly, under the TCA there is no mutual recognition of regulatory regimes and certifications between the EU and the UK. Since January 1, 2021, all medical devices placed on the market in the UK must be registered with the MHRA. Manufacturers based outside the UK will also need to appoint a UK Responsible Person (which may be an individual or a corporate entity). Only a manufacturer established in the UK or a UK Responsible Person will be able to place a device on the market in Great Britain. Under the terms of the Ireland / Northern Ireland Protocol, products placed on the market in Northern Ireland will continue to be subject to the EU regulatory regime. On June 26, 2022, the MHRA published its response to a 10- week consultation on the post- Brexit regulatory

framework for medical devices and diagnostics in the UK. The MHRA ' s proposes proposed amendments to the UK Medical Devices Regulations 2002 aim (which are based on EU legislation, primarily the EU Medical Devices Directive), in particular to foster create new access pathways to support innovation, create an innovative framework for regulating regulate software and artificial intelligence as in medical devices, reform in vitro diagnostic regulation, and foster promote sustainability through . Manufacturers with valid EU certifications can market the their reuse and 29remanufacture of medical devices . Regulations implementing the new regime were originally scheduled to come into force in July 2023, but the UK Government has recently confirmed that this date has been postponed until under the CE mark during transitional periods. However, from July 2024 . Devices which have valid certification issued by EU notified bodies under the EU Medical Devices Regulation or EU Medical Devices Directive are subject to transitional arrangements. In its consultation response , the MHRA indicated that the future UK regulations will allow devices certified under the EU Medical Devices Regulation to be placed on the market in Great Britain under the CE mark until either the certificate expires or for five years after the new regulations take effect, whichever is sooner. Devices certified under the EU Medical Devices Directive could continue to be placed on the market until either the certificate expires or for three -- the years after the new regulations take effect, whichever is sooner. Following these transitional periods, it is expected that all medical devices will require a UK Conformity Assessment (" UKCA ") mark . Manufacturers may choose to use the UKCA mark on a voluntary basis prior to the regulations coming into force. However, from July 2024, products which do not have existing and valid certification under the EU Medical Devices Directive or EU Medical Devices Regulation and are therefore not subject to the transitional arrangements will be required for medical devices to carry the UKCA mark if they are to be sold into the market in Great Britain. We do not intend to apply for the UKCA marking will not be recognized in the EU. The rules for our placing medical devices on the market in Northern Ireland, which is part of the UK, differ from those in Great Britain (England, Scotland and Wales) and continues to be based on EU law. Our CE mark cardiovascular and CanGaroo products are registered with the MHRA and are legally marketed in the UK. Other -- the near future International RegulationsThe 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 AdvocacyWe 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 AbuseWithin 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. A person Failure to meet all of the requirements of a particular applicable statutory exception or entity regulatory safe harbor, however, does not make need to have actual knowledge of the conduct per se Anti- Kickback Statute or specific intent in order to violate it to have committed a violation. The healthcare industry is facing a heightened enforcement environment related to the federal Civil False Claims Act, with specific attention on actions initiated through the Act' s whistleblower or qui tam provisions. This illegal -- legal under the U framework holds entities or individuals accountable for knowingly presenting false or fraudulent claims for payment by federal healthcare programs . S. It is noteworthy that claims stemming from violations of the federal Anti- Kickback Statute . Instead, may also trigger scrutiny under 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. 30Another 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 empower of the False Claims Act allow a private individual individuals to bring initiate actions on behalf of the federal government, providing alleging that the them defendant has submitted a false claim to the opportunity federal government, and to share participate in any monetary resulting financial recovery. The surge in legal actions In recent years, the number of suits brought against healthcare providers by private individuals has increased dramatically. In addition , along with the potential for insurance companies to pursue may also bring a private cause of action for treble damages against a manufacturer manufacturers for a pattern of causing false claims to be filed under the federal Racketeer Influenced and Corrupt

Organizations Act (~~the "~~ RICO ~~"~~) **for inducing false claims, underscores the industry' s increased regulatory scrutiny, emphasizing the necessity for stringent compliance measures** . 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~~ **21services** . 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~~ **State** , local **,** and foreign laws **impact** ~~and regulations may also restrict~~ business practices in the medical device and pharmaceutical industries, **including** ~~such as~~ state anti- kickback and false claims laws **affecting** ~~, which may apply to business practices, including but not limited to,~~ research, distribution, sales **,** and marketing ~~arrangements and~~ **. These laws also extend to** claims involving healthcare items ~~or services~~ reimbursed by ~~non- governmental~~ third- party payors ~~, including private insurers,~~ or ~~by~~ patients ~~themselves; state laws that require~~ **and may restrict payments to healthcare providers and referral sources. Additional regulations mandate** pharmaceutical companies to comply with ~~the~~ industry ~~' s voluntary compliance~~ guidelines and **federal** ~~the relevant compliance~~ guidance ~~promulgated by the federal government~~ , **while** ~~or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require~~ **requiring** drug manufacturers to ~~file reports~~ **report** ~~relating to~~ pricing and marketing information **.** ~~;~~ ~~and state~~ **State** and local laws ~~which require~~ **also necessitate** tracking gifts and ~~other~~ remuneration ~~and transfer of value~~ provided to physicians **and** ~~, other~~ healthcare ~~providers and~~ entities. Violations of **these** ~~fraud and abuse~~ laws, **carrying potential** ~~including federal and state anti- kickback and false claims laws, may be punishable by~~ criminal and civil ~~sanctions, including~~ **penalties such as** fines ~~and civil monetary penalties~~ , ~~the possibility of~~ exclusion from federal healthcare programs ~~(including Medicare and Medicaid)~~ , disgorgement **,** and corporate integrity agreements, **may** ~~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~~ **on** ~~executive~~ **executives** ~~officers~~ and employees ~~of such companies~~ **, including imprisonment** . Anti- Bribery LawsOur international operations are subject to compliance with a variety of complex foreign and United States laws that increase our costs of doing business in internal jurisdictions and could expose us or our employees to fines and penalties in the United States and abroad. Among others, we are subject to the United States Foreign Corrupt Practices Act of 1977 (the " FCPA "), which prohibits us, our officers, directors, employees, shareholders and agents acting on our behalf ~~31from~~ -- **from** offering, promising, authorizing or making corrupt payments to foreign officials for the purpose of influencing official decisions or securing an improper advantage to obtain or retain business. Data Privacy and Security LawsNumerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health- related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy laws, and consumer protection laws and regulations govern the collection, use, disclosure and protection of health- related and other personal information could apply to our operations or the operations of our partners. In addition, certain foreign laws govern the privacy and security of personal data, including health- related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and / or criminal penalties and restrictions on data processing. Coverage and ReimbursementMarket 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~~ **22the** 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. **In** ~~Based on~~ our experience ~~to date~~ , third- party payors ~~generally~~ **typically** reimburse for ~~the~~ surgical procedures **involving** ~~in which~~ our products **when** ~~are used only if the patient~~ **patients** ~~meets~~ **meet** ~~the~~ established medical necessity criteria ~~for surgery~~ . **A trend** ~~Some payors are moving toward~~ **towards** ~~a~~ managed care ~~system~~ **systems** ~~and~~ **has been observed among certain payors, where healthcare cost** control **involves restricting** ~~their healthcare costs by~~

~~limiting~~ authorizations for surgical procedures, including **those utilizing** ~~elective procedures using~~ our devices. ~~Although~~ **While there is** no uniform **coverage and reimbursement** policy ~~of coverage and reimbursement~~ among **U. S.** payors ~~in~~ **, decisions often hinge on factors such as** 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 **product** use ~~of a product~~ is ~~: ●~~ a covered benefit **,** ~~under its health plan; ● appropriate and~~ medically necessary for the specific indication **,** ~~; ●~~ cost ~~-~~ effective ~~;~~ **,** and **not** ~~● neither~~ experimental ~~nor~~ ~~-~~ **or** investigational **. Reimbursement landscape variations exist from payor to payor in the United States** . 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 ~~32by~~ **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. **The** ~~We believe the overall~~ escalating ~~cost~~ **costs** of medical products and services **, covered** ~~being paid for~~ by ~~the~~ government and private health insurance ~~has led to~~ , **are compelling** ~~and will continue to lead to, increased pressures on~~ the healthcare and medical device industry to reduce **expenses** ~~the costs of products and services~~ . ~~All third~~ **Third** - party reimbursement programs are **employing** ~~developing increasingly~~ sophisticated **strategies like** ~~methods of controlling healthcare costs through~~ prospective reimbursement ~~and~~ **,** capitation programs, **and** group purchasing, **alongside measures such as benefit** redesign **and mandatory** ~~of benefits, requiring~~ second opinions **for** ~~prior to~~ major ~~surgery~~ **surgeries** ~~, careful review of bills, encouragement of healthier lifestyles and other preventative services and exploration of more cost- effective methods of delivering healthcare~~ . **Additionally,** ~~In addition to~~ uncertainties ~~surrounding~~ **in** coverage policies **and** ~~, there are~~ periodic changes to reimbursement levels **, including** ~~. 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 **using** ~~during which~~ our products **, pose challenges. The industry must adeptly navigate these complexities to align with evolving cost control measures in healthcare. Healthcare ReformSince its enactment, the Affordable Care Act (" ACA ") has faced challenges in the judicial, executive, and Congressional arenas. On June 17, 2021, the U. S. Supreme Court dismissed a challenge asserting the ACA' s 23unconstitutionality on procedural grounds, affirming its continuation. President Biden' s executive order, preceding the Supreme Court ruling, initiated a special enrollment period for ACA marketplace health insurance coverage from February 15, 2021, through August 15, 2021, prompting a review of healthcare access policies. The impact of other healthcare reform measures under the Biden administration on our business remains uncertain. Legislative changes, including aggregate reductions in Medicare payments to providers, have occurred since the ACA' s inception. Notably, heightened governmental scrutiny on product pricing has led to Congressional inquiries and legislation, emphasizing transparency, pricing relationships, and reforming reimbursement methodologies. States** are **increasingly implementing regulations controlling** ~~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 **pricing** ~~lines and procedures. There can be no assurance that procedures using our products will be covered for a specific indication~~ , **while** ~~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~~ **and authorities** ~~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. 33Healthcare ReformSince 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 **show growing** other healthcare reform measures of the Biden administration will impact our business. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted, including aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013 and will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020, through March 31, 2022, unless additional Congressional action is taken. Moreover, there has recently been heightened governmental scrutiny, including increasing legislative and enforcement interest , over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Individual states in the United States have also become increasingly active in implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems **,** and publication of discounts **,** and list prices **price disclosures** . Human CapitalAs of December 31, 2022 **2023** , we had 164 **54** employees, with nearly 100 % of whom were full- time employees. We believe our employee relations are good. Diversity, Equity and InclusionWe believe that fostering diversity, equity, and inclusion is a key element to discovering, developing, and bringing transformative products to patients in need. As of December 31, 2022 **2023** , 43 **63** % of our workforce and 37 **47** % of our leadership (at the director level and above) were female. In addition, as of December 31, 2022 **2023** , 59 **37** % 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 RetentionWe believe that we have been successful in attracting and retaining qualified personnel with the appropriate background and skills to support our business and its growth. We monitor recruiting efforts using a variety of metrics such as internal placement rates, employee referrals, information on the retention of business critical hires, and the percentage of budgeted openings filled on time and on budget. We also track voluntary and involuntary turnover rates. Although we believe our recruiting efforts have been successful to date, headcount reductions taken as part of cost saving initiatives and as our business strategy evolves may negatively impact our ability to attract qualified personnel in the future. See Part I. Item 1A. Risk Factors- Risks Related to Our Business- Our success depends on our ability to retain and motivate key management personnel and other employees and consultants, to attract, retain and motivate additional qualified personnel and to effectively navigate changes in our senior management team. ” 34Compensation -- **Compensation** and BenefitsWe strive to offer competitive pay and benefits designed to attract and retain exceptional talent and drive company performance. In setting appropriate compensation levels, we look at the average base pay rate for each position based on market data. We also offer an annual cash incentive program and long- term equity incentive plans designed to assist in attracting, retaining and motivating employees, to align their interests with our stockholders and to promote the creation of long- term value for our investors. Our standard employee benefits include paid and unpaid leaves, medical, dental and vision insurance coverage, a 401 (k) plan, short- and long- term disability, life insurance, flexible spending accounts and an employee stock purchase plan. We benchmark our benefits program against others in our industry to help us make decisions on the size and elements of our compensation program. FiberCel **RecallsFiberCel** RecallOn 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 **PLC** , after learning of post- surgical infections reported in **24in** several patients treated with the product, including some patients that tested positive for tuberculosis **(the “ FiberCel Recall ”)** . After the recall, we worked with the U. S. Food and Drug Administration (“ FDA ”) and the U. S. Centers for Disease Control and Prevention (“ CDC ”) to identify and secure all unused product, ascertain the medical status of patients treated with the recalled product, understand whether there is any relationship between the post- surgical infections and the recalled product lot and determine the medical cause of these infections. We identified the 154 units comprising the single product lot in question. Based on information from the CDC, 136 units within this product lot were implanted into 113 patients and the remaining 18 units were returned to either us or the CDC. The CDC advised us that the CDC, working with state health agencies, contacted all patients treated with the recalled lot of FiberCel to help ensure they were directed to appropriate medical treatment and informed us that all patients were started on standard four- drug treatment for tuberculosis. Samples of the recalled product underwent **polymerase chain reaction (“** PCR **”)** analysis by a lab contracted by the CDC and tested positive for the presence of Mycobacterium tuberculosis **(“ MTB ”)** . Cell culture testing of the recalled product was also conducted by the same lab that showed the presence of **MTB** Mycobacterium tuberculosis , and this testing corroborated the PCR testing results. Twelve **Viable Bone Matrix Recall In July 2023, we announced a voluntary recall of a single** lots **lot** of FiberCel **one of our viable bone matrix (“ VBM ”) products and the market withdrawal of all of our VBM products** produced both before and after **a specified date (** the **“ VBM Recall ”). Notice of the voluntary recall was issued to centers after we learned of post- surgical MTB infections in two patients treated with product from a** single donor lot at issue underwent PCR analysis **of our VBM product. Consistent with the FiberCel Recall, after the VBM Recall, we worked with the FDA and 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. Prior to release, samples from this specific lot had tested negative for MTB by** and **an independent laboratory using a**

nucleic acid test that is designed to specifically detect the MTB organism. Additionally, in August and September 2023, cell culture testing **of the recalled product was conducted by the same lab** and ~~all tested negative for Mycobacterium tuberculosis~~ **showed no presence of MTB. In October 2023, the CDC received the results of several MTB tests on the recalled VBM lot. Three cultures and five nucleic acid tests resulted in no detection of MTB, and two other cultures of the recalled VBM lot detected MTB** . Based on **our discussions with** ~~these~~ -- **the** ~~findings~~ **CDC** , we ~~have no reason to~~ believe that **a total of 36 patients were treated with product from** ~~other~~ -- **the** ~~units of~~ **single donor lot. All VBM products, which includes** FiberCel **,** were **divested by us in connection** ~~affected. As part of our cooperation~~ with the **sale of** ~~FDA and CDC and~~ our ~~efforts~~ **Orthobiologics Business** to **Berkeley in November 2023. Berkeley** ~~conduct a prompt and fulsome investigation into this matter, we reviewed the processes for screening donors and producing FiberCel and~~ did not ~~identify~~ **assume** any ~~deviations from~~ **liabilities related to the FiberCel Recall** ~~our~~ - **or** ~~established protocols~~ **VBM Recall** , ~~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~~ - **our market withdrawal** ~~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 **our** ~~swelling of lymph nodes. To help ensure the safety of future production lots, we implemented a number of potential safeguards against Mycobacterium tuberculosis that we believe exceed applicable industry standards and currently available FDA- approved testing. We have implemented additional donor screening procedures to include screening for any donor utilizing hemodialysis for an extended period of time and to request additional background and information on any time spent by 35the donor outside the United States. In addition, we developed and utilize a methodology for testing processed~~ viable ~~cell~~ bone matrix ~~tissue~~ products **,** ~~for~~ - **or** ~~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~~ **any claims or lawsuits** ~~update on the legal proceedings~~ related ~~to the~~ **thereto. The** FiberCel Recall ~~, see~~ **and VBM Recall are described in further detail in** Part I, Item 3, " Legal Proceedings " and Note 17 to the consolidated financial statements **,** included elsewhere in this Annual Report. Available InformationWe 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~~ **elutia** . com as soon as reasonably practicable after they are filed with or furnished to the SEC. Our website and the information contained on or available through our website is not incorporated into this Annual Report. We may use our website as a distribution channel of material information about the Company. Financial and other important information regarding the Company is routinely posted on and accessible through the Investor Relations sections of its website at www. ~~aziyo~~ **elutia** . 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~~ **elutia** . 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~~ **25Item** 1A. Risk Factors. Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information contained in this Annual Report, including our consolidated financial statements and the related notes, as well as our other public filings with the SEC, before making an investment in our common stock. Our business, financial condition, results of operations and prospects could be materially and adversely affected if any of these risks occur, and as a result, the market price of our common stock could decline and you could lose all or part of your investment. This Annual Report also contains forward- looking statements that involve risks and uncertainties, and our actual results could differ materially and adversely from those anticipated in these forward- looking statements as a result of certain factors, including those set forth below. See " Forward- Looking Statements. " ~~36Risks~~ - **Risks** Related to Our BusinessWe have incurred operating losses and may continue to do so for the near- term future, and we cannot assure you that we will be able to generate sufficient revenue to achieve or sustain profitability. For the years ended December 31, **2023 and** 2022 ~~and 2021~~ , we had net ~~loss~~ **losses** of **$ 37. 7 million and** $ 32. 9 ~~million and $ 24. 8~~ million, respectively. We expect our losses to continue for the foreseeable future, and these losses will continue to have an adverse effect on our financial position. **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 ~~associated with~~ **affecting product sales and** our **ongoing** commercialization and **product** development efforts, including our ability to obtain FDA clearance for the next generation of our flagship CanGaroo product, ~~CanGaroo~~ **CanGarooRM** ~~RM and successfully commercialize this product~~ , we are unable to predict ~~when~~ **with any certainty whether** we will ~~become profitable. We cannot make assurances that~~ **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, may not offset our operating expenses. As a result, we expect to continue to incur operating losses in the future and may** ~~ever~~ **never** ~~generate sufficient revenue from our operations to~~ achieve profitability ~~and~~ **. Furthermore** , even if we **do** achieve profitability, we ~~cannot~~ **may not** be **able to sustain** ~~sure that we will remain profitable for~~ - **or increase profitability on** ~~any~~ - **an ongoing basis** ~~substantial period of time~~ . Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows, negatively affect the value of our securities and our ability to raise capital and continue operations. **We have identified** ~~Adverse~~

~~changes in general domestic and global economic~~ conditions and **events that raise substantial doubt regarding our** ~~instability~~ ---- **ability to continue as a going concern** ~~and disruption of credit markets could adversely affect our business, financial condition, results of operations and liquidity~~ . We **have incurred net losses since** ~~are subject to risks arising from adverse changes in general domestic and global economic conditions, including any recession, economic slowdown or~~ **our inception in 2015** ~~disruption of credit markets~~ . ~~During~~ **For** the year ended December 31, ~~2022~~ **2023** , ~~global markets continued to experience significant volatility~~ **we had net losses of $ 37. 7 million and as of December 31** , **2023** ~~driven by concerns over persistent inflation~~ , ~~rising interest rates~~ **we had an accumulated deficit of $ 175. 6 million. To date** , ~~slowing economic~~ **we have financed our operations primarily through amounts borrowed under our credit facilities, sales of our products, proceeds from offerings and sales of our common stock and more recently, through the sale of our Orthobiologics Business. We have devoted the majority of our resources to manufacturing costs, research and development, clinical and administrative 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. As noted above, we cannot assure you that we will achieve profitability or sustain it if we do. Without sustained profitability, we may not be able to satisfy our obligations as they become due, including our indebtedness or our obligations related to the FiberCel Recall or VBM Recall, which are described in further detail in Part I, Item 3, " Legal Proceedings " and Note 17 to the consolidated financial statements, in this Annual Report. As a result, we anticipate that we will need additional funding to support our continuing operations and pursue our** growth **strategy** ~~and geopolitical uncertainty~~ . ~~These events,~~ **In order to mitigate the current** and ~~any financial crisis that~~ **potential future liquidity issues, we** may ~~occur in~~ **seek to raise capital through** the **issuance of common stock** ~~future, could make it more difficult and more expensive for~~ - **or** ~~hospitals and health systems to obtain credit~~ **pursue asset sale or licensing transactions. However** , ~~which~~ **such transactions** may ~~contribute~~ **not be successful and we may not be able** to ~~pressures~~ **raise additional equity or sell or license assets** on ~~their operating margins~~ **acceptable terms, or at all** . As ~~a result, hospitals and healthcare systems may curtail and reduce capital and overall spending, which may have a significant adverse effect on our business. In addition, the current economic downturn related to the COVID-19 pandemic has resulted and may continue to result in, and any economic downturn that may occur in the future may also result in, higher unemployment and a reduction in the number of individuals covered by private insurance, which may result in an increase in the cost of uncompensated care for hospitals. Higher unemployment may also result in a shift in reimbursement patterns as unemployed individuals switch from private plans to public plans~~ such ~~as U. S. Medicaid or Medicare. As economic conditions deteriorate~~ , ~~any significant shift in coverage for the unemployed may have an unfavorable impact on our business. In addition, we maintain our cash and cash equivalents in accounts with financial institutions that exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, we could lose our deposits in excess of the federally insured or protected amounts and~~ there can be no assurance that we will be able to access uninsured funds in a timely manner..... raise substantial doubt regarding our ability to continue as a going concern. ~~We have incurred net losses since our inception in 2015. For the year ended December 31, 2022, we had net losses of $ 32. 9 million and as of December 31, 2022, we had an accumulated deficit of $ 138. 0 million. To date, we have financed our operations primarily through private placements of our convertible preferred stock, amounts borrowed under our credit facilities and sales of our products and, more recently, with proceeds from offerings and sales of our Class A common stock. We have devoted the majority of our resources to acquisition and integration, manufacturing costs, research 37and development, clinical activity and investing in our commercial infrastructure through our direct sales force and commercial partners in order to expand our presence and to promote awareness and adoption of our products. We expect that our operating expenses will continue to increase as we expand our product development and clinical and research activities, and incur additional costs associated with being a public company. Our~~ **26Our** ability to achieve profitability will depend on..... will remain difficult to forecast. Our indebtedness and our Revenue Interest Obligation to Ligand Pharmaceuticals Incorporated may limit our flexibility in operating our business and adversely affect our financial health and competitive position. As of December 31, ~~2022~~ **2023** , we had $ ~~24~~ **23** . ~~3~~ **7** million of indebtedness outstanding, consisting of $ ~~25~~ **24** . ~~3~~ **5** million outstanding under our SWK Loan Facility (as defined under Part II, Item 7. " Management' s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources — Credit Facilities "), net of $ ~~1.~~0 **. 8** million of unamortized discount and deferred financing costs ~~,~~. In addition, we are party to a royalty agreement with Ligand Pharmaceuticals Incorporated (" Ligand ") pursuant to ~~which we assumed~~ a ~~restructured,~~ long- term obligation to Ligand **, which we amended in January 2024** (the " Revenue Interest Obligation ") ~~, that~~ **. The Revenue Interest Obligation** requires us to pay Ligand 5. 0 % of future sales of ~~the~~ **our CanGaroo, ProxiCor, Tyke and VasCure** products **, and** ~~we acquired from CorMatrix (as well as products~~ substantially similar ~~to those~~ products ~~)~~ **, through May 31, 2027** , subject to annual minimum payments of $ ~~2~~ **4** . ~~75~~ **4** million ~~and certain milestone payments if sales of the acquired products exceed certain thresholds~~ . See Part II, Item 7. " Management' s Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Significant Judgment and Estimates — Revenue Interest Obligation. " In order to service this indebtedness and our Revenue Interest Obligation, and any additional indebtedness or other long- term obligations we may incur in the future, we need to generate sufficient levels of cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient levels of cash from operations or that future borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness, satisfy our obligations under the Revenue Interest Obligation and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness and satisfy our obligations under the Revenue Interest Obligation instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy

generally. This will place us at a competitive disadvantage compared to our competitors that have less indebtedness. In addition, the agreements governing our SWK Loan Facility contains, and any agreements evidencing or governing other future indebtedness may also contain, certain covenants that limit our ability to engage in certain transactions that may be in our long-term best interests. Subject to certain limited exceptions, these covenants limit our ability to, among other things: ~~55~~ ● 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~~ **and27** ● enter into sale and leaseback transactions. In addition to these covenants, the agreement governing our SWK Loan Facility also contains two financial covenants, the first of which is measured quarterly, and requires us to achieve a specified minimum aggregate revenue (as defined therein) for the preceding 12- month period, and the second of which requires us to maintain a minimum liquidity (as defined therein) of the greater of $ 5. 0 million and the sum of the operating burn (as defined therein) for the two prior consecutive fiscal quarters then ended. While we were in compliance with all covenants under the agreement as of December 31, ~~2022~~ **2023** , there can be no guarantee that we will not breach these covenants in the future. Our ability to comply with these covenants may be affected by events and factors beyond our control. In the event that we breach one or more covenants, our lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding, terminate any commitment to extend further credit and foreclose on the collateral granted to them to collateralize such indebtedness. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations. In addition, we may incur significant additional indebtedness in the future. Although the agreement governing our SWK Loan Facility contains restrictions on the incurrence of additional indebtedness by us, such restrictions are subject to a number of qualifications and exceptions, and the indebtedness incurred in compliance with these restrictions could be substantial. Also, these restrictions do not prohibit us from incurring obligations that do not constitute indebtedness as defined therein. To the extent that we incur additional indebtedness or such other obligations, the risks associated with our substantial indebtedness described above will increase. Various events permit the lender under the SWK Loan Facility to terminate the agreement, following a cure period. Such events include, without limitation, a failure to timely pay interest or principal, insolvency, or an action by the FDA or such other material adverse event impacting the operations of ~~Aziyo~~ **Elutia** . If the lender were to terminate either the SWK Loan Facility, the lender may declare all or any portion of these obligations to become immediately due and payable. ~~56Our~~ -- **Our future results depend upon the success a smaller suite of established products than has historically been the case in the past, and upon the success of our CanGarooRM product, which has not yet been approved for sale. On November 8, 2023, we sold our Orthobiologics Business for consideration of approximately $ 14. 6 million up front, as adjusted, and up to $ 20 million payable in the form of earn- out payments over the five years following the closing. The purchaser did not assume any liabilities related to the FiberCel or VBM Recalls, or any claims or lawsuits related thereto. Our former Orthobiologics segment accounted for 52 % and 39 % of our consolidated net sales and gross profit, respectively in the year ended December 31, 2022. Our future results depend on the success of our Device Protection, Women' s Health and Cardiovascular businesses. There can be no guarantee, however, that we will be able to increase the sales or profitability of the remaining businesses sufficiently to replace or exceed the financial contribution from the Orthobiologics Business. Moreover, the Company has focused much of its attention recently on a version of its established CanGaroo product known as CanGarooRM, a biomatrix that combines the CanGaroo envelope with antibiotics. CanGarooRM will require FDA clearance of a 510 (k) submission to be marketed in the United States. We submitted the required 510 (k) premarket notification in April 2022 and, in March 2023, received a Not Substantially Equivalent letter from FDA requiring us to address questions relating to drug testing. On December 18, 2023, the Company submitted a 510 (k) notification to address the FDA' s questions. Although the Company anticipates a favorable approval decision in the first half of 2024 and is preparing for a commercial launch of CanGarooRM, there is no assurance that the FDA will approve the new product on our anticipated timeline, or at all. See the risk factors captioned " Our long- term growth depends on our ability to enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings " and " 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 28be substantially harmed " below for further information. Delays and other adverse developments in the approval process for CanGarooRM and other future products may adversely delay or change the Company' s plans and its future success. Our enhanced reliance in the wake of the disposition of the Orthobiologics Business on a smaller suite of existing products and on future products may pose risks to the Company' s growth. If the financial contribution from remaining legacy products and the future contribution from planned products like CanGarooRM fail to replace lost contribution from the Orthobiologics Business, or otherwise fail to meet expectations, the Company' s business and financial condition may be materially adversely affected. We face significant litigation related to FiberCel. In June of 2021, the Company announced the FiberCel Recall. Our FiberCel products were included in the sale of our former Orthobiologics Business to Berkeley, but Berkeley did not assume any liabilities related to the FiberCel Recall, our market withdrawal of all of our viable bone matrix products, or any claims or lawsuits related thereto. 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, which are described in further detail in Part I, Item 3, " Legal Proceedings " and Note 17 to the consolidated financial statements included elsewhere in this Annual Report. We have**

incurred and will continue to incur costs to defend these lawsuits. Furthermore, these proceedings are still expected to continue for the reasonably foreseeable future, and we cannot predict the course the proceedings will take or their ultimate outcome. As discussed below under " We face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance ", we have recorded a total estimated contingent liability of $ 15. 0 million related to the resolution of all FiberCel lawsuits and claims and have recorded insurance receivables of $ 2. 7 million in respect of our insurance coverage for the FiberCel Recall product liability losses, as well as related legal defense costs incurred as of December 31, 2023. While we believe our estimated liability to be reasonable, the actual loss amounts are highly variable and turn on a case- by- case analysis of the relevant facts. As such, actual settlement amounts may differ from our estimates and such differences may be material. In addition, this contingent liability excludes the future costs to defend against the lawsuits and claims. As of December 31, 2023, the estimated contingent liability for FiberCel lawsuits exceeds the FiberCel insurance receivable by $ 12. 3 million and as such, the excess will be our financial responsibility. The satisfaction of this net obligation and the future costs incurred are expected to have a material adverse effect on our cash flow, results of operations, financial position and prospects. We face significant risks related to our Viable Bone Matrix recall. In July 2023, we announced the VBM Recall, a voluntary recall of a single lot of one of our VBM products and the market withdrawal of all of our VBM products produced after a specified date. Our VBM products were included in the sale of our former Orthobiologics Business to Berkeley, but Berkeley did not assume any liabilities related to the VBM Recall, our market withdrawal of all of our viable bone matrix products, or any claims or lawsuits related thereto. Notice of the VBM Recall was issued to centers after we learned of post- surgical MTB infections in two patients treated with product from a single donor lot of our VBM product. Prior to release, samples from this specific lot had tested negative for MTB by an independent laboratory using a nucleic acid test that is designed to specifically detect the MTB organism. A total of 36 patients were treated with product from the single donor lot. At present, two lawsuits and 15 claims have been asserted as a result of the VBM Recall. We have purchased insurance coverage that, subject to common contract exclusions, is expected to provide full coverage for the VBM Recall as well as legal defense costs. While unknown at this time, possible losses in connection with the VBM Recall could have a material effect on our financial position and results of operations. 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, within our recently divested Orthobiologics Business, in June 2021, the FiberCel Recall occurred and in July 2023, the VBM Recall 29occurred. Since September 2021, we have received notice of 109 separate lawsuits or claims related to the FiberCel Recall alleging that the plaintiffs contracted tuberculosis and / or suffered substantial symptoms and complications following the implantation of FiberCel during spinal fusion operations. As of December 31, 2023, 80 lawsuits or claims related to the FiberCel Recall remain outstanding and unsettled. Furthermore, with respect to the VBM Recall, we have received notice of two lawsuits and 15 claims, all of which remain unsettled as of December 31, 2023. These lawsuits and claims are described in further detail in See Part II, Item 1, " Legal Proceedings " and Note 17 to the consolidated financial statements included elsewhere in this Annual Report. We are, and may in the future be, subject to product liability claims and lawsuits, including additional claims or lawsuits from the FiberCel and VBM Recalls noted above, and potential class actions or mass tort claims, alleging that our products have resulted or could result in an unsafe condition or injury. Product liability claims may be made by patients and their families, healthcare providers or others selling our products. Product liability claims may include, among other things, allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Additionally, we may be subject to product liability claims, proceedings and lawsuits, even if the apparent injury is due to the actions of others or the pre- existing health of the patient. For example, we rely on physicians and other healthcare providers to properly and correctly use our products. If these physicians or other healthcare providers are not properly trained or are negligent in using our products, the capabilities of our products may be diminished, or the patient may suffer critical injury. In addition, we may be subject to product liability claims, as well as a number of other risks, as a result of physicians and other healthcare providers using our products " off- label. " See the risk factor entitled " The misuse or off- label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business " included in this Annual Report. Defending any current or future claims, proceedings or lawsuits, regardless of merit, could be costly, divert management attention and result in adverse publicity, which could result in the withdrawal of, or reduced acceptance of, our products in the market. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in: ● harm to our business reputation; ● investigations by regulators; ● significant legal costs; ● distraction of management' s attention from our primary business; ● substantial monetary awards to patients or other claimants; ● loss of revenue; ● exhaustion of any available insurance and our capital resources; and ● decreased demand for our products. Our product liability insurance is subject to deductibles and coverage limitations, and we may not be able to maintain this insurance. As of December 31, 2023, we have recorded insurance receivables of $ 2. 7 million on our balance sheet in respect of our insurance coverage for the FiberCel Recall product liability losses with such receivable representing the total remaining insurance coverage for the FiberCel Recall as of that date. As of December 31, 2023, we have recorded insurance receivables of $ 0. 1 on our balance sheet in respect of our insurance coverage for the VBM Recall. 30As described above, our future FiberCel Recall litigation costs and obligations now significantly exceed insurance coverage and are expected to have a material adverse effect on our cash

flow and financial position. Additionally, it is possible that future claims related to the VBM Recall or other product liability claims could exceed the limits of, or be excluded from, coverage under our policies, and claims against us could also increase the cost of maintaining our coverage. If these or other claims are excluded from our coverages, or if we are unable to maintain product liability insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect ourselves against potential product liability claims, or if we underestimate the amount of insurance we need, we could be exposed to significant liabilities, which may harm our business. One or more product liability claims could have a significant adverse effect on our business, financial condition and results of operations. Our future capital needs are uncertain and we may need to raise funds in the future, and such funds may not be available on acceptable terms or at all. Our future capital needs are uncertain and, as such, we may seek to raise additional capital through equity offerings, debt financings, collaborations or other arrangements. Any future funding requirements will depend on many factors, including, among other things: ● continued patient, physician and market acceptance of our products; ● the scope, rate of progress and cost of our current and future pre- clinical and clinical studies; ● the cost of our research and development activities and the cost of commercializing new products or technologies; ● the cost and timing of expanding our sales and marketing capabilities; ● the cost of filing and prosecuting patent applications and maintaining, defending and enforcing our patent or other intellectual property rights; ● the cost of defending, in litigation or otherwise, any claims that we infringe, misappropriate or otherwise violate third- party patents or other intellectual property rights; ● the costs of defending against or damages payable (to the extent above the applicable insurance coverage), for example, in connection with **lawsuits and** claims involving the FiberCel **Recall or VBM** 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; **and** ● 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~~ **31In** 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 ~~57the~~ ~~-~~ **the** price per share paid by you. Furthermore, investors purchasing any securities we may issue in the future may have rights superior to your rights as a holder of our common stock. In addition, any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. If we raise additional funds through collaboration and other arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. Furthermore, we cannot be certain that additional funding will be available to us on acceptable terms, if at all. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our business, financial condition and results of operations. ~~to~~ **Adverse changes in general domestic and global economic conditions and instability and disruption of** ~~predict~~ ~~-~~ **credit markets could adversely affect our business,financial condition,results of operations and liquidity.We are subject to risks arising from adverse changes in general domestic and global economic conditions,including any recession,economic slowdown or disruption of credit markets.During the year ended December 31,2023,global markets continued to experience significant volatility,driven by concerns over persistent inflation,rising interest rates,slowing economic growth and geopolitical uncertainty.These events,and any financial crisis that may occur in the future,could make it more difficult and more expensive for hospitals and health systems to obtain credit,which may contribute to pressures on their operating margins.As a result,hospitals and healthcare systems may curtail and reduce capital and overall spending,which may have a significant adverse effect on our business.In addition,we maintain our cash in accounts** with **financial institutions that exceed insured limits.Market conditions can impact the viability of these institutions.In the event of failure of** any ~~certainty whether we will be able to increase sales~~ of ~~our products~~ **the financial institutions where we maintain** ~~or~~ **our** ~~the timing~~ **cash and cash equivalents,we could lose** ~~or~~ **our deposits in excess of the federally insured or protected** ~~amount~~ **amounts** ~~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~~ **and** ~~ongoing basis.As a result,we anticipate that we will need additional funding to support our continuing operations and pursue our growth strategy.In order to mitigate the current and potential future liquidity issues,we may seek to raise capital through the issuance of common stock,restructure our Revenue Interest Obligation (as defined below) or pursue asset sale or licensing transactions.However,such transactions may not be successful and we may not be able to raise additional equity,refinance our Revenue Interest Obligation,or sell or license assets on acceptable terms,or at all.As such,~~ there can be no assurance that we will be able to ~~continue as~~ **access uninsured funds in** a ~~going concern~~ **timely manner or at all.In addition,the current volatility in the capital and credit markets could impede our access to**

capital.Should we have limited access to additional financing sources,we may need to defer capital expenditures or seek other sources of liquidity,which may not be available to us on acceptable terms or at all.All of these factors related to global economic conditions,which are beyond our control,could adversely impact our business,financial condition,results of operations and liquidity .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~~ **32products** ,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; ~~38~~ ● maintain full compliance with FDA ~~,European Union (" EU ")~~ medical devices regulations and other regulatory requirements applicable to new devices or products or modifications of existing devices or products;● provide adequate training to potential users of our products;● receive adequate coverage and reimbursement for our products;and ● otherwise compete effectively against products and enhancements developed by our competitors.If we are not successful in expanding our indications and developing,acquiring and commercializing new products and product enhancements,our ability to increase our net sales may be impaired,which could have a material adverse effect on our business,financial condition and results of operations.In addition,our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product,technology or other innovation. ~~On~~ **In** March ~~16,~~ 2023,we received a ~~NSE determination~~ **Not Substantially Equivalent letter** from **FDA requiring us to address questions relating to drug testing,primarily a request by FDA to modify an in vitro drug release assay employed as a manufacturing control.In December 2023,we submitted a 510 (k) premarket notification to** the FDA for **our next- generation DEB product,** ~~CanGaroo~~ **CanGarooRM** ~~RM,requiring us to address additional items relating to drug testing in furtherance of potential market clearance~~ .If we are not able to obtain FDA regulatory clearance for this product candidate within our planned timeline,if at all,our ability to commercialize this product and generate sales therefrom will be adversely impacted.Even if we are successful in obtaining the required regulatory clearance,there can be no assurances that we will be able to achieve market acceptance or that we will able to realize the intended benefits from commercializing this product candidate.In addition,we will be required to invest additional time and resources to address the outstanding items and provide the additional data requested to FDA,which could divert management' s attention from core business and result in additional research and development expenses.Even if we are able to successfully develop and commercialize new product offerings or enhancements,they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features and / or otherwise not produce sales in excess of the costs of development,any of ~~which~~ **33which** 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." **We may not realize all of the potential consideration associated with the sale of our Orthobiologics Business.On November 8,2023,we completed the sale of the assets of our former Orthobiologics Business to Berkeley.In the sale,we received approximately $ 14.6 million,and we may earn up to an additional $ 20 million,in the aggregate,in the form of earn- out payments.The earn- out payments are equal to 10 % of the actual revenue earned by Berkeley in each of the five years after the closing of the sale from sales of specified Orthobiologics products under the purchase agreement (including improvements,modifications,derivatives and enhancements related to those products).Additionally,the purchase agreement provides for a customary indemnity holdback in the amount of $ 1.5 million to be retained by Berkeley for 24 months after close.There can be no assurance that we will be able to realize the expected benefits of the transaction,or that we will receive all of the potential consideration associated with the earn- out payments or customary indemnity holdback.If we are unable to or do not realize the expected strategic,economic,or other benefits of the transaction,it could adversely affect our business and financial position.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,for reasons of quality assurance,cost- effectiveness,availability or constraints resulting from regulatory requirements,we rely on a single supplier,Cook Biotech,to source the SIS ECM biomaterial used to manufacture CanGaroo and our cardiovascular products.Additionally,with the sale of our Orthobiologics Business in November 2023 to Berkeley,we no longer operate**

our former Richmond,California human tissue processing and distribution facility;however,we continue to have contract manufacturing relationship with Berkeley under which we receive SimpliDerm.At present,Berkeley is our single source of supply for SimpliDerm,but we are evaluating additional options for supply redundancy.For us to be successful,our suppliers must be able to provide us with products and components in substantial quantities,in compliance with regulatory requirements,in accordance with agreed upon specifications,at acceptable costs and on a timely basis.Our efforts to maintain a continuity of supply and high quality and reliability may not be successful on a timely basis or at all.Manufacturing disruptions experienced by our suppliers may jeopardize our supply of finished products.Due to the stringent regulations and requirements of the FDA and other similar non- U.S.regulatory agencies regarding the manufacture of our products,we may not be able to quickly establish additional or replacement sources for certain raw materials.A change in suppliers could require significant effort or investment in circumstances where the items supplied are integral to product performance or incorporate unique technology.Transitioning to a new supplier could be time-consuming and expensive,may result in interruptions in our operations and product delivery,could affect the performance specifications of our products or could require that we modify the design of those systems.A reduction or interruption in manufacturing,or an inability to secure alternative sources of raw materials or supplies,could have a material and adverse effect on our business,financial condition,results of operations and cash flows.One or more of our suppliers may refuse to extend us credit with respect to our purchasing or leasing of equipment,supplies,products or components,or may only agree to extend us credit on significantly less favorable terms or subject to more onerous conditions.This could significantly disrupt our ability to purchase or lease required equipment,supplies,products and components in a cost- effective and timely manner,and could have a material adverse effect on our business,financial condition and results of operations.Any casualty,natural disaster or other disruption of any of our sole- source suppliers' operations,for example due to a COVID- 19 infection of employees of the supplier,or any unexpected loss of any existing exclusive supply contract,could have a material adverse effect on our business,financial condition and results 34of operations.In addition,if a change in manufacturer results in a significant change to any product,a new 510 (k) clearance from the FDA or similar international regulatory authorization,or certification may be necessary before we implement the change,which could cause substantial delays. A substantial portion of our net sales is generated through our commercial partners and independent sales agents,which subjects us to various risks.We currently rely on the efforts of our commercial partners and independent sales agents to generate a substantial portion of our net sales,and we expect to continue to rely on these third parties to generate a substantial portion of our net sales in the future while we work to grow our direct sales force.For example,we have commercial agreements with major medical device companies,including Boston Scientific, ~~Biotronik and beginning in March 2023,~~ Sientra **and LeMaitre Vascular** .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 ~~39and --~~ **and** independent sales agents,there remains a risk that they will not comply with regulatory requirements or our requirements and policies.Actions by the sales representatives and other employees of our commercial partners and independent sales agents that are beyond our control could adversely impact sales in that territory or result in harm to the reputation of the Company or our products or legal liability,any of which could have a material adverse effect on our business,financial condition and results of operations.In addition to the risk of losing customers,the operation of local laws and our agreements with our commercial partners and independent sales agents would make it difficult for us to replace a commercial partner or independent sales agent we believe is underperforming ~~.In order to increase our sales,we intend to develop relationships and arrangements with additional commercial partners and / or independent sales agents,which we may not be able to do on commercially reasonable terms or at all.If we are unable to establish new commercial partner and independent sales agent relationships and maintain our relationships with our existing commercial partners and independent sales agents,in each case,on commercially reasonable terms,we will be unable to increase sales of our products,which,in turn,could materially and adversely affect our business,financial condition and results of operations.In addition,certain of our commercial partners may,from time to time,account for a significant portion of our net sales and / or accounts receivable.Sales to one of our commercial partners accounted for 11 % of our net sales during the year ended December 31,2022 and represented 12 % of our accounts receivable as of December 31,2022.As previously disclosed,in December 2021,we terminated our distribution agreement with Medtronic,which accounted for 11 % of our net sales during the year ended December 31,2021,as a result of our voluntary recall of our FiberCel product.The loss of one or more significant commercial partners,a material reduction in their purchases of our products,such as what we have experienced with Medtronic,or their inability to perform their contractual obligations,including,for example,committed purchase requirements,has affected and could continue to adversely affect our business,financial condition and results of operations~~ .We are also subject to the risk that any such commercial partner will

experience financial difficulties **,or seek protection in bankruptcy.For example,in February 2024,Sientra reported** that **it had filed for chapter 11 bankruptcy protection in the Bankruptcy Court for the District of Delaware.If a commercial partner experiences financial difficulties,that could** prevent them from making payments to us on a timely basis or at all **,** ~~.Our revenue~~ and ~~profitability~~ **if a commercial partner seeks bankruptcy protection,our contracts with that partner** could be **rejected** ~~materially and adversely affected if we fail to maintain our~~ **or** ~~relationships with~~ **a purchaser of the partner' s business could elect not to assume** our ~~existing~~ contract **.The loss** ~~manufacturing customers or enter into agreements with new contract manufacturing customers,or if existing contract manufacturing customers reduce purchases~~ of **one** ~~our~~ **or more significant commercial partners** ~~products.Our relationships with these customers also subject us to certain risks.Our contract manufacturing operations are an important component of our business~~ , **a** ~~enabling us to utilize as much as possible of the human biological~~ material **reduction in** ~~from which we produce our core orthopedic / spinal repair and soft tissue reconstruction products,leverage our existing overhead and improve our cash flow.In addition,we have historically generated a significant portion of our total net sales from these sales,with such sales representing approximately 26.1 % and 20.7 % of our total net sales for the years ended December 31,2022 and 2021,respectively.If we are unable to maintain our relationships and contracts with our existing contract manufacturing customers and establish relationships with new contract manufacturing customers on terms that are favorable to us,or if our existing contract manufacturing customers materially reduce~~ their purchases of our ~~products~~ **product** ,~~our~~ **or their inability** ~~sales and profitability may be adversely affected.In addition,although we have invested,and expect~~ to ~~continue to invest~~ **perform their contractual obligations** , **including** ~~significant time and resources cultivating our relationships with these customers~~ , **for** ~~these relationships subject us to certain risks.For~~ example, **committed purchase** ~~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 40risk that~~ **In order to increase our sales,we intend to develop relationships and arrangements with additional commercial partners and / or independent sales agents,which** we may **not be able to do on commercially reasonable terms or at all.If we are unable to establish new commercial partner and independent sales agent relationships and maintain our relationships with our existing commercial partners and independent sales agents,in each case,on commercially reasonable terms,we will** be unable to **increase sales** ~~supply products in the quantities and~~ of **our products** ~~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~~ , **in turn** ~~to the extent they cause our customers to reduce purchases of our products or terminate their relationships with us~~ ,could ~~have a material~~ **materially and** ~~adverse~~ **adversely** ~~effect~~ **affect** ~~on~~ our business,financial condition and results of operations. ~~In addition,our sales to these customers may be impacted by changes in their buying habits over which we have no control.Such changes may be driven by,among other things,changes in market share,cyclicality,inventory reductions,spending patterns,cost- cutting measures,product development activity and timelines and changes in supply chain management,as well as the impact of general economic conditions.These customers may also experience financial difficulties or other problems that may prevent them from making payments to us on a timely basis or at all.Any of these events could cause our operating results to fluctuate from period to period,make it more difficult for us to manage our inventory and production schedules and otherwise adversely affect our business,financial condition and results of operations.Our~~ **35Our** ~~business has been,and may continue to be,adversely affected by the COVID- 19 pandemic,and we may be adversely affected by any future pandemic,epidemic or outbreak of an infectious disease in the United States or worldwide.The COVID- 19 pandemic continues to evolve,with pockets of resurgence and the emergence of variant strains contributing to continued uncertainty about its scope,duration,severity,trajectory,and lasting impact.The COVID- 19 pandemic negatively impacted our business,financial condition and results of operations by intermittently decreasing and delaying the number of procedures performed using our products,as healthcare organizations in the United States prioritized the treatment of patients with COVID- 19 or otherwise altered their operations to prepare for and respond to the pandemic.The COVID- 19 pandemic has also adversely impacted the initiation,continuation and completion of our clinical studies by,for example,intermittently delaying procedures using our products or reducing the number of patients,healthcare providers or clinical facilities available or willing to participate in the clinical studies.These delays have resulted in increased costs,delays in advancing our product development,delays in testing the effectiveness of our technology or termination of the clinical studies altogether.We have experienced and may in the future experience these or other disruptions from the COVID- 19 pandemic or other pandemic,epidemic or outbreak of an infectious disease that could reduce our net sales in the future and negatively impact our business,financial condition and results of operations.The extent to which the COVID- 19 pandemic or any future pandemic,epidemic or outbreak of an infectious disease impacts our business,will depend on future events and developments,which are highly uncertain and cannot be predicted,including the severity and spread of the disease and the effectiveness of actions to contain the disease or treat its impact and the emergence of new variants,among other developments.Our~~ future growth depends on physician awareness of the distinctive characteristics,benefits,safety,clinical efficacy and cost- effectiveness of our products.We focus our sales,marketing and training efforts on physicians,surgeons and other healthcare professionals.The acceptance of our products depends in part on

our ability to educate these individuals as to the distinctive characteristics,benefits,safety,clinical efficacy and cost- effectiveness of our products compared to alternative products,procedures and therapies.We support our direct sales force,commercial partners and independent sales agents through in- person and online educational programs,among other things.We also produce and distribute marketing and educational materials,including materials outlining our products,for our sales teams using printed,video and multimedia formats.However,our efforts to educate physicians,surgeons and other healthcare professionals regarding our products may not be successful,particularly ~~with respect to our orthobiologics products in light of the recent events involving the FiberCel Recall,and~~ in markets where we rely exclusively on the efforts of our commercial partners and independent sales agents.If we do not adequately educate physicians,surgeons and other healthcare professionals about our products,as well as any adverse events involving these products,our products may not gain or maintain market acceptance,which may adversely affect our business,financial condition and results of operations. ~~41Our~~ -- **Our** success depends on the continued and future acceptance of our products by the medical community.Even if we are able to increase awareness of our products among healthcare professionals,there can be no assurance that this will translate into greater acceptance of our products by the medical community.We believe physicians,surgeons and other healthcare professionals will only adopt our products if they determine,based on experience,clinical data and published peer reviewed journal articles,that the use of our products in a particular procedure is a favorable alternative to other available methods. ~~In light of the events surrounding the FiberCel Recall,described in Part I,Item 3,“ Legal Proceedings ” and Note 17 to the consolidated financial statements included elsewhere in this Annual Report,such positive evaluation of our Bone Repair products may become more challenging.~~ Physicians also are more interested in using cost- effective products as they face increasing cost- containment pressure.In general,physicians may be slow to change their medical treatment practices and adopt our products for a variety of reasons,including,among others:● their lack of experience using our products and the time that must be dedicated to learning how to use our products;● lack of evidence supporting additional patient benefits from use of our products over conventional methods;● pressure to contain costs;● preference for other treatment modalities or our competitors’ products;● perceived liability risks generally associated with the use of new products and procedures;and ● limited availability of coverage and / or reimbursement from third- party payors.The degree of market acceptance of our products will continue to depend on a number of factors,some of which are outside of our control,including,among other things:● the actual and perceived safety and efficacy of our products;● the potential and perceived advantages of our products over alternative treatments;● clinical data and the clinical indications for which our products are approved or certified;● product labeling or product insert requirements of the FDA ~~,the EU~~ or other regulatory authorities,including any limitations or warnings contained in approved labeling;● the cost of using our products relative to the use of our competitors’ products or alternative treatment modalities; **36** ● 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; ~~42~~ ● the shelf life of our products and our ability to manage the logistics of the end- user supply chain;and ● sufficient and readily accessible third- party insurance coverage and reimbursement for procedures incorporating our products.In addition,we believe recommendations for,and support of our products by,influential physicians are essential for market acceptance and adoption.If we do not receive this support (e.g.,because we are unable to demonstrate favorable long- term clinical data or otherwise),physicians and hospitals may not use our products,which would significantly impair our ability to increase our sales and prevent us from achieving and sustaining profitability. ~~Unfavorable results from any of our pre- clinical or clinical studies,comparative effectiveness,economic or other studies,or from similar studies conducted by others,may negatively affect the use or adoption of our products by physicians,hospitals and payors,which could have a negative impact on the market acceptance of our products and their profitability.We regularly conduct a variety of pre- clinical and clinical studies,comparative effectiveness studies and economic and other studies of our products in an effort to generate clinical and real- world outcomes and cost effectiveness data in order to obtain product approval and drive further penetration in the markets we serve.If a clinical study conducted by us or a third party fails to demonstrate statistically significant results supporting performance,use benefits or compelling health or economic outcomes from using our products,physicians may elect not to use our products.Furthermore,in the event of an adverse clinical study outcome,our products may not achieve “ standard- of- care ” status,where they exist,for the conditions in question,which could deter the adoption of our products.Also,if serious adverse events are reported during the conduct of a study,it could affect continuation of the study,product approval,certification or clearance and product adoption.In addition,U.S.and foreign regulatory authorities routinely conduct audits of clinical studies and such audits may result in adverse regulatory actions.If we are unable to develop a body of statistically significant evidence from our clinical study program,whether due to adverse results or the inability to complete properly designed studies,domestic and international public and private payors could refuse to cover procedures using our products,limit the manner in which they cover our products or reduce the price they are willing to pay or reimburse for procedures using our products.Any of these events could have a negative impact on market acceptance of procedures using our products and their profitability,which could have a material adverse effect on our business,financial condition and results of operations.~~ We may need to continue to expand our organization and managing growth may be more difficult than we expect.Managing our growth may be more difficult than we expect.We anticipate that a period of significant expansion will be required to penetrate and service the markets for our existing and anticipated future products and to continue to develop new products.This expansion will place a significant strain on our management,operational and financial resources.To manage the expected growth of our operations and personnel,we must both modify our existing operational and financial systems,procedures and controls and implement new systems,procedures and controls.We must also expand our finance,administrative and operations staff.Management may be unable to hire,train,retain,motivate and manage necessary personnel or to identify,manage and exploit existing and potential strategic relationships and market opportunities.If we fail to meet these challenges effectively,there may be an adverse effect on our business,financial condition and results of operations.We

regularly evaluate opportunities to make acquisitions of,investments in,and licenses or other commercial arrangements involving,other companies or technologies,and to enter into other strategic transactions.These transactions entail significant risks.Our success depends,in part,on our ability to continually enhance and broaden our product offerings in response to changing customer demands,competitive pressures and advances in technologies.Accordingly,although we have no current commitments with respect to any acquisition or investment,we regularly review potential acquisitions of,investments in,and licenses or other commercial arrangements involving,complementary businesses,products or technologies instead of developing them ourselves.In addition,in regularly evaluating our financial and operating performance,we may decide to sell one or more of our product lines or another portion of our business **as we did with our Orthobiologics Business** .Opportunities to engage in these transactions may not be readily available to us at commercially reasonable prices,on other terms acceptable ~~43to~~ **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; **37** ● 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 **dis-** ~~dissynergies~~ --- **synergies** 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. ~~44We~~ **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~~ **38many** 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 **and VBM** ~~Recall~~ **Recalls** ;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 ~~45procedures~~ -- **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~~ **39Pricing** pressure as a result of cost- containment efforts of our customers,purchasing groups,third- party payors and governmental organizations could adversely affect our sales and profitability.Medical technology companies,healthcare systems and group purchasing organizations (“ GPOs ”) have intensified competitive pricing pressure as a result of industry trends and new technologies.Rising healthcare costs have resulted in numerous cost reform initiatives by legislators,regulators and third- party payors.This cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power and,as a result,purchasing decisions are increasingly shifting to hospitals,integrated delivery networks (“ IDNs ”) and other hospital groups,and away from individual surgeons and physicians.Many existing and potential facility customers for our products within the United States are members of GPOs and IDNs,including accountable care organizations or public- based purchasing organizations,and our business is partly dependent on contracts with these organizations.Purchases of our products can be contracted under national tenders or with larger hospital GPOs.GPOs and IDNs negotiate pricing arrangements with healthcare product manufacturers and distributors and offer the negotiated prices to affiliated hospitals and other members.GPOs and IDNs typically award contracts on a category- by- category basis through a competitive bidding process and,at any given time,we are typically in various stages of responding to bids and negotiating and renewing GPO and IDN agreements.Bids are generally solicited from multiple manufacturers or service providers with the intention of obtaining lower pricing.Due to the highly competitive nature of the bidding process and the GPO and IDN contracting processes in the United States,we may not be able to obtain or maintain contract positions with major GPOs and IDNs across our product portfolio.Furthermore,GPO and IDN contracts are typically terminable without cause upon 60 to 90 days’ notice.In addition,while having a contract with a major purchaser for a given product category can facilitate sales,there can be no guarantee that sales volumes for those products will be maintained.For example,GPOs and IDNs are increasingly awarding contracts to multiple suppliers for the same product category and,even when we are the sole contracted supplier of a GPO or IDN for a certain product category,members of the GPO or IDN are generally free to purchase from other suppliers.If we are unable to maintain and renew our contracts with our current GPO and IDN customers and negotiate contracts with new customers on favorable terms,or if sales volumes under these agreements decline,our business,financial condition and results of operations could be materially and adversely affected.In addition,most of our customers purchase our products directly and then bill third- party payors for procedures using those products.Because there is typically no separate reimbursement for supplies used in surgical procedures,the additional cost associated with the use of our products can affect the profit margin of the hospital or surgery center where the procedure is performed.Some of our target customers may be unwilling to adopt our products in light of the additional associated cost or may negotiate for lower pricing.Further,any decline in the amount payors are willing to reimburse our customers for procedures using our products,including those as a result of healthcare reform initiatives,could make it difficult for existing customers to continue using or to adopt our products and could create additional pricing pressure for us.In addition to these competitive forces,we continue to see pricing pressure as hospitals introduce new pricing structures into their contracts and agreements,including fixed price formulas,capitated pricing and episodic or bundled payments intended to contain healthcare costs.If we are forced to lower the price we charge for our products,our margins will decrease,which could impair our ability to grow our business and have a material adverse effect on our business,financial condition and results of operations and impair our ability to grow our business. ~~Outside of the United States,centralized governmental healthcare authorities may exert pricing pressures in an effort to lower healthcare costs.Implementation of healthcare reforms and competitive bidding contract tenders may limit the price or the level at which reimbursement is provided for our products and adversely affect both our pricing flexibility and the demand for our products.Healthcare providers may respond to such cost- containment pressures by substituting lower- cost products or other therapies for our products.Our failure to offer acceptable prices to these customers could adversely affect our sales and profitability in these markets.~~ We expect that market demand,government regulation,third- party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide,resulting in further business consolidations and alliances among our customers,which may exert further downward pressure on the prices for our products. ~~46The~~ -- **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~~ **subject** 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~~ **40inventory** ,customer returns and,in some cases,recalls,with consequential damage to our reputation and customer relationships and the risk of product liability. **Product** ~~For example,in June 2021,we issued a voluntary recall~~ **recalls** ~~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 **investigations** ,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 **porcine** 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. 47If **If** our facilities are damaged or become inoperable,we will be unable to continue to research,develop and supply our products and,as a result,there will be an adverse effect on our business until we are able to secure new facilities and rebuild our inventory.We do not have redundant facilities .We manufacture our human tissue- based products at our facility in Richmond,California .The SIS ECM biomaterial used in our medical device products are manufactured by Cook Biotech at their facility in West Lafayette,Indiana and converted to a finished product at our facility in Roswell,Georgia.Regulatory approvals or certifications of our products are limited to one or more specifically approved manufacturing facilities.As a result,if we fail to produce enough of a product at a facility,or if any of our production facilities were to be shut down or otherwise become unavailable for any reason,finding alternative manufacturing capabilities and obtaining the necessary regulatory approvals or certifications would require a considerable amount of time and expense and would cause a significant disruption in service to our customers.Disruption to our facilities could arise for a variety of reasons,including technical,labor or other difficulties,equipment malfunction,contamination due to a COVID- 19 infection or otherwise,the failure of our employees to follow specific protocols and procedures,the destruction of,or damage to,any facility (as a result of a natural or man- made disaster,including,but not limited to,a tornado,flood,fire,power outage or other event),quality control issues or other reasons.Any disruption in the operation of our facilities as a result of any of the above could impair our product development and commercialization efforts and result in lost sales,lost customers and harm to our reputation,any of which would negatively impact our growth prospects and profitability and have a material adverse effect on our business,financial condition and results of operations.In addition,certain of these events,such as natural or man- made disasters,would cause us to incur additional losses,including the time and expense required to repair and / or replace our equipment and to rebuild our inventory.Our insurance for damage to our property and the disruption of our business may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms or at all. Because we depend upon a limited number of third- party suppliers and manufacturers and,in certain cases,exclusive suppliers for products essential to our business,we may incur significant product development costs and experience material delivery delays if we lose any significant supplier,which could materially and adversely affect our business,financial condition and results of operations.We obtain some of our raw materials from a limited group of suppliers and rely on a single supplier to source the SIS ECM biomaterial used to manufacture CanGaroo and our cardiovascular products for reasons of quality assurance,cost- effectiveness,availability or constraints resulting from regulatory requirements.For us to be successful,our suppliers must be able to provide us with products and components in substantial quantities,in compliance with regulatory requirements,in accordance with agreed upon specifications,at acceptable costs and on a timely basis.Our efforts to maintain a continuity of supply and high quality and reliability may not be successful on a timely basis or at all.Manufacturing disruptions experienced by our suppliers may jeopardize our supply of finished products.Due to the stringent regulations and requirements of the FDA and other similar non- U.S.regulatory agencies regarding the manufacture of our products,we may not be able to quickly establish additional or replacement sources for certain raw materials.A change in suppliers could require significant effort or investment in circumstances where the items supplied are integral to product performance or incorporate unique technology.Transitioning to a new supplier could be time- consuming and expensive,may result in interruptions in our operations and product delivery,could affect the performance specifications of our products or could require that we modify the design of those systems.A reduction or interruption in manufacturing,or an inability to secure

alternative sources of raw materials or supplies,could have a material and adverse effect on our business,financial condition,results of operations and cash flows.One or more of our suppliers may refuse to extend us credit with respect to our purchasing or leasing of equipment,supplies,products or components,or may only agree to extend us credit on significantly less favorable terms or subject to more onerous conditions.This could significantly disrupt our ability to purchase or lease required equipment,supplies,products and components in a cost- effective and timely manner,and could have a material adverse effect on our business,financial condition and results of operations.Any casualty,natural disaster or other disruption of any of our sole-source suppliers' operations,for example due to a COVID- 19 infection of employees of the supplier,or any unexpected loss of any existing exclusive supply contract,could have a material adverse effect on our business,financial condition and results of operations.In addition,if a change in manufacturer results in a significant change to any product,a new 510 (k) clearance 48from the FDA or similar international regulatory authorization,or certification may be necessary before we implement the change,which could cause substantial delays.Certain of our products are dependent on the availability of tissue from human donors,and any disruption in supply could adversely affect our business,financial condition and results of operations.The products we manufacture for the orthobiologics and soft tissue reconstruction markets require that we obtain human tissue.The success of our business depends,in part,on the availability of tissue from human donors.Any inability to obtain tissue from our sources will interfere with our ability to effectively meet demand for these products.The recovery of human tissue for our products is very labor- intensive,and it is,therefore,difficult to maintain a steady supply stream.In addition,the availability of acceptable donors is relatively limited and may be impacted by regulatory changes,general public opinion of the donation process and the reputation of our company and the third- party procurement firms with which we partner to manage the donation process.Media reports or other negative publicity concerning both improper methods of tissue recovery from donors and disease transmission from donated tissue,including bones and dermis,may limit widespread acceptance of our products.Unfavorable reports of improper or illegal tissue recovery practices,both in the United States and internationally,as well as incidents of improperly processed tissue leading to transmission of disease,may broadly affect the rate of future tissue donation and market acceptance of allograft technologies and donated tissue use.Potential patients may not be able to distinguish our products,technologies and tissue recovery and processing procedures from others engaged in tissue recovery.In addition,unfavorable reports about us or any of our third- party procurement firms may make families of potential donors or donors themselves,from whom we are required to obtain consent before processing tissue,reluctant to agree to donate tissue to for- profit tissue processors.For the year end December 31,2022,we received donated tissue from seven third- party procurement firms,including one third- party procurement firm that supplied 52 % of the donors received during the year.Any disruption in the supply of any human tissue component could materially harm our ability to manufacture our products until a new source of supply,if any,could be found.We may be unable to find a sufficient alternative supply channel within a reasonable period of time,on commercially reasonable terms or at all,which would have a material adverse effect on our business,financial condition and results of operations.Increased **41Increased** prices for raw materials or supplies used in our products could adversely affect our business,financial condition and results of operations.Our profitability is affected by the prices of the raw materials and supplies used in the manufacture of our products.These prices may fluctuate based on a number of factors beyond our control,including changes in supply and demand,general economic conditions,labor costs,delivery costs,competition,import duties,excises and other indirect taxes,currency exchange rates and government regulation.Due to the highly competitive nature of the healthcare industry and the cost containment efforts of our customers and third- party payors,we may be unable to pass along cost increases for key supplies or raw materials through higher prices to our customers.If the cost of key supplies or raw materials increases,and we are unable to fully recover these increased costs through price increases or offset these increases through other cost reductions,we could experience lower margins and profitability.Significant increases in the prices of raw materials and supplies that cannot be recovered through productivity gains,price increases or other methods could adversely affect our business,financial condition and results of operations.If we are not able to accurately forecast demand for our products and manage our inventory,our margins could decrease and we could lose sales,either of which could have a material adverse effect on our business,financial condition and results of operations.While we must maintain sufficient inventory levels to operate our business successfully and meet customer demand for our products,we must be careful to avoid amassing excess inventory.To ensure adequate inventory supply,we must forecast inventory needs and place orders with our suppliers based on our estimates of future demand for our products.Demand for our products can change,and has changed,rapidly and unexpectedly,including during the time between when raw materials are ordered from our suppliers and the finished product is offered for sale.Our ability to accurately forecast demand for our products could be negatively affected by a number of factors,many of which are beyond our control,including our failure to accurately manage our expansion strategy,product introductions by competitors,an increase or decrease in customer demand for our products or for products of our competitors,our failure 49to **to** accurately forecast customer acceptance of new products,unanticipated changes in general market conditions,reimbursement or regulatory matters and weakening of economic conditions.Inventory levels that exceed the demand for our products may result in inventory write- downs or write- offs,which would adversely affect our gross margins .For example,since our launch of SimpliDerm 2019,evolving demand for different dimensions of the product have periodically resulted in excess inventory write- downs .Conversely,if we underestimate demand for our products,additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us or at all,and suppliers or our third- party manufacturer may not be able to allocate sufficient capacity in order to meet our increased requirements.As a result,we may not be able to meet customer demand for our products,resulting in lost sales and potential damage to our reputation and customer relationships,any of which would adversely affect our business,financial condition and results of operations.In addition,while we seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions,our products generally have a shelf life of two to three years.We are,therefore,subject to the risk that a portion of our inventory will become obsolete or expire,which could have a material adverse effect on our profitability and cash

flows due to the resulting inventory impairment charges and costs required to replace such inventory.If hospitals and other healthcare providers are unable to obtain coverage or adequate reimbursement for procedures performed with our products,it is unlikely our products will be widely used.In the United States,the commercial success of our existing products and any products we may develop or acquire in the future will depend,in part,on the extent to which governmental payors at the federal and state levels,including Medicare and Medicaid,private health insurers and other third- party payors,provide coverage and establish adequate reimbursement levels for procedures utilizing our products.Hospitals and other healthcare providers that purchase our products for treatment of their patients generally rely on third- party payors to pay for all or part of the costs and fees associated with our products as part of a " bundled " rate for the associated procedures.The existence of coverage and adequate reimbursement for procedures using our products by government and private payors is critical to market acceptance of our existing and future products.Neither hospitals nor surgeons are likely to use our products if they do not receive adequate reimbursement for the procedures utilizing our products. ~~Many~~ **42Many** 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.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 43depend 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.Compliance with these regulatory requirements,including but not limited to the FDA' s Quality System Regulation (" QSR "),current Good Manufacturing Practices (" GMPs ") and adverse events / recall reporting requirements in the United States and other applicable regulations worldwide,is subject to continual review and is monitored rigorously through periodic inspections by the FDA.If we fail to comply with our reporting obligations,the FDA 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 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 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.We had two recalls in products formerly distributed through our recently divested Orthobiologics Business – one in June 2021 and one in July 2023.These recalls had negative effects on our business,financial condition and results of operations and resulted in a number of lawsuits filed against us as discussed under the risk factor " We face significant litigation related to FiberCel " included in this Annual Report.Any product recall we or a third- party manufacturer may conduct in the future,whether voluntary or required,could also have a negative impact on 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.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 the patients' out- of- pocket costs.44Other 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 rate of reimbursement for procedures using our products by government and private insurers;● whether our products are granted pass- through reimbursement status or included in the " bundled " reimbursement structure;● changes in purchasing patterns by our commercial partners or customers,or the loss of any significant customer or group of customers;● our ability to upgrade and develop our systems and infrastructure to accommodate growth;● the amount and timing of operating costs and capital expenditures relating to the expansion of our business,operations and infrastructure;● changes in,or enactment of,new laws or regulations promulgated by federal,state or local governments;● changes in our supply or manufacturing costs;● cost containment initiatives or policies developed by government and commercial payors that create financial incentives not to use our products;● our inability to demonstrate that our products are cost- effective or superior to competing products;● our ability to develop new products;● the degree of competition in our industry and any changes in the competitive landscape;● discovery of product defects during the manufacturing process;● initiation of a government investigation into potential non-compliance with laws or regulations,or the initiation of a voluntary or involuntary recall with respect to one or more of our products;● sanctions imposed by federal or state governments due to non- compliance with laws or regulations;● general global economic conditions and political instability,such as the conflict between Russia and Ukraine;and ● economic conditions specific to the healthcare industry.We have based our current and future expense levels largely on our investment plans and estimates of future events,although certain of our expense levels are,to a large extent,fixed.We may be unable to adjust spending in a timely manner to compensate for any unexpected revenue shortfall.Accordingly,any significant shortfall in sales relative to our planned expenditures would have an immediate adverse effect on our business,results of operations and financial condition.Further,as a strategic response to changes in the competitive environment or to changes in laws and regulations,45we 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. Security breaches, loss of or damage to data, information technology system failures and

other disruptions could compromise sensitive information related to our business or our customers' patients, or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation. In the ordinary course of our business, we may become exposed to, or collect and store, sensitive data, including procedure- based information and legally protected health information, credit card, and other financial information, insurance information and other potentially personally identifiable information. We also store sensitive intellectual property and other proprietary business information. Regardless of any precautions we may take, our information technology (" IT ") and infrastructure, and that of our technology partners and providers, may be vulnerable to attack, damage and interruption from computer viruses and malware (e. g. ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation- state and nation- state- supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. Attacks upon IT systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. In addition to unauthorized access to or acquisition of personal information, confidential information, intellectual property or other sensitive information, such attacks could include the deployment of harmful malware and ransomware, and may use a variety of methods, including denial- of- service attacks, social engineering and other means, to attain such unauthorized access or acquisition or otherwise affect service reliability and threaten the confidentiality, integrity and availability of information. As a result of the COVID- 19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and often are not foreseeable or recognized until launched against a target, we may be unable to anticipate these techniques or to implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Any breakdowns or breaches of our systems, or resulting access, disclosure, or other loss of information, could significantly disrupt our business and result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and damage to our reputation, any of which could have a material and adverse effect on our business, financial condition and results of operations. We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and result in the unauthorized disclosure of sensitive or confidential patient or employee data, it could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. ~~58Despite --~~ **Despite** our security measures, there can be no assurance that our efforts will prevent breakdowns or breaches to our or our third- party providers' databases or systems, or any resulting unauthorized access to, or disclosure and use of, non-public or other legally protected information. Our general liability and cybersecurity insurance coverage may not cover all claims, continue to be available to us on reasonable terms or be sufficient in amount to cover one or more large claims. Additionally, the insurer may disclaim coverage as to any claim. The successful assertion of one or more large claims against us that exceed or are not covered by our insurance coverage or changes in our insurance policies, including premium increases or the imposition of large deductible or co- insurance requirements, could have a material adverse effect on our business, prospects, operating results and financial condition. ~~Our~~ **46Our** success depends on our ability to retain and motivate key management personnel and other employees and consultants, to attract, retain and motivate additional qualified personnel and to effectively navigate changes in our senior management team. Our success depends to a significant extent on our ability to attract, retain and motivate key management personnel and other employees and consultants for our business, including scientific, technical and sales and marketing personnel. There is currently a shortage of skilled executives and other personnel in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms, given the competition among numerous regenerative medicine and other healthcare companies, for individuals with similar skill sets. Many of the companies that we compete against for qualified personnel have substantially greater financial and other resources and different risk profiles than we do. They may also provide more diverse opportunities, better chances for career advancement and / or more attractive compensation. Some of these characteristics may be more appealing to high quality candidates than what we can offer. Furthermore, in order to offer attractive compensation, we may need to increase the level of cash compensation that we pay to them, which will reduce funds available for research and development and support of our commercialization and sales growth objectives. In addition, any headcount reductions taken as part of cost saving initiatives and as our business strategy evolves may negatively impact our ability to attract qualified personnel in the future. There can be no assurance that we will have sufficient cash available to offer our employees and consultants attractive compensation or that we will realize any corresponding benefits from the payment of such compensation. We are also vulnerable to the risk that these individuals may take actions, either within or outside the scope of their duties, that intentionally or unintentionally tarnish our brand and reputation or otherwise adversely affect our business. We also cannot prevent our senior management team from terminating their employment with us. Losing the services of any member of our senior management team could materially harm our business until a suitable replacement is found, and such replacement may not have equal experience and capabilities. In addition, we do not maintain " key person " insurance policies on the lives of any of our management team or other employees. The inability to recruit or a loss of the services of any executive, key employee or consultant may impede the progress of our research, development, commercialization and sales growth objectives, which could have a material adverse effect on our business, financial condition, results of operations and our

ability to grow our business. ~~In addition, we have recently had changes within our senior management team. These changes, and any other changes to our senior management team we experience in the future, subject us to a number of additional risks, including risks pertaining to the coordination of responsibilities and tasks, the creation of new management systems and processes, differences in management style, effects on corporate culture and the need for transfer of historical knowledge. If our management team does not work together harmoniously, efficiently allocate responsibilities between themselves and implement and abide by effective controls, our operations will be adversely affected.~~ Our sales into foreign markets expose us to risks associated with international sales and operations. Though we have historically focused our market development and commercial activities primarily in the United States, we have obtained marketing registrations, developed commercial and distribution capabilities and are currently selling CanGaroo and our cardiovascular products in several countries outside the United States through commercial partnerships or independent sales agents. Our international sales subject us to additional risks as compared to those we face in the United States. The sale and shipment of our products across international borders subject us to extensive U. S. and foreign governmental trade, import and export and customs regulations and laws, including but not limited to, the Export ~~59Administration~~ -- **Administration** Regulations, which are administered by the Bureau of Industry and Security (" BIS ") within the Department of Commerce, and economic and trade sanctions, which are administered by the Office of Foreign Assets Control (" OFAC ") within the U. S. Department of the Treasury. These regulations limit our ability to market, sell, distribute or otherwise transfer our products or technology to prohibited countries, territories, or persons. Compliance with these regulations and laws is costly, and failure to comply with applicable legal and regulatory obligations could adversely affect us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, monetary fines, denial of export privileges, seizure of shipments and restrictions on certain business activities. The failure to comply with applicable legal and regulatory obligations could also result in the disruption of our distribution and sales activities. These risks may limit or disrupt our sales and commercialization efforts outside the United States, restrict the movement of funds or result in the deprivation of contractual rights or the taking of property by nationalization or expropriation without fair compensation. Operating in international markets also requires significant management attention and financial support, and, as a result, will divert these resources away from our other operations. ~~We~~ **47We** are subject to anti- bribery, anti- corruption and anti- money laundering laws, including the U. S. Foreign Corrupt Practices Act, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, any of which would adversely affect our business, financial condition and results of operations. We are subject to anti- corruption, anti- bribery, and other similar laws and regulations in various jurisdictions in which we operate, including the U. S. Foreign Corrupt Practices Act (" FCPA "), the U. K. Bribery Act 2010 (" Bribery Act "), and other anti- corruption laws and regulations. These laws generally prohibit us and our officers, directors, employees and business partners acting on our behalf, including agents, from corruptly offering, promising, authorizing or providing anything of value to obtain or retain business or otherwise obtain favorable treatment and require companies to maintain accurate books and records and a system of internal controls or adequate procedures to prevent bribery. We are also subject to economic sanctions laws, export control laws and regulations, as well as customs regulations, in the various jurisdictions in which we operate, including those administered and enforced by OFAC, the U. S. Department of State, BIS, His Majesty' s Treasury of the United Kingdom, the United Nations Security Council, the European Union (and its member states) and other relevant sanctions authorities. Such laws and regulations prohibit or restrict certain operations, investment decisions, and sales activities, including dealings with certain countries or territories, and with certain governments and designated persons. Investigations of alleged sanctions and export controls violations can be expensive and disruptive. As our international operations increase, we expect to implement policies and procedures designed to promote compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, the Bribery Act and other anti- corruption laws, as well as economic sanctions and export controls. We cannot assure you, however, that any such policies and procedures will be sufficient or that directors, officers, employees, representatives, consultants and agents have not engaged, and will not engage, in conduct for which we may be held responsible, nor can we assure you that our business partners have not engaged, and will not engage, in conduct that could materially affect their ability to perform their contractual obligations to us or result in our being held liable for such conduct. Violations of the FCPA, Bribery Act, other anti- corruption laws, economic sanctions, export control laws and / or anti- money laundering and anti- terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition and results of operations. Our officers, employees, independent contractors, principal investigators, consultants, commercial partners and independent sales agents may engage in misconduct or activities that are improper under other laws and regulations, which would create liability for us. We are exposed to the risk that our officers, employees, independent contractors (including contract research organizations (" CROs ")), principal investigators, consultants, commercial partners and independent sales agents may engage in fraudulent conduct or other illegal activity and / or may fail to disclose unauthorized activities to us. Misconduct ~~60by~~ **by** these parties could include, but is not limited to, intentional, reckless and / or negligent failures to comply with the laws and regulations of the FDA and its foreign counterparts, including, but not limited to, those relating to the manufacture, processing, packing, holding, investigating or distributing in commerce of medical devices, biological products and / or HCT / Ps, requiring the reporting of true, complete and accurate information to such regulatory bodies (including any safety problems associated with the use of our products), and relating to the conduct of clinical studies and the protection of human research subject. In particular, companies involved in the manufacture of medical products are subject to laws and regulations intended to ensure that medical products that will be used in patients are safe and effective, and specifically that they are not adulterated or contaminated, that they are properly labeled, and have the identity, strength, quality and purity that they are represented to possess. Further, companies involved in the research and development of medical products are subject to extensive laws and regulations intended to protect research subjects and ensure the integrity of data

generated from clinical studies and of the regulatory review process. Any misconduct in any of these areas, whether by our own employees or by contractors, vendors, business associates, consultants or other entities acting as our agents, could result in regulatory sanctions, criminal or civil liability and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in preventing such conduct, ~~mitigating 48~~**mitigating** risks, or reducing the chance of governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such investigations or other actions or lawsuits are instituted against us, those actions could have a significant impact on our business, financial condition and results of operations, including, without limitation, the imposition of significant fines and other sanctions that may materially impair our ability to run a profitable business. Even if we are successful in defending against the imposition of any such fines or other sanctions, we could be required to incur substantial legal fees and other costs, and management' s attention will be diverted from our core business operations, either of which would negatively affect our business, financial condition and results of operations. Our ability to use certain tax attributes to offset future income tax liabilities may be subject to limitations. We have net operating losses and other tax attributes, including net operating loss carryforwards (" NOLs ") for federal income tax purposes of approximately $ ~~86~~ **102** . ~~9~~ **1** million and state NOLs of approximately $ ~~26~~ **33** . ~~4~~ **5** million as of December 31, ~~2022~~ **2023** . If not utilized, $ 17. 7 million of our NOLs will begin to expire for federal income tax purposes beginning in 2036, and our state NOLs will expire beginning in 2030. Our ability to utilize our federal NOLs will depend on our future income, and there is a risk that our NOLs could expire unused and be unavailable to offset future income tax liabilities, which could adversely affect our operating results. In addition, our ability to utilize our NOLs may be subject to an annual limitation under the Internal Revenue Code of 1986, as amended (the " Code "). In general, under Sections 382 and 383 of the Code, a corporation that undergoes an " ownership change " is subject to limitations on its ability to utilize its pre- change NOLs or tax credits to offset future taxable income. If we undergo an ownership change or have previously undergone an ownership change, our ability to utilize federal NOLs or tax credits could be limited by Sections 382 and 383 of the Code. Additionally, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our state NOLs or credits may also be impaired under state tax law. Accordingly, we may not be able to utilize a material portion of our federal and state NOLs or credits. Our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U. S. federal and state taxable income. Valuation allowances have been provided for all deferred tax assets related to our federal and state NOLs. In addition, other tax attributes, such as interest carryforwards, are also subject to various limits on their use under the Code. We have established valuation allowances for our interest carry forwards to reflect these limitations and their anticipated impact on our ability to utilize these tax attributes. Changes in tax laws, unfavorable resolution of tax contingencies or exposure to additional income tax liabilities could have a material impact on our results of operations or financial condition. We are subject to income taxes as well as non- income based taxes in the United States. We may from time to time be subject to tax audits in various jurisdictions. Tax authorities may disagree with certain positions we have taken and assess additional taxes. We regularly assess the likely outcomes of any tax audits to which we are subject in order to ~~61determine~~ -- **determine** the appropriateness of our tax provision and have established contingency reserves for material, known tax exposures. However, the calculation of such tax exposures involves the application of complex tax laws and regulations in many ~~jurisdictions, as well as interpretations as to the legality under state aid rules of the EU of tax advantages granted in certain~~ jurisdictions. Therefore, there can be no assurance that we will accurately predict the outcomes of any tax audits to which we may be subject or that issues raised by tax authorities will be resolved at a financial cost that does not exceed our related reserves and the actual outcomes of any such audit could have a material impact on our results of operations or financial condition. Changes in tax laws and regulations, or their interpretation and application, in the jurisdictions where we are subject to tax, could materially impact our effective tax rate. For example, changes in tax law implemented by the tax reform legislation known as H. R. 1, commonly referred to as the Tax Cuts and Jobs Act (the " TCJA ") in the United States became effective in 2018 and 2019, and we expect the U. S. Treasury to continue to issue future notices and regulations under the TCJA. Certain provisions of the TCJA and the regulations issued thereunder could have a significant impact on our future results of operations as could interpretations made by us in the absence of regulatory guidance and judicial interpretations. In addition, in 2018, we established valuation allowances against all deferred tax assets (including interest carry forwards) to reflect certain limitations on these assets and their anticipated impact on our ability to utilize these tax assets following the adoption of the TCJA. ~~Additionally 49~~**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 ~~sales~~ **our business,financial condition** and **results of operations** ~~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. As we conduct clinical studies designed to generate long- term data on some of our existing products, the data we generate may not be consistent with our existing data and may demonstrate less favorable safety or efficacy. We are currently collecting and plan to continue collecting long- term clinical data regarding the quality, safety and effectiveness of some of our existing products. The clinical data collected and generated as part of these studies will further strengthen our clinical evaluation concerning safety and performance of these products. We believe that this additional data will help with the marketing of our products by providing surgeons and physicians with additional confidence in their long- term safety and efficacy. If the results of these clinical studies are negative, these results could reduce demand for our products and significantly reduce our ability to achieve expected net sales. We do not expect to undertake such studies for all of our products and will only do so in the future where we anticipate the benefits will outweigh the costs and risks. For these reasons, surgeons and physicians could be less likely to purchase our products than competing products for which longer- term clinical data are available. Also, we may not choose or be able to generate the comparative data that some of our competitors have or are generating and we may be subject to greater regulatory and product liability risks. If we are unable to or determine not to collect sufficient long- term clinical data supporting the quality, safety and effectiveness of our existing products, our business, financial condition and results of operations could be adversely affected. Our estimates of market opportunity and forecasts of market and sales growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business could fail to grow at similar rates, if at all. Market opportunity estimates and growth forecasts are inherently uncertain. Our estimates of the annual total addressable markets for our products are based on a number of internal and third- party estimates and assumptions, including, without limitation, the number of implantable electronic device procedures ~~and orthopedic / spinal repair procedures,~~ as well as the number of procedures ~~using~~ **50using** 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 ~~62accuracy~~ -- **accuracy** of these underlying factors. As a result, our estimates of the annual total addressable market for any of our products may prove to be incorrect. If the actual number of procedures, the price at which we are able to sell any of our products, or the annual total addressable market is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business, financial condition and results of operations. Risks Related to Government RegulationThe regulatory approval, certification and clearance processes of the FDA and comparable foreign authorities and notified bodies are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval or other marketing authorizations or certifications for our products and product candidates, our business will be substantially harmed. The medical device and biologics industries are regulated extensively by governmental authorities ~~, principally the FDA, the EU legislative bodies, and corresponding state and foreign regulatory agencies and authorities~~ . The time required to obtain approval, clearance, certification of conformity or other marketing authorizations from the FDA ~~, notified bodies in the EU, approved bodies in the UK,~~ and comparable foreign authorities is unpredictable but can often take many years following the commencement of clinical studies and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, policies, regulations, or the type and amount of clinical data necessary to gain clearance, certification or approval may change during ~~the course of~~ a product candidate' s ~~clinical~~ development ~~and may vary among jurisdictions~~ . Before we can market or sell a new medical device or a new use of or a claim for or significant modification to an existing medical device in the United States, we must obtain either clearance from the FDA under Section 510 (k) of the Federal Food, Drug, and Cosmetic Act (the " FDCA ") or approval of an application for premarket approval, or PMA, unless an exemption applies. In the United States, we have obtained 510 (k) premarket clearance from the FDA to market products such as our CanGaroo, VasCure, ProxiCor and Tyke products. In the 510 (k) premarket clearance process, the FDA must determine that a proposed device is " substantially equivalent " to a device legally on the market, known as a " predicate " device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support a finding of substantial equivalence. Under certain conditions, a medical device is required to be approved under a PMA before it may be legally marketed. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based ~~, in part,~~ on extensive data, including, but not limited to, technical, nonclinical, clinical study, manufacturing and labeling data. The ~~PMA process is typically required for devices that are deemed to pose the greatest risk, such as life- sustaining, life- supporting or implantable devices. However, some devices are automatically subject to the PMA pathway regardless of the level of risk they pose because they have not previously been classified into a lower risk class by the FDA. Manufacturers of these devices may request that FDA review such devices in accordance with the de novo classification procedure, which allows a manufacturer whose novel device would otherwise require the submission and approval of a PMA prior to marketing to request down- classification of the device on the basis that the device presents low or moderate risk. If the FDA agrees with the down classification based on a de novo submission, the FDA will authorize the device for marketing. This device type can then be used as a predicate device for future 510 (k) submissions. The~~ process of obtaining regulatory clearances or approvals ~~, or completing the de novo classification~~

process, to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre-market reviews on a timely basis, if at all. If the FDA requires us to go through a lengthier, more rigorous examination for our products than we expect, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. Further, even where a PMA is not required, we cannot assure you that we will be able to obtain 510 (k) clearances with respect to such product candidates or modifications to previously cleared products. Subject to the transitional provisions and to the extent we sell medical devices in EU member states, our products must comply with the general safety and performance requirements of the EU Medical Devices Regulation (Regulation (EU) No 2017 / 745). Compliance with these requirements is a prerequisite to be able to affix the European Conformity (" CE ") mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation including the requirement that a medical device must be designed and manufactured in such a way 63that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and – where applicable – other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. To demonstrate compliance with the general safety and performance requirements, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Except for low risk medical devices (Class I), where the manufacturer can self-assess the conformity of its products with the general safety and performance requirements (except for any parts which relate to sterility, metrology or reuse aspects), a conformity assessment procedure requires the intervention of a notified body. The notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. If we fail to comply with applicable laws and regulations, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU. The aforementioned EU rules are generally applicable in the European Economic Area (" EEA ") (which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland). Non-compliance with the above requirements would also prevent us from selling our products in these three countries. Since the end of the Brexit transition period on January 1, 2021, Great Britain (England, Scotland and Wales) has not been subject to EU laws, however under the terms of the Ireland / Northern Ireland Protocol, Northern Ireland continues to follow EU law. The EU laws that have been transposed into United Kingdom (" UK ") law through secondary legislation remain applicable in Great Britain. However, under the Retained EU Law (Revocation and Reform) Bill 2022, which is currently before the UK parliament, any retained EU law not expressly preserved and " assimilated " into domestic law or extended by ministerial regulations (to no later than June 23, 2026) will automatically expire and be revoked by December 31, 2023. In addition, new legislation such as the EU Medical Devices Regulation (Regulation (EU) No 2017 / 745) will not be applicable. The UK government has passed a new Medicines and Medical Devices Act 2021, which introduces delegated powers in favor of the Secretary of State or an ' appropriate authority' to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices. Since January 1, 2021, the Medicines and Healthcare Products Regulatory Agency (" MHRA ") has become the sovereign regulatory authority responsible for Great Britain. Following the end of the Brexit transition period, new regulations require all medical devices to be registered with the MHRA. From January 1, 2022, manufacturers based outside the UK need to appoint a UK responsible person that has a registered place of business in the UK to register devices with the MHRA. On June 26, 2022, the MHRA published its response to a 10- week consultation on the post- Brexit regulatory framework for medical devices and diagnostics. MHRA seeks to amend the UK Medical Devices Regulations 2002 (which are based on EU legislation, primarily the EU Medical Devices Directive and the EU In Vitro Diagnostic Medical Devices Directive), in particular to create a new access pathway to support innovation, create an innovative framework for regulating software and artificial intelligence as medical devices, reform IVD regulation and foster sustainability through the reuse and remanufacture of medical devices. Regulations implementing the new regime were originally scheduled to come into force in July 2023, but have recently been postponed to July 2024. Devices bearing CE marks issued by EU notified bodies under the EU Medical Devices Regulation or EU Medical Devices Directive are now subject to transitional arrangements. In its consultation response, the MHRA indicated that the future UK regulations will allow devices certified under the EU Medical Devices Regulation to be placed on the market in Great Britain under the CE mark until either the certificate expires or for five years after the new regulations take effect, whichever is sooner. Devices certified under the EU Medical Devices Directive could continue to be placed on the market until either the certificate expires or for three years after the new regulations take effect, whichever is sooner. Following these transitional periods, it is expected that all medical devices will require a UK Conformity Assessed (" UKCA ") mark. Manufacturers may choose to use the UKCA mark on a voluntary basis until June 30, 2023. However, UKCA marking will not be recognized in the EU. The rules for 64placing medical devices on the market in Northern Ireland, which is part of the UK, differ from those in the rest of the UK. Compliance with this legislation is a prerequisite to be able to affix the UKCA mark to our products, without which they cannot be sold or marketed in Great Britain. Under the terms of the Ireland / Northern Ireland Protocol, Northern Ireland follows EU rules on medical devices and devices marketed in Northern Ireland require assessment according to the EU regulatory regime. Such assessment may be conducted by an EU notified body, in which case a CE mark is required before placing the device on the market in the EU or Northern Ireland. Alternatively, if a UK approved body conducts such assessment, a' UKNI' mark is applied and the device may only be placed on the market in Northern Ireland and not the EU. The EU- UK Trade and Cooperation

~~Agreement (" TCA "), came into effect on January 1, 2021. The TCA does not specifically refer to medical devices, but does provide for cooperation and exchange of information in the area of product safety and compliance, including market surveillance, enforcement activities and measures, standardization related activities, exchanges of officials, and coordinated product recalls (or other similar actions). For medical devices that are locally manufactured but use components from other countries, the " rules of origin " criteria will need to be reviewed. Depending on which countries products will be ultimately sold in, manufacturers may start seeking alternative sources for components if this would allow them to benefit from no tariffs. The rules for placing medical devices on the Northern Ireland market will differ from those in Great Britain. These modifications may have an effect on the way we intend to conduct our business in these countries.~~ The FDA or any foreign regulatory agency or notified body can delay, limit or deny approval, certification or clearance of our product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for many reasons, including: ● the FDA or the applicable foreign regulatory agency or notified body' s disagreement with the design or implementation of our clinical studies; ● negative or ambiguous results from our clinical studies or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies ~~or notified body for approval or certification~~ ; ● serious and unexpected drug or device- related side effects experienced by participants in our clinical studies or by individuals using devices similar to our products ~~or natural product candidates~~ ; **51** ● our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory agency or notified body that our product candidates are safe and effective for their intended uses, or in the case of the 510 (k) clearance process, that our product candidate is substantially equivalent to a predicate device; ● the FDA' s or the applicable foreign regulatory agency or notified body' s disagreement with the interpretation of data from pre- clinical or clinical studies; ● our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks; ● the FDA' s or the applicable foreign regulatory agency or notified body' s requirement for additional pre-clinical studies or clinical studies; ● the FDA' s or the applicable foreign regulatory agency or notified body' s disagreement regarding the formulation, labeling or the specifications of our products or future product candidates; ● the FDA' s or the applicable foreign regulatory agency' s failure to approve the manufacturing processes or facilities of third- party manufacturers with which we contract; ~~or65~~ **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. **Certain** ~~Some of our~~ marketed products are subject to Medical Device Reporting (" MDR ") obligations, ~~which require~~ **requiring** ~~that we~~ **us to** report **incidents** to the FDA, ~~the~~ **EU** competent authorities **,** ~~of the EU member states~~ or ~~any~~ other foreign regulatory **bodies if** ~~authorities, any incident in which~~ our products may have caused or contributed to a death ~~or ,~~ serious injury, or ~~in which our products malfunctioned and, if the~~ malfunction **that** ~~were to recur, it~~ could likely **lead** ~~cause or contribute~~ to **such outcomes upon recurrence** ~~a death or serious injury~~ . The ~~timing of our obligation to report~~ **reporting timeline** ~~under the MDR regulations~~ is triggered by **our awareness** ~~the date we become aware~~ of the adverse event ~~as well as the nature of the event~~ . **Failure** ~~We may fail~~ to report **within the prescribed timeframe or to recognize reportable** adverse events **could result in regulatory actions** ~~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~~ , **such** ~~especially if it is not reported to us~~ as ~~an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our product. If we fail to comply with our reporting obligations, the FDA, or the competent authorities of the EU member states, could take action, including~~ warning letters, ~~untitled letters,~~ administrative actions, criminal prosecution, ~~imposition of~~ civil ~~monetary~~ penalties, ~~revocation of~~ **product seizure,** ~~our~~ - **or** ~~device~~ **delays in** clearance or approval ~~, seizure of our products or~~ **for** ~~delay in clearance, certification or approval of~~ future products. The FDA, the competent authorities of the EU member states, and foreign regulatory authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA' s authority to require a recall for a medical device must be based on a finding that there is reasonable probability that the device could cause serious injury or death. With respect to human cells, tissues, and cellular and tissue- based products (" HCT / Ps "), the FDA may also require a recall where the conditions of manufacture of the HCT / P do not provide adequate protections against risks of communicable disease transmission, or where the HCT / P is infected or contaminated so as to be a source of dangerous infections to humans. We may also choose to voluntarily recall a product if any

material deficiency is found. A government- mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future. ~~In~~ **52In** the EU, **compliance** ~~we must comply~~ with the ~~EU~~ medical device vigilance system **is imperative** . ~~Under this system, serious~~ **Serious** incidents and Field Safety Corrective Actions (" FSCAs ") must be reported to the relevant authorities of ~~the~~ EU member states **, facilitated** ~~. 66These reports will have to be submitted~~ through Eudamed ~~– once functional – and aim to ensure that, in addition to reporting to the relevant authorities of the EU member states, other actors such as the economic operators in the supply chain will also be informed. Until Eudamed is fully functional, the corresponding provisions of the EU Medical Devices Directive continue to apply~~ . FSCAs **necessitate** ~~must be communicated~~ **communication** by the manufacturer or its legal representative to ~~its~~ customers and ~~/ or to the~~ end ~~-~~ users **via** ~~of the device through~~ Field Safety Notices (" FSNs "). ~~For~~ **In cases of** 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~~ **submit** periodic summary reports instead of individual ~~serious~~ incident reports ~~. The aforementioned EU rules are generally applicable in the EEA~~ . Depending on the corrective action we take to redress a product' s deficiencies or defects, the FDA or foreign regulatory authorities may require, or we may decide, that we will need to obtain new clearances, certifications or approvals for the device before we may market or distribute the corrected device. Seeking such clearances, certification or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA or foreign regulatory body warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines ~~. Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA or foreign regulatory bodies. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA or foreign regulatory bodies. If the FDA or foreign regulatory body disagrees with our determinations, it could require us to report those actions as recalls, and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results~~ . Modifications to our medical device products may require new 510 (k) clearances or other marketing authorizations or certifications, and if we make modifications to such products without obtaining requisite marketing authorization, we may be required to cease marketing or recall the modified products until clearances or other marketing authorizations or certifications are obtained. Any **significant** modification to a cleared or approved medical device **,** ~~that could significantly affect~~ **affecting** its safety ~~or ,~~ effectiveness, or ~~that would constitute a major change in its~~ intended use, **necessitates** ~~design or manufacture, requires~~ a new 510 (k) clearance or, ~~possibly~~ **in some cases** , approval of a PMA. ~~The~~ **While the** FDA **expects** ~~requires every manufacturer~~ **manufacturers** to make this determination ~~in~~ **, it retains the authority to review** ~~the~~ **these** ~~first instance, but~~ **decisions. Disagreement with** the FDA **on** ~~may review any manufacturer' s decision. The FDA may not agree with our decisions regarding~~ whether new clearances or approvals are necessary **could lead to regulatory actions, including the cessation of marketing or product recalls until clearance or approval is obtained** . ~~We~~ **This** may **result** ~~make modifications or add features to any of our product candidates that are cleared under the 510 (k) clearance process~~ in **substantial** ~~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. **Additionally** ~~In addition~~ , the FDA may not approve ~~or clear~~ our products for ~~the~~ **desired** indications ~~that are necessary or desirable for successful commercialization~~ or could ~~require~~ **mandate** clinical studies **for** ~~to support any~~ modifications. Any ~~delay~~ **delays** or ~~failure~~ **failures** in obtaining required clearances or approvals **may impede the timely** ~~for such changes would adversely affect our ability to introduce~~ **introduction of** new or enhanced products ~~in a timely manner~~ , **adversely affecting** ~~which in turn would harm~~ our future growth **and** ~~. Any of these actions would harm our~~ operating results ~~. In the EU, devices lawfully placed on the market pursuant to the EU Medical Devices Directive prior to May 26, 2021 may generally continue to be made available on the market or put into service until at least the end of 2027, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid and no substantial change must be made to the device as such a modification would trigger the obligation to obtain a new certification under the EU Medical Devices Regulation and therefore to have a notified body conducting a new conformity assessment of the devices. Once our devices will be certified under the EU Medical Devices Regulation, we must inform the notified body that carried out the conformity assessment of the medical devices that we market or sell in the EU and EEA of any planned substantial changes to our quality system or substantial changes to our medical devices that could affect compliance with the general safety and performance requirements laid down in Annex I to the EU Medical Devices 67Regulation or cause a substantial change to the intended use for which the device has been CE marked. The notified body will then assess the planned changes and verify whether they affect the products' ongoing conformity with the EU Medical Devices Regulation. If the assessment is favorable, the notified body will issue a new certificate of conformity or an addendum to the existing certificate attesting compliance with the general safety and performance requirements and quality system requirements laid down in the Annexes to the EU Medical Devices Regulation. The notified body may disagree with our proposed changes and product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business~~ . The misuse or off- label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business. Our currently marketed

products have been cleared by the FDA for specific indications. ~~For example, our SimpliDerm product has been labeled for use to repair or replace damaged or inadequate integumental tissue, our CanGaroo Envelope is intended to securely hold an implantable electronic device to create a stable environment when implanted in the body and, in January 2021, we received CE certification for updated labeling of our CanGaroo envelope to allow for the addition of the antibiotic gentamicin in EU markets.~~ We train our marketing personnel and direct sales force to not promote our devices for uses outside of the FDA- approved indications for use, known as " off- label uses. " We cannot, however, prevent a physician from using our products off- label, when in the physician' s independent professional medical judgment, he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off- label. Furthermore, the use of our products for indications other than those authorized or certified by the FDA or by any foreign regulatory body or notified body may not effectively treat such conditions, which could harm our reputation in the marketplace ~~among physicians and patients~~. If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off- label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off- label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations. ~~In addition, physicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. As described above, product liability claims could divert management' s attention from our core business, harm our reputation, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.~~ Failure to comply with post- marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market. ~~We are subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, import, export, registration and listing of devices. For example, we must submit periodic reports to the FDA as a condition of receiving 510 (k) clearances and other marketing authorizations. These reports include information about failures and certain adverse events associated with the device after its clearance. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.~~ The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, and higher than anticipated costs or lower than anticipated sales. Even after we have obtained the proper regulatory clearance to market a device, we have ~~ongoing~~ **53ongoing** responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign ~~68regulatory~~ **regulatory** authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions: ● untitled letters or warning letters; ● fines, injunctions, consent decrees and civil penalties; ● recalls, termination of distribution, administrative detention or seizure of our products; ● customer notifications or repair, replacement or refunds; ● operating restrictions or partial suspension or total shutdown of production; ● delays in or refusal to grant our requests for future clearances or approvals or foreign marketing authorizations or certification of new products, new intended uses or modifications to existing products; ● withdrawals or suspensions of our current 510 (k) clearances, or certifications resulting in prohibitions on sales of our products; ● FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and ● criminal prosecution. Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations. ~~In addition~~ **Our ability to develop and gain approval for medical products is subject to potential challenges stemming from regulatory changes** , **particularly** ~~the~~ **those initiated by the FDA and other authorities. The** FDA may ~~change~~ **alter** its clearance policies, ~~adopt additional~~ **introduce new** regulations **,** or ~~revise~~ **modify** existing ~~regulations~~ **ones** , **possibly causing** ~~or take other actions, which may prevent or delay~~ **delays** ~~clearance or~~ **in the** approval of our ~~future~~ **upcoming** products ~~under development~~ or ~~impact~~ **hindering** our ability to ~~modify our~~ **make timely adjustments to** currently cleared products ~~on a timely basis~~. ~~Such~~ **These changes in** policy or ~~regulatory~~ **regulations may** ~~changes could~~ impose additional requirements ~~upon us that could~~ **, potentially leading to** ~~delay~~ **delays in** ~~our ability to obtain~~ **obtaining** new clearances ~~or approvals~~, ~~increase~~ **increased** ~~the~~ **compliance** costs **,** ~~of compliance or restrict our~~ **or** ~~ability to~~ **limitations on** ~~maintain~~ **maintaining** ~~our~~ **current product** clearances ~~of our current products~~. **It' s important to note that** ~~For example, on February 23, 2022,~~ the FDA ~~issued a proposed rule to amend the QSR, which establishes current good manufacturing practice requirements for medical device manufacturers, to align more closely with the International Organization for Standardization standards. This proposal has not yet been finalized or adopted. Accordingly, it is unclear the extent to which this or any other proposals, if adopted, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise negatively affect our business. Additionally, in September 2019, the FDA finalized guidance describing an optional " safety and performance based " premarket review pathway for manufacturers of " certain, well- understood device types " to demonstrate substantial equivalence under the 510 (k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA is developing a list of device types appropriate for the " safety and performance based " pathway and will continue to develop product- specific guidance documents that identify the performance criteria for each such device type, as well as the testing~~

methods recommended in the guidance documents, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510 (k) clearances or otherwise create competition that may negatively affect our business. The FDA' s and other regulatory authorities' and notified bodies ' **may alter their** policies **,** may change and additional **new** government regulations may **emerge** be promulgated that could prevent , limit or delay **further complicating the** regulatory **landscape** clearance or approval of our product 69candidates . We cannot predict **The unpredictability of** the likelihood, nature or extent **, and scope** of **future** government regulation **regulations** that may arise from future legislation or administrative action , either **both** in the United States or abroad **and internationally, adds an additional layer of uncertainty** . **Failure** If we are slow or unable to **promptly** adapt to **changing** changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance , we may **could result in the** lose **loss** any **of** marketing approval that we may have obtained and we may not achieve or **for** sustain profitability **our products** . 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, **termed** such as ViBone, Fiber VBM, and OsteGro V, which are referred to by the FDA as HCT / Ps **by the FDA** . Certain HCT / Ps **fall** are regulated by the FDA solely under Section 361 of the **Public Health Service Act (“** PHSA **”)** and are **known** referred to as “ **"** Section 361 HCT / Ps **." These products** , **meeting specific criteria like" minimally manipulated" and intended** ” while other HCT / Ps are subject to FDA' s regulatory requirements applicable to medical devices or **for " homologous use,"** biologies. Section 361 HCT / Ps do not require 510 (k) clearance, PMA approval, **or Biologics License Applications (“** BLAs **”)** , or other premarket authorization from FDA before marketing. **Our** 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 **believed to be** our HCT / Ps are regulated solely under Section 361 of the PHSA and , **and** therefore, we **have haven** not **' t** sought or obtained 510 (k) clearance, PMA approval, or **BLA** licensure through a BLA . The **However, the** FDA could disagree **, potentially** with our determination that our human tissue products are Section 361 HCT / Ps and could determine that these products are biologies requiring **us to** a BLA or medical devices requiring 510 (k) clearance or PMA approval, and could require that we cease marketing such **or recall** products and / or recall them pending **proper authorization** appropriate clearance, approval or license from the FDA . For example, in public comments, the FDA has suggested **may decide** that the **certain** use **uses** of human- derived acellular dermal matrices, such as SimpliDerm , may not be considered HCT / Ps when utilized in certain **specific** breast reconstruction procedures . As a result , **necessitating** we may be required to conduct clinical studies and **potential PMA** / or seek approval of a PMA before we are able to market SimpliDerm for use in breast reconstruction . Even though we believe that our HCT / Ps are not subject to premarket approval or review, HCT / Ps are subject to donor eligibility and **,** screening, Good **54Good** Tissue Practices, product labeling **,** and post- market reporting requirements. **Failure** If we or our suppliers fail to comply **may result in** with these requirements, we could be subject to FDA enforcement action **actions** , including , for example, warning letters, fines, injunctions, product recalls or **,** seizures and , **and,** in **severe** 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 **poses significant challenges, requiring careful design and implementation. It** is **time- consuming** difficult to design and implement , can take many years, can be expensive **,** and carries **outcomes are** uncertain outcomes . The long- term effects of using our products in a large number of patients have not been studied, and the results **Results from** 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 **initial** clinical studies of our products conducted to date and ongoing or future studies of our current, planned or future products may not be **accurately** predictive --- **predict** of the results of later clinical studies , and interim results of a clinical study do not necessarily predict final results . Our interpretation **Interpretation** of data **is subjective,** and results from our clinical **past successes in early** studies do not **guarantee success** 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 **Clinical** studies may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical studies. Failure **failure** can occur at any **point, leading to inconclusive or** 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 . 70The **Factors like delays in study** initiation and completion of any of clinical studies may be prevented , **disagreements with** delayed or halted for numerous reasons. We may experience delays in our ongoing clinical studies for a number of reasons, which could adversely affect the costs, timing or successful completion of our clinical studies, including related to the following: ● we may be required to submit an investigational device exemption (“ IDE ”), application to the FDA, which must become effective prior to commencing certain human clinical studies of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical studies; ● regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical studies; ● regulators and / or IRBs , **difficulties in** 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~~ **unexpected costs, slow patient enrollment, protocol amendments, safety concerns, or** manufacturing ~~products~~ **issues may disrupt** or ~~conducting~~ **halt** clinical studies **. Regulatory changes** ~~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; 71 ● approval policies or regulations of the FDA, the EU legislative bodies or applicable foreign regulatory agencies may change in a manner rendering~~ --- **render existing** ~~our clinical~~ data insufficient for approval ~~; and ●~~ **. Unexpected side effects** ~~our~~ - **or characteristics in** current or future products ~~may have undesirable side effects or~~ **can also impact outcomes. The complex and unpredictable nature of clinical studies underscores** ~~other~~ -- **the** ~~unexpected characteristics~~ **challenges and uncertainties inherent in the development of medical products** . **The** ~~In addition,~~ disruptions caused by the COVID- 19 pandemic **have heightened** ~~has increased and may increase~~ the likelihood **of** ~~that we encounter~~ **encountering** ~~such~~ difficulties or delays in initiating, enrolling, conducting **,** or completing ~~our~~ planned and ongoing clinical studies **, posing a** ~~. Any of these occurrences may significantly~~ -- **significant** ~~harm~~ **threat to** our business, financial condition **,** and prospects. ~~In addition, many of the factors~~ **Factors influencing patient enrollment and study** ~~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~~ **include** ~~the size of the patient population, the nature of~~ the study protocol, ~~the~~ **patient** proximity ~~of patients~~ to clinical sites, ~~the~~ eligibility criteria ~~for the clinical study~~ , ~~patient~~ compliance, ~~competing~~ -- **competition** ~~clinical~~ **from other** studies **,** and ~~clinicians' and patients'~~ perceptions **of product advantages. Challenges such** 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~~ , **concurrent competitor** ~~or they may be persuaded to participate in contemporaneous clinical~~ studies ~~of a competitor's product candidate. In addition~~ , ~~patients~~ - **patient** ~~participating in~~ **dropouts,** ~~our~~ - **or** ~~clinical studies may drop out before completion of the~~ **unrelated adverse events can lead to delays, increased costs, or** study ~~or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure~~ **failures** ~~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 **' s** , foreign regulatory authorities **',** and notified bodies **' ability** to review and ~~clear, certify or~~ approve new products **is influenced** ~~can be affected~~ by **various** ~~a variety of~~ factors, including government budget ~~and funding levels~~ , ~~statutory, regulatory and~~ policy changes, ~~the FDA' s, foreign regulatory authorities~~ and ~~notified bodies' ability to hire and retain key~~ personnel **availability** ~~and accept the payment of user fees and other events that may otherwise affect the FDA' s, foreign regulatory authorities and notified bodies' ability to perform routine functions~~ . Average review times ~~at the FDA, foreign regulatory authorities and notified bodies'~~ have fluctuated in recent years ~~as a result. In addition~~ , ~~government funding of other government agencies that fund research~~ and ~~development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions~~ **disruptions** ~~at the FDA, other agencies and notified bodies may also slow the time necessary for medical devices and biologics or modifications to be cleared or for approved medical devices and biologics to be reviewed and / or approved or certified by necessary government agencies, or notified bodies which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies~~ , such as **government shutdowns and** ~~the FDA, have had to furlough~~ **furloughs** ~~critical FDA employees and stop critical activities. Subsequently~~ , **can impede** ~~in response to~~ the ~~global~~ **clearance and approval process. The** COVID- 19 pandemic **further impacted regulatory activities** , **with** ~~the FDA~~ postponed ~~most~~ inspections ~~of domestic~~ and **ongoing adaptations** ~~foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional~~

activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID- 19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays . **Continued** Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID- 19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue 72to prevent the FDA, other **may lead to additional delays in inspections and** regulatory authorities **processes. Prolonged government shutdowns** or **persistent pandemic- related disruptions** notified bodies from conducting their regular inspections, audits, reviews, or other regulatory activities, it could significantly **affect** impact the ability of the FDA, or other -- **the** regulatory authorities and notified bodies to timely review **of** and process our regulatory submissions, **posing** which could have a material adverse effect on our business. For instance, in the EU, notified bodies must be officially designated to certify products and services in accordance with the EU Medical Devices Regulation. While several notified bodies have been designated, the COVID- 19 pandemic has significantly slowed down their designation process and the current designated notified bodies are facing a large amount of requests for (re) certification under the new regulation as a consequence of which notified body review times have lengthened significantly. This situation could impact our ability to grow our business in the EU and EEA. We are **bound by** subject to certain federal, state **,** and foreign fraud and abuse laws, **violations of** which , if violated, could **result in significant** subject us to substantial penalties. Additionally, any challenge **Challenges** to or investigation **investigations** into our practices under these laws could cause **may lead to** adverse publicity **, incurring substantial** and be costly to respond **response costs** to, and **potential** thus could harm **to** 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; **55** ● 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 73to **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. **The heightened** 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 **providers by enforcement bodies enforcing** healthcare **regulatory laws** providers, which has **resulted in numerous** led to a number of investigations, prosecutions, convictions and settlements **in within** the healthcare industry. Responding to investigations **these inquiries** can be time- and resource- consuming **intensive** and can divert management ' s attention from the business . **Any** Additionally, as a result of these investigations , **investigation or settlement** , 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~~ **adversely impact** ~~effect on~~ our business. Even an unsuccessful challenge ~~or investigation into our practices~~ could ~~cause~~ **lead to** adverse publicity ~~,~~ and be ~~costly~~ **expensive** to **address** ~~respond to~~ . ~~If our operations are found to be in violation~~ **Violations** of ~~any of the~~ healthcare laws **may result in penalties, fines, exclusion from government programs, imprisonment, reputational harm, and operational curtailment or restructuring. Members of** ~~or~~ **our management, and** ~~regulations described above or any other~~ **their affiliations** ~~healthcare regulations that apply to us~~ , ~~we~~ **have been and** 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 **investigations, prosecutions, convictions, or settlements** . For ~~example~~ **instance** , Kevin Rakin, ~~the~~ **our board** chairman ~~of our board of directors~~ , **faced allegations** ~~was named as a defendant~~ in **the** United States ex rel. Webb v. Advanced BioHealing, Inc. ~~(" ABH ")~~ , a whistleblower suit ~~relating~~ **related** to sales **practices at** ~~methods employed by sales representatives of~~ ABH, **where** ~~a biotechnology company for which~~ Mr. Rakin served as **CEO** ~~its chief executive officer~~ . All claims ~~in the lawsuit~~ were dismissed with prejudice **in** ~~pursuant to~~ a settlement ~~agreement~~ , **where** ~~in which~~ Mr. Rakin ~~expressly~~ denied ~~that he engaged in~~ any **56wrongdoing** ~~wrongful conduct, and Mr~~ . **Such events could harm** ~~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 **adversely impact** ~~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~~ **The Affordable Care Act (" ACA "), enacted in** March 2010, **brought about** ~~the ACA was enacted in the United States, which made a number of~~ substantial changes **to** ~~in the way~~ healthcare **financing, introducing reforms such as** ~~is financed by both governmental and private insurers. Among other~~ -- **the creation of** ~~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~~ **and** ~~effort to coordinate and develop such research, implemented~~ payment system **changes like** ~~reforms, including a national pilot program on payment bundling to encourage hospitals, physicians and other 74providers to improve the coordination, quality and efficiency of certain healthcare services through~~ bundled ~~payment~~ **payments** ~~models, and expanded the eligibility criteria for Medicaid programs~~ . **Despite facing legal** ~~Since its enactment, there have been judicial, U. S. Congressional and executive branch~~ challenges **,** ~~to certain aspects of~~ the ACA ~~. On~~ **remained in effect as of** June 17, 2021, ~~the~~ **following a** U. S. Supreme Court ~~dismissed~~ **dismissal** ~~the most~~ **of a** 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~~ **' s** executive order **during this** ~~that initiated a special enrollment~~ period ~~for purposes of obtaining~~ **aimed to enhance access to** health insurance coverage **by** ~~through the ACA marketplace from February 15, 2021 through August 15, 2021. The executive order instructed certain governmental agencies to review~~ **reviewing** ~~and reconsider their~~ existing policies and **removing** ~~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. **Subsequent** ~~In addition, other~~ legislative changes **post-** ~~have been proposed and adopted since the~~ ACA ~~was enacted. On August 2~~ , **including** ~~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~~ , **have impacted** ~~which, among other things, reduced~~ Medicare payments ~~to several~~ **, influencing healthcare** providers ~~, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years~~ . **The ongoing evolution** ~~In addition, the Medicare Access and CHIP Reauthorization Act~~ of ~~2015 enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments began in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. We expect additional~~ state, federal **,** and foreign healthcare reform measures **suggests potential** ~~to be adopted in the~~ future **changes that** ~~, any of which~~ could limit reimbursement for healthcare products and services, ~~which could result in reduced~~ **adding pressure on pricing dynamics and impacting** demand for our products ~~or additional pricing pressure~~ . Actual or perceived failure to comply with data protection laws and regulations could lead to government enforcement actions ~~(which could include civil or criminal penalties)~~ , private litigation and / or adverse publicity and could negatively affect our ~~operating results and~~ business. We and our ~~commercial~~ partners **are** ~~, independent sales agents, suppliers and other business partners may be~~ subject to federal, state **,** and foreign data protection laws **, including the Health Insurance Portability** and ~~regulations~~ **Accountability Act** (**" HIPAA "** ~~i. e., laws and regulations that address data privacy and security~~) **in** ~~. In~~ the ~~United States~~ **U. S.** , ~~numerous federal and state laws and regulations govern~~ **governing** the collection, use, ~~disclosure~~ and protection of health- related and ~~other~~ personal information ~~could apply to our operations or the operations of our partners. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder, or collectively HIPAA, imposes privacy, security and breach notification obligations. We may obtain health information from third parties (including research institutions from which we obtain clinical study data) that are subject to privacy and security requirements under HIPAA~~ . While we **currently** ~~do not~~

believe ~~that~~ we ~~are currently acting as a covered entity or business associate under HIPAA and thus~~ are not directly regulated under HIPAA, ~~any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding- and- abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could be subject to~~ criminal penalties **may apply** if we knowingly **misuse** ~~obtain, use, or disclose individually identifiable~~ health information **from** ~~maintained by~~ a HIPAA- covered entity ~~in a manner that is not authorized or permitted by HIPAA~~. **Additionally** ~~In addition~~, the California Consumer Privacy Act (" CCPA "), ~~became~~ effective ~~on~~ **since** January 1, 2020 ~~. The CCPA gives~~ **, grants expanded rights to** California residents **regarding** ~~expanded rights to access and delete~~ their personal information ~~, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt out of certain sales of personal information~~. The ~~CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. Although there are limited exemptions for certain health- related information, including certain 75clinical study data, the CCPA may increase our compliance costs and potential liability. Further the~~ California Privacy Rights Act **(" , or the** CPRA **")**, ~~generally went into effect~~ **effective** ~~on~~ January 1, 2023, ~~and significantly amends the CCPA. The CPRA~~ imposes **more** ~~additional data protection~~ obligations on ~~covered~~ businesses, **potentially increasing compliance costs** ~~including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data,~~ and **liabilities** ~~opt outs for certain uses of sensitive data~~. **Similar** ~~It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased~~ privacy ~~and information security enforcement. Additional compliance investment and potential business process changes may be required. Similar~~ laws ~~have passed in Virginia, Connecticut, Utah and Colorado, and have been proposed~~ in other states and at the federal level **may pose challenges** , **with** ~~reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially~~ -- **potential** conflicting requirements ~~that would make compliance challenging~~. **Moreover, enforcement actions** ~~In the event that we are subject to or affected~~ by ~~HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Furthermore,~~ the Federal Trade Commission (**"** FTC **"**) and ~~many~~ state Attorneys General **are ongoing, targeting** ~~continue to enforce federal and state consumer protection laws against~~ companies for **unfair or deceptive** online ~~collection, use, dissemination~~ **data practices. The FTC emphasizes the importance of reasonable** and **appropriate data** security ~~practices that appear~~ **measures, and failure** to **comply may** be **deemed** unfair **under** ~~or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of~~ Section 5 (a) of the Federal Trade Commission Act. **Such regulatory scrutiny** ~~The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. In Europe, the European Union General Data Protection Regulation, or GDPR, went into effect in May 2018 and imposes~~ -- **poses** ~~strict requirements~~ **risks to our financial condition, emphasizing the need** for **robust** ~~processing the personal data of individuals within the EEA. Failure to comply with the requirements of GDPR and the applicable national~~ data protection **measures** and ~~marketing~~ **compliance efforts. Ensuring compliance with U. S. and foreign privacy and security** laws may ~~result~~ **necessitate assuming more burdensome obligations** in ~~fines of up to € 20, 000, 000 or~~ **our contracts** ~~up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher,~~ and **engaging in costly compliance efforts** ~~other administrative penalties as well as individual claims for compensation~~. **These regulations** ~~In addition to the foregoing, a breach of the GDPR~~ could ~~result in regulatory investigations, reputational damage, orders to cease / change our processing of our data and / or enforcement notices. We may also face civil claims including representative actions and other class action type litigation (where individuals have suffered harm), potentially amounting to significant compensation or damages liabilities, as well as associated costs, diversion of internal resources, and reputational harm. The GDPR also imposes~~ - **impose** ~~strict rules on the transfer of personal data out of the EEA, to the United States and other third countries that have not been found to provide adequate protection to such personal data. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States, e. g. on July 16, 2020, the Court of Justice of the European Union, or the " CJEU, " invalidated the EU- U. S. Privacy Shield Framework, for purposes of international transfers and imposed further~~ restrictions on ~~the use of standard contractual clauses, or SCCs. In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU- US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 16, 2020 have taken a restrictive approach to international~~ data **collection** ~~transfers. As supervisory authorities issue further guidance on personal data export mechanisms~~, **usage** ~~including circumstances where the SCCs cannot be used~~, and **disclosure** ~~/ or start taking enforcement action~~, **potentially** ~~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~~ **affecting** ~~the manner in which we provide our services, the geographical location or~~ **our** ~~segregation of our relevant systems and~~ operations ~~,~~ and ~~could adversely affect our financial results. From January 1, 2021, we have been subject to the~~ **those of our partners** ~~GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR~~ in **specific jurisdictions** ~~UK national law~~. The ~~UK GDPR mirrors~~ **evolving nature of** ~~the~~ **these** ~~fines under the GDPR, e. g. fines up to the greater of € 20 million (£ 17. 5 million) or 4 % of global turnover. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional~~ laws **introduces** ~~and regulations that may affect how we conduct business. Compliance with U. S. and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to~~

~~76collect, 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 **non- compliance may lead to** ~~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~~ **impacting** our **business and** operating results ~~and business~~ . ~~Moreover~~ **Additionally** , **contractual limitations imposed by** patients **and providers on** ~~about whom we or our partners obtain~~ information **use and disclosure** ~~, as well as the providers who share this information,~~ may **hinder** ~~contractually limit~~ our **operations** ~~ability to use and disclose the information~~ . Claims **of** ~~that we have violated individuals'~~ privacy ~~rights~~ **violations** , ~~failed to comply~~ **non- compliance** with data protection laws, or ~~breached~~ **breaches** ~~our~~ **of** contractual obligations, even if **unfounded** ~~we are not found liable~~ , ~~could~~ **can** be **resource** ~~expensive and time~~ - ~~consuming~~ **intensive** to defend and ~~could~~ result in adverse publicity **,** ~~that could have a material and adverse~~ **adversely affecting** ~~effect on~~ our business, financial condition **,** and results of operations. Risks Related to Intellectual PropertyIf 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~~ **57to** 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 ~~77against~~ -- **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~~ **58to** 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; ~~78~~ ● 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~~ **59We** 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 **into** 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. ~~79Pending~~ -- **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~~ **60Moreover** , 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 ~~80commercialization~~ -- **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~~ **61Any** 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 ~~81initiate~~ -- **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~~ **62third** 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. ~~82Third~~ -- **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~~ **63Third** 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. ~~83Outside --~~ **Outside** of the United States we cannot be certain that any country' s patent or trademark office will not implement new rules that could seriously affect how we draft, file, prosecute and maintain patents, trademarks and patent and trademark applications. We cannot be certain that the patent or trademark offices of countries outside the United States will not implement new rules that increase costs for drafting, filing, prosecuting and maintaining patents, trademarks and patent and trademark applications or that any such new rules will not restrict our ability to file for patent or trademark protection. For example, we may elect not to seek patent protection in some jurisdictions or for some drug candidates in order to save costs. We may be forced to abandon or return the rights to specific patents due to a lack of financial resources. For example, the impact of the withdrawal of the U. K. from the EU will not be known for some time, which could lead to a period of uncertainty relating to our ability to obtain and maintain patents and trademarks in the U. K. In ~~2012~~ **642012** , the European Patent Package, or EU Patent Package, regulations were passed with the goal of providing for a single pan- European Unitary Patent, and a new European Unified Patent Court, or UPC, for litigation of European patents. It is possible that implementation of the EU Patent Package will occur in the first half of 2023. If the EU Patent Package is ratified and in effect, all European patents, including those issued prior to ratification, would by default automatically fall under the jurisdiction of the UPC and allow for the possibility of obtaining pan- European injunctions. Under the EU Patent Package as currently proposed, once the UPC is established, patent holders are permitted to " opt out " of the UPC on a patent- by- patent basis during an initial seven year period after the EU Patent Package is ratified. Owners of traditional European patent applications who receive notice of grant after the EU Patent Package is ratified could either accept a Unitary Patent or validate the patent nationally and file an opt- out demand. The EU Patent Package may increase the uncertainties and costs surrounding the enforcement or defense of our issued European patents and pending applications. The full impact on future European patent filing strategy and the enforcement or defense of our issued European patents in member states and / or the UPC is not known. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and European and other patent agencies over the lifetime of a patent. In addition, the USPTO and European and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which such noncompliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position, could impair our ability to successfully commercialize our product candidates in any indication for which they are approved, and could have a material and adverse effect on our business, financial condition and results of operations. In addition, any of the intellectual property rights that we own or license that are developed through the use of U. S. government funding will be subject to additional federal regulations. Pursuant to the Bayh- Dole Act of 1980 (the " Bayh- Dole Act "), the government will receive a license under inventions developed under a government- funded program and may require us to manufacture products embodying such inventions in the

United States. Under certain circumstances, the government may also claim ownership in such inventions or compel us to license them to third parties. Any failure by us to comply with federal regulations regarding intellectual property rights that were developed through the use of U. S. government funding could have a material and adverse effect on our business, financial condition and results of operations. ~~84If~~ **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~~ **65In** 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. ~~85As~~ **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~~ **66parties** 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. ~~86In~~ **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~~ **67We** 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 StockWe expect that the price of our Class A common stock will fluctuate substantially ~~and you~~ **. You** may not be able to sell the shares you purchase at or above the price you paid for such shares **, and our common stock could be subject to delisting if its price falls too low** . The market price of our Class A common stock is likely to be highly volatile and may fluctuate substantially due to a variety of factors, many of which are outside of our control, including, among other things: ● the volume and timing of sales of our products; ● the introduction of new products or product enhancements by us or others in our industry; ● disputes or other developments with respect to our or others' intellectual property rights; ~~87~~ ● our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis, including our ~~CanGaroo~~ **CanGarooRM** ~~RM~~ ; ● changes or proposed changes in laws or regulations or differing interpretations or enforcement thereof affecting our business; ● product liability claims, other litigation or regulatory investigations; ● annual or quarterly variations in our results of operations or those of others in our industry, or results of operations that otherwise vary from those expected by securities analysts and investors; **68** ● publications, reports or other media exposure of our products or those of others in our industry, or of our industry generally; ● announcements by us or others in our industry, or by our or their respective suppliers, distributors or other business partners, regarding, among other things, significant contracts, price reductions, capital commitments or other business

developments, the entry into or termination of strategic transactions or relationships, securities offerings or other financing initiatives, and public reaction thereto; ● additions or departures of key management personnel; ● changes in governmental regulations or in reimbursement; ● changes in earnings estimates or recommendations by securities analysts, or other changes in investor perceptions of the investment opportunity associated with our Class A common stock relative to other investment alternatives; ● the development and sustainability of an active trading market for our Class A common stock; ● general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors; and ● other factors discussed in Part I, Item 1A. " Risk Factors " of this Annual Report. In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies, including, as a result of the pandemic related to COVID- 19 including variants and resurgences. Broad market and industry factors may significantly affect the market price of our Class A common stock, regardless of our actual operating performance. If the market price of shares of our Class A common stock does not ever exceed the price you paid for your shares, you may not realize any return on your investment in us and may lose some or all of your investment. In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management' s attention and resources away from our business. **The listing of our common stock on the Nasdaq Capital Market (" Nasdaq ") is subject to a number of conditions, including that the total market value of the Company' s listed securities remain at or above a certain level. In the past, the Company has not maintained that required level and has been at risk of its common stock being delisted by Nasdaq. Although the Company was able to regain compliance with the rule and avoid having its common stock delisted, there is no guarantee that, in view of the volatility of the Company' s stock and other factors, the Company might not run afoul of the market value listing condition or other similar listing conditions in the future. The delisting of the Company' s common stock would have a material adverse effect on the liquidity of the common stock, and could have a material adverse effect on its price. Moreover, the threat of delisting could have similar consequences.** Our principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders. As of December 31, ~~2022~~ **2023** , our principal stockholder, HighCape Partners L. P. and its affiliates, held approximately ~~47~~ **48** . ~~3~~ **7** % of our outstanding Class A common stock. As a result, HighCape Partners L. P. and its affiliates are able to significantly influence the management and affairs of our company and the outcome of most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The interests of these ~~88stockholders~~ -- **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~~ **69stockholders** , thereby depriving our other stockholders of an opportunity to receive a premium for their common stock as part of a sale of the company or our assets. Conversely, these stockholders may pursue acquisitions, divestitures and other transactions that, in their judgment, could enhance the value of their investment, even though such transactions might involve risks to you. Even in the absence of any actual conflict of interest, the degree of control possessed by these stockholders may affect the prevailing market price of our Class A common stock due to investors' perceptions that such conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in the best interests of our other stockholders and may impair your ability to realize any return on your investment in us and may impair your ability to avoid losing some or all of your investment. A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our Class A common stock to drop significantly, even if our business is doing well. Sales of a substantial number of shares of our outstanding Class A common stock in the public market could occur at any time. In addition, conversions of a substantial number of shares of our outstanding Class B common stock into Class A common stock and sales of such converted shares of our Class A common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of such shares intend to sell shares, could reduce the market price of our Class A common stock. As of December 31, ~~2022~~ **2023** , we had outstanding approximately ~~11~~ **18** . ~~8~~ **9** million shares of Class A common stock, of which ~~6~~ **9** . ~~2~~ **5** million shares of our Class A common stock were freely tradable without restriction or further registration under the Securities Act of 1933, as amended (the " Securities Act "), by persons other than our " affiliates, " as that term is defined under Rule 144 of the Securities Act and approximately ~~5~~ **9** . ~~6~~ **4** million shares were held by our affiliates and eligible for resale subject to volume, manner of sale and other limitations under Rule 144. Additionally, we had outstanding approximately 4. 3 million shares of Class B common stock which may be converted on a one to one basis into shares of Class A common stock, of which all were freely tradable and held by persons other than our " affiliates. " **We also** ~~Moreover, as of the date of this Annual Report, several of our affiliates~~ have ~~rights, subject to conditions and limitations, to require us to file registration statements covering up to approximately 4. 5 million of their shares or to include such shares in registration statements that we may file for ourselves or other stockholders. We have also~~ registered shares of our Class A common stock issued and available for issuance under our equity compensation plans, which can be freely sold in the public market, subject to vesting requirements and volume limitations applicable to affiliates. If these shares are sold, or if it is perceived that they will be sold, in the public market, or when we are required to register the sale of our stockholders' remaining shares of our Class A common stock, the trading price of our Class A common stock could decline. A decline in the trading price of our Class A common stock might impede our ability to raise capital through the issuance of additional shares of our Class A common stock or other equity securities and may impair your ability to sell shares of our Class A common stock at a price higher than the price you paid for them or at all. The dual class structure of our common stock and the option of the holders of shares of our Class B common stock to convert into shares of our Class A common stock may limit your ability to influence corporate matters. Our Class A common stock has one vote per share, while our Class B common stock is non- voting. Nonetheless, each share of our Class B common stock may be

converted at any time into one share of Class A common stock at the option of its holder, subject to the limitations provided for in our certificate of incorporation that prohibit the conversion of our Class B common stock into shares of Class A common stock to the extent that, upon such conversion, such holder would beneficially own in excess of 4. 9 % of any class of our securities registered under the Exchange Act. Consequently, if holders of Class B common stock exercise their option to make this conversion, such exercise will have the effect of increasing the relative voting power of those prior holders of our Class B common stock (subject to the ownership limitation described in the previous sentence) and increasing the number of outstanding shares of our voting common stock, and correspondingly decreasing the relative voting power of the current holders of our Class A common stock, ~~89which~~ -- **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~~ **70You** may be diluted by the future issuance of additional common stock in connection with our incentive plans, acquisitions or otherwise. As of December 31, ~~2022~~ **2023**, we had ~~188~~ **181**, ~~176~~ **115**, ~~555~~ **804** shares of Class A common stock authorized but unissued and 15, 686, 594 shares of Class B common stock authorized but unissued. We are authorized under our certificate of incorporation to issue these shares of common stock and other securities convertible into or exercisable or exchangeable for shares of our common stock for the consideration and on the terms and conditions established by our board of directors in its sole discretion, whether in connection with acquisitions or otherwise. As of December 31, ~~2022~~ **2023**, we had a total of 1, ~~864~~ **501**, ~~739~~ **193** 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 **Amended and Restated** 2020 Incentive Award Plan (the " 2020 Plan ") at a weighted average exercise price of $ ~~9~~ **8**. ~~41~~ **37** per share, ~~723~~ **786**, ~~793~~ **058** of which were vested as of such date, ~~192~~ **335**, ~~070~~ **608** shares of Class A common stock issuable upon the settlement of RSUs granted under our 2020 Plan to several of our executive officers, employees and consultants, ~~656~~ **3**, ~~689~~ **401, 678** additional shares of our Class A common stock reserved for future issuance under our 2020 Plan, not including the additional shares of Class A common stock that will be reserved for future issuance under our 2020 Plan pursuant to provisions in the 2020 Plan that automatically increase the number of shares of our Class A common stock reserved for future issuance thereunder, and ~~279~~ **335**, ~~345~~ **808** shares of our Class A common stock available for future issuance under our 2020 Employee Stock Purchase Plan (the " 2020 ESPP "), not including the additional shares of Class A common stock that will be reserved for future issuance under our 2020 ESPP pursuant to provisions in the 2020 ESPP that automatically increase the number of shares of our Class A common stock reserved for future issuance thereunder. Additionally, as of December 31, ~~2022~~ **2023**, we had ~~a~~ **total** ~~warrant~~ **warrants outstanding of 11, 724, 831** to purchase ~~up to 187, 969 shares of~~ our Class A common stock **comprised of up to 187, 969 warrants** issued to the lender under the SWK Loan Facility ~~that was outstanding~~ **and 11, 536, 862 warrants issued to investors in our September 2023 Class A common stock private placement. On January 31, 2024, we granted stock options covering 1, 615, 561 shares of Class A common stock and restricted stock units covering 2, 267, 500 shares of Class A common stock to employees and consultants under the 2020 Plan**. Any additional shares of common stock that we issue, including under our 2020 Plan, 2020 ESPP or other equity incentive plans that we may adopt in the future, or as a result of any exercise of the warrant, would dilute the percentage ownership and voting power held by investors who purchase our common stock. In the future, we may also issue additional securities if we need to raise capital, including, but not limited to, in connection with acquisitions, which could constitute a material portion of our then- outstanding shares of our common stock. We are an " emerging growth company " and a " smaller reporting company, " and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors. We are an " emerging growth company, " as defined in the JOBS Act, and a " smaller reporting company, " as defined in Rule 12b- 2 under the Exchange Act. Emerging growth companies and smaller reporting companies may take advantage of certain exemptions from various reporting requirements that are applicable to other publicly- traded entities that are not emerging growth companies or smaller reporting companies. With respect to emerging growth companies, these exemptions include: ● the option to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with a correspondingly reduced Management' s Discussion and Analysis of Financial Condition and Results of Operations; ● not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act; ● not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements (i. e., an auditor discussion and analysis); ~~90~~ ● 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~~ **and71** ● not being required to disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer' s compensation to median employee compensation. We have elected to take advantage of certain of these reduced disclosure obligations and may elect to take advantage of other reduced reporting requirements in the future. As a result, the information that we provide to our stockholders may be different than the information you might receive from other public reporting companies in which you hold equity interests. In addition, the JOBS Act permits emerging growth companies to delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements and the reported results of operations contained therein may not be directly comparable to those of other public companies. We cannot predict whether investors will find our common stock less attractive because of our reliance on these exemptions. If some investors do find our common stock less attractive, there may be a less active trading

market for our Class A common stock and our stock price may be reduced or more volatile. We will remain an emerging growth company, and will be able to take advantage of the foregoing exemptions, until the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues are $ 1. 235 billion or more; (ii) the last day of 2025; (iii) the date that we become a " large accelerated filer " as defined in Rule 12b- 2 under the Exchange Act, which would occur if the market value of our common equity held by non- affiliates is $ 700 million or more as of the last business day of our most recently completed second fiscal quarter; or (iv) the date on which we have issued more than $ 1. 0 billion in non- convertible debt securities during the previous three years. Even after we cease to be an emerging growth company, we will still be a smaller reporting company until such time as (i) we determine that the market value of the voting and non- voting shares held by non- affiliates is $ 250 million or more but less than $ 700 million as of the last business day of our second fiscal quarter and our annual revenues are $ 100 million or more during our most recently completed fiscal year, or (ii) the market value of the voting and non- voting shares held by non- affiliates is $ 700 million or more measured on the last business day of our second fiscal quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies, including reduced financial and executive compensation disclosure. In addition, even if we cease to be an emerging growth company, we will remain exempt from the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act provided we do not qualify as an " accelerated filer " as defined in Rule 12b- 2 under the Exchange Act, which would occur if our annual revenue was $ 100 million or more during our most recently completed fiscal year and the market value of our common equity held by non- affiliates is $ 75 million or more as of the last business day of our most recently completed second fiscal quarter, and only after we have been subject to the reporting requirements of the Exchange Act for a period of at least 12 calendar months. We will continue to incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices. **Failure to comply may result in delisting of our common stock, government penalties or other materially adverse consequences.** As a public company, and particularly after we are no longer an emerging growth company, we incur and will continue to incur significant legal, accounting and other expenses. The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq ~~Global~~ **Capital** Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives, which has and we expect will continue to divert their attention away from our core business operations and revenue- producing activities. Moreover, these rules and regulations ~~has~~ **have** and will continue to increase our legal and financial compliance costs and make some activities more time- consuming and costly. For example, these rules and regulations make it more difficult and more ~~91expensive~~ -- **expensive** for us to obtain director and officer liability insurance, which requires us to incur substantially higher costs to ~~obtain~~ **72obtain** 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~~ **Governance requirements include matters such as the composition of our board of directors and its committees, and include matters such as the degree of independence of a director from the Company. Because of the Company' s size and risk profile, among other reasons, it may be more difficult for the Company** to ~~comply~~ **recruit qualified directors than other companies. In the past, the Company has been out of compliance** with ~~requirements to design~~ **certain board composition rules** , ~~implement~~ **which put the Company' s common stock at risk of being delisted. Although the Company regained compliance with that rule** and **avoided delisting of its common stock, there can be no guarantee that the Company will be able to** maintain **such compliance, which** ~~effective internal control over financial reporting~~ could **put the Company' s common stock at risk of delisting again. The delisting of the Company' s common stock would** have a material adverse effect on ~~our business and~~ **the liquidity of the common** 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~~ **and** ~~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 **its** ~~the trading~~ price **. Moreover, the threat of delisting could have similar consequences. 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** . ~~92Provisions~~ -- **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; **73** ● 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. ~~93Our~~ -- **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~~ **74Because** we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, would be your sole source of gain. We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock would be your sole source of gain on an investment in our common stock for the foreseeable future. We could be subject to securities class action litigation. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because medical device companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business. General Risk FactorsChanges 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 **, warrants** and stock- based compensation. Changes in these rules, guidelines or interpretations could significantly change our reported or expected financial performance or financial condition. ~~94~~ **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. 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. 75As 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. 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 76