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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31 , 2023

OR

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

Commission File Number: 001-37906

ORGANOGENESIS HOLDINGS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**98-1329150**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

85 Dan Road
Canton , MA 02021
(Address of Principal Executive Offices, Including Zip Code)
(781) 575-0775
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A Common Stock, $0.0001 par value	**ORGO**	**Nasdaq Capital Market**

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting common shares held by non-affiliates of the registrant was approximately $

235.7

million, computed by reference to the closing sale price of the Class A common stock as reported by The Nasdaq Capital Market on June 30, 2023, the last trading day of the registrant's most recently completed second fiscal quarter. The Company has no non-voting common shares.

The number of shares of the registrant's Class A common stock outstanding as of February 26, 2024 was

131,963,176

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DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be provided in Part III of this Annual Report on Form 10-K will be provided by a Definitive Proxy Statement for our 2024 Annual Meeting of Stockholders (the "Proxy Statement") to be filed with the Securities and Exchange Commission on or before April 29, 2024.

Auditor Firm Id:	Auditor Name:	Auditor Location:
49	RSM US LLP	Boston, Massachusetts

ORGANOGENESIS HOLDINGS INC.
ANNUAL REPORT ON FORM 10-K
FOR FISCAL YEAR ENDED DECEMBER 31, 2023

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the sections entitled "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements. These statements may relate to, but are not limited to, expectations of our future results of operations, business strategies and operations, financing plans, potential growth opportunities, potential market opportunities and the effects of competition, as well as assumptions relating to the foregoing. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. These risks and other factors include, but are not limited to, those listed under "Risk Factors." In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "intend," "potential," "might," "would," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially.

As used herein, except as otherwise indicated by context, references to "we," "us," "our," "the Company," "Organogenesis" and "ORGO" will refer to Organogenesis Holdings Inc. and its subsidiaries.

TRADEMARKS AND SERVICE MARKS

All trademarks, trade names, product names, graphics and logos of Organogenesis contained herein are trademarks or registered trademarks of Organogenesis Holdings Inc. or its subsidiaries, as applicable, in the United States and/or other countries. All other party trademarks, trade names, product names, graphics and logos contained herein are the property of their respective owners. The use or display of other parties' trademarks, trade names, product names, graphics or logos is not intended to imply, and should not be construed to imply a relationship with, or endorsement or sponsorship of Organogenesis by such other party.
Solely for convenience, the trademarks, service marks and trade names referred to in this annual report are listed without the ®, (sm) and (TM) symbols, but we will assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and trade names.

PART I

ITEM 1. BUSINESS

Overview

Organogenesis is a leading regenerative medicine company focused on the development, manufacture and commercialization of solutions for the Advanced Wound Care and Surgical & Sports Medicine markets. Our products have been shown through clinical and scientific studies to support and in some cases accelerate tissue healing and improve patient outcomes. We are advancing the standard of care in each phase of the healing process through multiple breakthroughs in tissue engineering and cell therapy. Our solutions address large and growing markets driven by aging demographics and increases in comorbidities such as diabetes, obesity, cardiovascular and peripheral vascular disease. We offer our differentiated products and in-house customer support to a wide range of health care customers including hospitals, wound care centers, government facilities, ambulatory surgery centers (ASCs) and physician offices. Our mission is to provide integrated healing solutions that substantially improve medical outcomes and the lives of patients while lowering the overall cost of care.

We offer a comprehensive portfolio of products in the markets we serve that address patient needs across the continuum of care. We have and intend to continue to generate data from clinical trials, real-world outcomes and health economics research that validate the clinical efficacy and value proposition offered by our products. Several of our existing and pipeline products in our portfolio have Premarket Application (PMA) approval, or 510(k) clearance from the United States Food and Drug Administration (FDA). Given the extensive time and cost required to conduct clinical trials and receive FDA approvals, we believe that our data and regulatory approvals provide us a strong competitive advantage. Our product development expertise and multiple technology platforms provide a robust product pipeline, which we believe will drive future growth.

In the Advanced Wound Care market, we focus on the development and commercialization of advanced wound care products for the treatment of chronic and acute wounds in various treatment settings. We have a comprehensive portfolio of regenerative medicine products, capable of supporting patients from early in the wound healing process through wound closure regardless of wound type. Our advanced wound care products include Apligraf for the treatment of venous leg ulcers (VLUs) and diabetic foot ulcers (DFUs); Dermagraft for the treatment of DFUs (manufacturing and distribution currently suspended pending transition to a new manufacturing facility or engagement of a third-party manufacturer); PuraPly AM as an antimicrobial barrier and native, cross-linked extracellular matrix scaffold for a broad variety of wound types; and Affinity, Novachor, and NuShield placental allografts to address a variety of wound sizes and types as a protective barrier and extracellular matrix scaffold. We have a highly trained and specialized direct wound care sales force paired with comprehensive customer support services.

In the Surgical & Sports Medicine market, we are leveraging our broad regenerative medicine capabilities to address chronic and acute surgical wounds and tendon and ligament injuries. Our Sports Medicine products include NuShield as a surgical barrier and PuraForce as a reinforcement matrix in targeted soft tissue repairs; and Affinity, Novachor, PuraPly MZ, PuraPly AM, and PuraPly SX for management of open wounds in the surgical setting. We currently sell these products through independent agencies and our direct sales force.

As of December 31, 2023, we had approximately 862 full-time employees worldwide. For the year ended December 31, 2023, we generated revenue of $433.1 million and we incurred operating expenses of $314.1 million.

Competitive Strengths

We believe we have several unique strengths that have been instrumental to our success and position us well for future growth:

- **Leader in Regenerative Medicine Technology with Strong Brand Recognition.** Given our extensive history in regenerative medicine, we have strong brand recognition and market-leading positions across our portfolio, which includes flagship products Apligraf, Dermagraft, and PuraPly AM, as well as our placental-based (amnion & chorion tissue) products NuShield, Affinity, and Novachor. Organogenesis is well recognized as an innovator that has advanced the science of regenerative medicine, as well as the methodology to manufacture living technology at a large commercial scale and ship it worldwide. We first entered the market in 1998 with Apligraf, which is still considered one of the major breakthroughs of the Company in the regenerative medicine market, and a leader in the skin substitute category. In addition, our product Dermagraft received FDA approval in 2001 and is a well-known brand in the global regenerative medicine market.

- **Well-Positioned in Large, Attractive and Growing Global Markets—Advanced Wound Care and Surgical & Sports Medicine.** We believe both markets will continue to see accelerated growth given favorable global demographics that include an aging population and a greater incidence of comorbidities such as diabetes, obesity, cardiovascular and

peripheral vascular disease. We believe there is growing adoption of regenerative medicine products by the physician community due to their clinical superiority and cost effectiveness for all major stakeholders compared to traditional products.

• **Comprehensive Suite of Products to Address the Clinical and Economic Needs of Wound Care Patients and Providers.** Our comprehensive portfolio of wound care products allows physicians to personalize solutions to meet the needs of individual wound care patients. We engage with the physician at the earliest incidence of the patient's healing process with our PuraPly AM product, which has antimicrobial properties that are beneficial for most types of wounds. If the underlying healing issues persist, we offer an array of bioactive products and placental-based (amnion & chorion tissue) protective barriers and extracellular matrix (ECM) scaffolds customizable for various sizes and types of wounds. Our experienced wound care sales force is highly trained to assist clinicians in effectively deploying the full complement of our wound care products.

• **Large and Growing Body of Clinical Data and FDA Approved Products.** We have a deep body of scientific, clinical and real-world outcomes data, including over 100 publications that review the technical and clinical attributes of our products. Several of our existing and pipeline products in our product portfolio have FDA regulatory approval, including PMA approval or 510(k) clearance. Given the extensive time and cost required to conduct clinical trials and receive FDA approval, we believe our data and regulatory approvals provide us with a strong competitive advantage.

• **Robust and Extensive Relationships Across the Continuum of Care.** We have established robust and extensive customer relationships across the entire continuum of care and sites of care including hospitals, wound care centers, government facilities, ASCs, and physician offices to sell our broad portfolio of products. We serve more than 4,000 health care facilities, hospital systems, integrated delivery networks (IDNs) and Group Purchasing Organizations (GPOs). In addition, we have developed important relationships with various physician specialties (Plastics, General, Vascular, Orthopedic, Podiatry, Dermatology), nurses, and other key decision-makers as well as third-party payers. Given these relationships across the continuum of care, we believe we are well positioned to increase our penetration in the Advanced Wound Care market and leverage those relationships in the Surgical & Sports Medicine market.

• **Differentiated In-house Customer Support Capabilities Including Third-Party Reimbursement Support.** We strengthen our customer relationships with extensive in-house customer support capabilities. Through our dedicated team of experienced professionals, our Circle of Care program provides in-house third-party reimbursement, and medical and technical support.

• **Established and Scalable Regulatory, Manufacturing and Commercial Infrastructure.** We have developed significant in-house expertise on the regulatory approval process that is based on our successful management of multiple products through various FDA approval pathways including PMA approval, Biologics License Application (BLA) approval and Premarket Notification 510(k) clearance. We have also developed rigorous and proven FDA-compliant manufacturing, distribution, and logistics capabilities. We pair our operational capabilities with a strong commercial team of sales and marketing professionals. Our established regulatory, operational and commercial infrastructure provides a firm foundation for growth as we continue to scale our business.

• **Extensive Executive Management Experience in Regenerative Medicine.** Our executive management team has extensive experience in the regenerative medicine industry, boasting over 100 years of collective experience in the space. This experience allows us to operate from a deep understanding of the underlying trends in regenerative medicine and the intertwined scientific, clinical, regulatory, commercial and manufacturing issues that drive success in the industry.

Our Business Strategy

We believe the following strategies will play a critical role in our future growth:

• **Drive Penetration in the Fast-Growing Advanced Wound Care Market.** We intend to leverage our comprehensive product portfolio and relationships with key constituents to deepen our presence in the Advanced Wound Care market. We believe the breadth and flexibility of the portfolio we now offer allow us to address a wide variety of wound types (chronic and acute), sizes, and reimbursement levels, offering significant new opportunities for growth. Furthermore, we believe our expanded product portfolio is enhancing the ability of our sales representatives to reach and penetrate customer accounts, contributing to strong growth over time. Additionally, we believe there is significant room for expansion of the Advanced Wound Care market as a whole and our wound biologics product category in particular as more physicians and payers are educated about the benefits of regenerative medicine technologies versus traditional therapies. We continue to invest to support physician and payer education as well as preclinical and clinical trials, real-world evidence, and other research to confirm the benefits of our products. We will continue to seek expanded payer coverage for all of our products, particularly PuraPly AM/XT, Novachor, NuShield and Affinity, for which we do not yet have the broad commercial payer coverage enjoyed by Apligraf and Dermagraft.

• **Continued Expansion into Surgical & Sports Medicine Market.** We entered the Surgical & Sports Medicine market with the acquisition of NuTech Medical and its established and leading presence in placental-based products in 2017. We plan to continue to accelerate penetration into this market with our placental-based and collagen biomaterial products by leveraging our established commercial and operational infrastructure including our direct sales force and independent sales agencies. We also plan to continue to take advantage of significant opportunities to cross-sell within our established customer bases in both the Advanced Wound Care and Surgical & Sports Medicine markets. We believe that the Surgical & Sports Medicine market presents a strong near-term opportunity with respect to our current product portfolio as well as a significant long-term opportunity with respect to chronic inflammatory and degenerative conditions. Given our experience in the Advanced Wound Care market and regenerative medicine in general, we believe we are well positioned to capture this opportunity.

• **Launch Robust Pipeline of Products and Drive Innovation with a Proven Research and Development Platform.** We have a robust pipeline of products in both the Advanced Wound Care and Surgical & Sports Medicine markets that we expect to launch in the next few years. We expect these products will deepen our portfolios and allow us to address additional clinical applications. In addition, we anticipate our ongoing efforts to complete clinical studies and publish research regarding our products will further enhance physician and payer receptiveness to our products over time. Our proven research and development capabilities and established technology platforms also support a robust and adaptable product pipeline for future applications.

• **Continue to Maximize Our Sales Force and Increase Sales Productivity and Geographic Reach.** We plan to continue to expand the reach and penetration of our products by optimizing our sales organization to serve the Advanced Wound Care and Surgical & Sports Medicine markets. This effort should allow us to achieve more focused and effective sales coverage for specific market categories, broaden our geographic footprint, and leverage our expanding relationships with large hospital systems and GPOs. We also plan to increase our focus on sales outside of the United States, including the European Union and the Middle East. Currently, substantially all of our sales are in the United States.

• **Supplement Organic Growth Through Selective Acquisitions.** We have demonstrated our ability to successfully identify and integrate assets that complement our strategy through the acquisitions of Dermagraft and TransCyte from Shire and our placental-based products from NuTech Medical. We continue to evaluate tuck-in acquisitions which complement our existing portfolios in both the Advanced Wound Care and Surgical & Sports Medicine markets and will leverage our established commercial and manufacturing infrastructure.

Industry Overview

We focus our efforts on medical conditions that involve difficult-to-heal wounds and musculoskeletal injuries. Healing difficulties arise from a variety of causes and in various types of tissue and anatomic areas. Impaired healing is commonly associated with an inability to move beyond the inflammatory stages of healing, resulting in a chronic wound or injury, an ongoing inflammatory cycle, and an inability to achieve normal tissue healing. Biofilm and other infectious conditions also play a key role in disrupting wound healing processes. Regenerative medicine is a collection of technologies aimed at generating tissue as close as possible to native or natural tissue, to replace damaged tissue, and to fill or replace defects. Demand for these technologies is increasing as physician understanding of the underlying wound healing processes grows and as demographic and population health trends result in the increased prevalence of systemic comorbidities that contribute to healing problems throughout the body.

Our products use regenerative medicine technologies to provide solutions in the Advanced Wound Care (Chronic Wound) and Surgical (Acute Wound) & Sports Medicine markets. Based on industry reports and management estimates, we believe that our addressable Advanced Wound Care and Surgical & Sports Medicine markets totaled approximately $25 billion in 2021, which included an estimated $10 billion addressable market for Advanced Wound Care and an estimated $15 billion for Surgical & Sports Medicine. Within the Advanced Wound Care market in 2021, 49% of treatments used advanced wound dressings, 18% used biologics, 21% used external wound healing devices, and 13% consisted of more traditional wound care dressings. The skin substitute market, within biologics, is expected to grow from $1.1 billion in 2021 to $2 billion in 2026. Within the Surgical & Sports Medicine market, the surgical/acute wound sub-market accounts for $9.1 billion, the chronic inflammatory and degenerative condition sub-market accounts for approximately $3.8 billion, and the tendon and ligament injuries sub-market accounts for approximately $2.1 billion in 2021.

Key drivers of growth in these two markets include:

• favorable global demographics and aging population;

• greater incidence of comorbidities that contribute to impaired healing, such as diabetes, obesity, cardiovascular and peripheral vascular disease; and

• increasing acceptance of advanced technologies to treat complex wounds and musculoskeletal injuries.

Advanced Wound Care Market

Wounds represent a large and growing burden on the public health as well as a significant cost to the health care system. Wounds are divided into two primary types, chronic and acute. It is estimated that approximately 80 million patients suffer from chronic and acute wounds globally each year, excluding surgical incisions. Chronic wounds account for most of the expenses due to their complexity and length of treatment.

Chronic Wounds

Chronic wounds are wounds that have not appropriately closed after four weeks of traditional treatment such as dressings. Chronic wounds include:

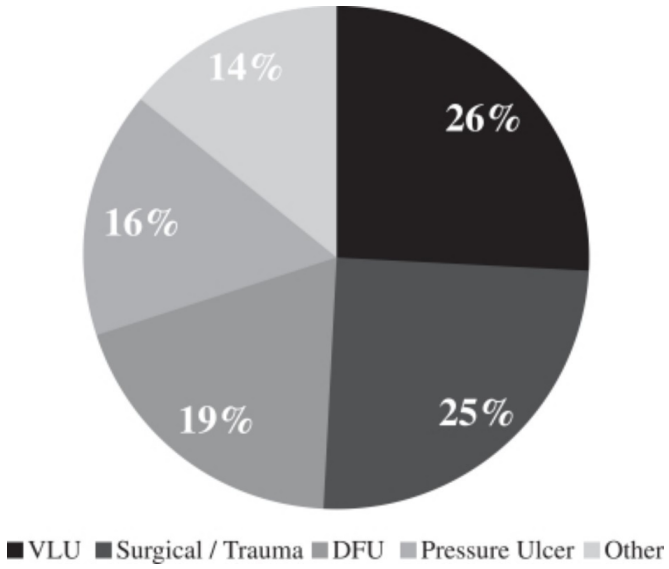
- *VLUs:* wounds that occur in the lower extremities when blood does not circulate properly to the heart, caused by abnormal or damaged veins.
- *DFUs:* open sores or wounds that occur in patients with diabetes and are commonly located on the bottom of the foot.
- *Pressure Ulcers:* localized injuries to the skin and/or underlying tissues as a result of pressure or pressure in combination with shear.
- *Surgical Wounds:* acute wounds caused by surgical incisions that become chronic wounds if they do not heal properly.

While the underlying etiology of these chronic wounds is different, at a cellular level many of the problems that result in failed healing are the same. These include uncontrolled inflammatory processes, shortages of cell types, and reduced growth factors secreted or sensitivity to those factors by cells that are critical to healing, and that result in disrupted cell signaling pathways.

Relative Prevalence of Wounds

Our customers in outpatient wound care facilities are faced with a wide variety of types of wounds with different anatomical locations and underlying causes. Based on a retrospective cohort study of data from wound care centers from June 2008 and June 2012, the distribution of wound types in hospital outpatient wound care centers is detailed below:

Distribution of Wound Types*



* Based on a September 2013 JAMA Dermatology published retrospective cohort study.

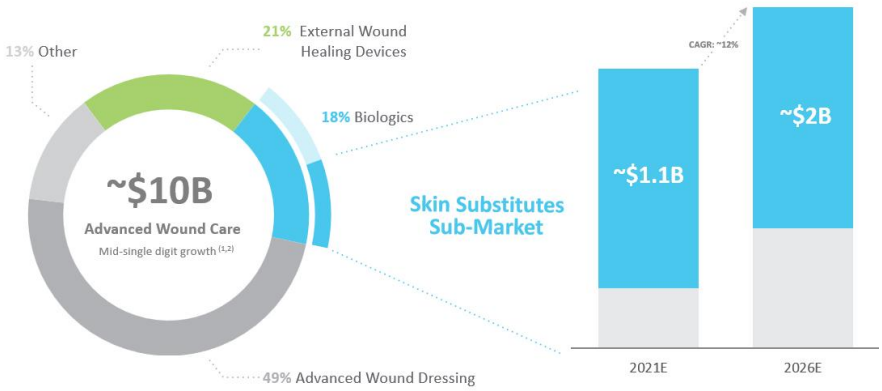
Due to the breadth of our wound care portfolio, our products are able to address both chronic and acute wounds across all of these wound types.

Our Solution

The wound care market includes traditional dressings such as bandages, gauzes, and ointments and advanced wound care products such as mechanical devices, advanced dressings, and biologics. These advanced wound care products target chronic and acute wounds not adequately addressed by traditional therapies. Our products are primarily classified as skin substitutes, which fall within the biologics category of the Advanced Wound Care market.

According to Grand View Research, the Global Advanced Wound Care market was estimated to be approximately $10 billion in 2021 and is expected to grow at a compound annual growth rate, or CAGR, of 4% through 2028. This market consists of several product categories including advanced wound dressings, external wound healing devices such as negative pressure wound therapy (NPWT), biologics such as skin substitute and growth factors and other traditional wound dressings. The approximate breakdown for these product categories in 2021 is set forth below.

Advanced Wound Care Market



Wound biologics represents one of the smallest segments of the Advanced Wound Care market but is the fastest growing and has seen the highest level of innovation. According to BCC Research, the worldwide wound biologics market, which includes skin substitutes and growth factors, was estimated to be approximately $1.7 billion in 2021, of which skin substitute products are estimated to represent approximately 62%. Skin substitutes, bioengineered or biologic grafts that cover skin defects and support healing, are one of the fastest-growing categories of the Advanced Wound Care market. The skin substitute market, within biologics, is expected to grow from $1.1 billion in 2021 to $2 billion in 2026. Going forward, the skin substitute market is projected to continue to grow as patients with hard-to-heal wounds transition from other therapies to skin substitute treatment.

We expect this market to continue to grow at a rapid rate as physicians are educated about the use of these products and understand the benefits as compared to other currently marketed products, payers incentivize doctors to use more cost-effective treatments, patients demand more effective treatment solutions and advanced wound care becomes more common outside of the United States. We also believe that adoption of these products will increase as clinical evidence supporting the benefits of skin substitutes over traditional therapies continues to grow. Skin substitutes have demonstrated improved chronic and acute wound healing rates at a lower overall cost than the current standard of care. In a matched cohort study we commissioned, Medicare treatment costs for DFUs treated with Apligraf were $5,253 ($p$=0.49) lower per patient than the standard of care and for DFUs treated with Dermagraft, these costs were $6,991 ($p$=0.84) lower per patient than the standard of care. See Rice et al. "Economic outcomes among Medicare patients receiving bioengineered cellular technologies for treatment of diabetic foot ulcers." J Med Econ. 2015;18(8):586-95.

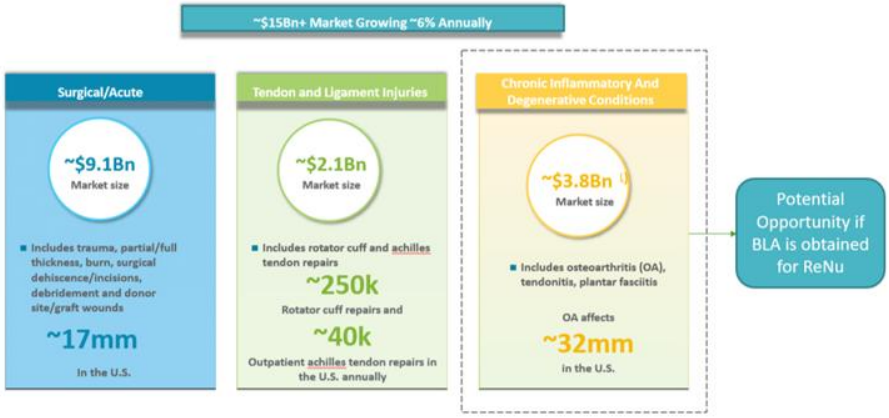
Our products compete with other skin substitutes as well as other advanced wound care products such as NPWT and growth factors. Due to its market position as a skin substitute with antimicrobial properties appropriate for the treatment of wounds with biofilm or otherwise at high risk of infection, our PuraPly AM product also competes with antimicrobial dressings. Antimicrobial wound products have historically represented a more than $1 billion annual market. We are a market leader in the antimicrobial skin substitute market and have supported the expansion of that market with our comprehensive marketing and educational campaigns.

Finally, the skin substitute market remains substantially underpenetrated. According to BioMed GPS, by 2027 there will be approximately 8.0 million wounds in the United States, requiring medical care and that are classified as difficult-to-heal wounds where traditional therapies are unlikely to succeed. Market growth will be propelled by the aging population and rise of diabetes, obesity, and cardiovascular disease, all of which are associated with poor vascularity, increasing the susceptibility of chronic, hard-to-heal wounds. Despite the vast need and proven benefits of advanced wound care products in general including skin substitutes, market penetration remains low in relation to the size of the total addressable market.

We believe that we are well positioned in the skin substitute market as adoption continues to increase. According to BioMed GPS, we are a leading skin substitute company in the United States, and we have an experienced and established sales force with deep relationships with clinicians, wound care centers, and hospitals. We also have a diverse array of products to address the different varieties of wounds throughout the wound healing process.

Surgical & Sports Medicine Market

An estimated 313 million surgical procedures are performed worldwide annually. An analysis of Medicare beneficiaries reveals that surgical wound care is associated with the highest wound care expenses, followed by DFUs. Trauma wounds, including burns, are included in the surgical/acute wound area. It is estimated that traumatic injury is responsible for more than 5 million deaths worldwide per year. Sports Medicine has displayed considerable growth as compared to other healthcare fields as a result of the rise in incidence of sports-associated injuries along with increase in awareness among people regarding physical fitness. We estimate the immediate addressable Surgical & Sports Medicine market for our products to be approximately $15 billion with a CAGR of approximately 6% through 2028.



Surgical/Acute Wounds

A surgical or acute wound is an injury that causes a rapid break in the skin and sometimes the underlying tissue. Acute wounds can be traumatic wounds, such as abrasions, lacerations, penetrating injuries or burns, or surgical wounds (skin grafts, dehiscences, necrotizing soft tissue infections) from surgical incisions. In contrast to chronic wounds, which would normally heal but stall due to biologic factors, acute wounds can be so severe that they overwhelm the body's normal healing capacity. Biofilm and other infectious conditions, particularly in acute wounds with a high risk of infection such as open fractures, may also pose challenges to the healing of acute wounds. According to the American Association for the Surgery of Trauma, in the United States alone more than 150,000 deaths stem from traumatic injuries and there are more than 3 million nonfatal injuries per year. According to the World Health Organization, an estimated 180,000 deaths every year are caused by burns, and nonfatal burn injuries are a leading cause of morbidity. According to the American Burn Association, approximately 450,000 Americans sustain serious burn injuries every year, and more than 40,000 require hospitalization and advanced medical care.

Tendon and Ligament Injuries

Tendon and ligament injuries are common orthopedic conditions in an active and aging population. There are approximately 250,000 rotator cuff repairs performed in the United States annually. Additionally, in 2015, there were approximately 40,000 outpatient Achilles tendon repairs in the United States. Re-rupture and reoperation continue to be a significant source of concern with non-operative management, occurring in 4.8% of Achilles tendon repair cases and as many as 25% or more rotator cuff repair cases. Comorbidities such as diabetes and obesity, as well as age, are correlated with a higher risk of failed healing and re-rupture. Regenerative tissue scaffolds may be used to support the healing of tendons, ligaments, and other soft tissues.

Sports Medicine--Orthobiologics

While our current portfolio of products has applicability across a wide variety of clinical specialties and wound types in the advanced wound care and surgical wound care market, our goal is to re-enter the regenerative orthobiologics market in the future (if BLA approval for ReNu is obtained). Orthobiologics are biologic substances that are used to address injuries of the musculoskeletal system. Orthobiologic products are used to treat people with long-term disabling musculoskeletal disorders and injuries. The majority of musculoskeletal injuries occur due to recreational and sports activities. The patient demographics include both younger populations and those involved in professional sports, as well as the elderly population, usually requiring treatment for degenerative disorders and chronic diseases. The market has seen an increase in surgical volumes in part due to a higher incidence of comorbidities and chronic inflammatory and degenerative conditions, such as osteoarthritis (OA) and tendonitis. The growing and aging population affected with OA that is still looking to remain active will continue to seek non-surgical or minimally invasive alternatives. The prevalence of knee OA has been increasing over the past several decades in the U.S., mirroring the aging population and the growing obesity epidemic.

Chronic Inflammatory and Degenerative Conditions (Future Pipeline Opportunity)

Chronic inflammatory and degenerative orthopedic conditions are increasingly prevalent, driven in part by an aging demographic and higher levels of comorbidities such as diabetes and obesity. OA is the most common chronic condition of the joints, affecting approximately 27 million individuals in the United States. OA can affect multiple joints in the body, with arthritis of the knee being the most commonly treated. One in two adults will develop symptoms of knee OA during their lives. Other chronic inflammatory conditions such as Achilles and rotator cuff tendinosis and plantar fasciitis are also increasingly common. Similar to many of the other conditions that we seek to address, chronic inflammatory and degenerative orthopedic conditions are often correlated with smoking, obesity, and diabetes, among other factors. Collectively, these and other related conditions were treated with an estimated 9 million injections in 2016, including steroids and hyaluronic acid (HA). According to Grand View Research, the global chronic inflammatory and degenerative orthopedic market (Viscosupplementation Market) exceeded $3.8 billion in 2020.

Our Solution

We believe our multiple regenerative technology platforms will allow us to build a broad portfolio covering the full range of needs in the Surgical & Sports Medicine market. In the short term, our focus will be on providing clinicians with placental allografts and solutions to support soft tissue healing with our placental-based technologies as protective barriers for open acute wounds and tendon and ligament surgical repair procedures. In the long-term, we plan to deepen our focus and provide solutions for chronic inflammatory and degenerative conditions, and in particular, OA as illustrated by our current Phase III Clinical Trials for ReNu. We intend to address patient needs with our portfolio in the inpatient hospital, ASC, and clinic settings. We estimate the immediate addressable Surgical & Sports Medicine market for our products to be approximately $15 billion respectively with a CAGR of approximately 6% through 2028.

For surgical and acute wounds, as skin substitutes continue to gain market adoption based on their demonstrated efficacy in improving healing rates with lower overall costs for these comprised healing situations, we believe we are well positioned with our comprehensive portfolio of technologies. Our placental-based technologies (Affinity, Novachor, NuShield) and skin substitutes with antimicrobial properties (PuraPly AM, PuraPly SX, and PuraPly XT) are highly differentiated both in composition along with their level of clinical utility. These product attributes coupled with our current market-leading position and high level of organizational competency give us the confidence that we have the ability to capture a significant portion of this growing market.

In tendon and ligament repair, conventional surgical approaches rely on mechanical fixation to temporarily approximate damaged tissues, assuming that the natural healing process will then result in a permanent repair. Patients with impaired healing may be unable to generate the necessary tissue structures, resulting in unacceptable failure rates over time. As additional clinical evidence and technology adoption is gained with our placental-based technologies, we believe we are well positioned with our current offering (NuShield as a surgical barrier) and our native collagen surgical matrix (PuraForce for soft tissue reinforcement).

OA and other degenerative conditions, as well as soft tissue injuries such as tendinosis and fasciitis, are currently treated by injection with steroids or HA. However, steroids offer pain relief for only a limited period and have been shown to further degrade some types of tissues over time, worsening the underlying condition. The evidence of HA’s efficacy has been questioned, and it is

clear that a significant percentage of patients do not adequately respond to HA treatment. Patients who fail these less invasive therapies have limited options and may require surgical intervention, including total joint replacement.

Orthobiologics have been shown to be an effective alternative to traditional treatments. Due to their anti-inflammatory and pro-healing effects, they go beyond mechanical intervention to support the healing process in the damaged tissue and often result in faster healing times and shorter hospital stays. The orthobiologics market includes bone morphogenetic protein, viscosupplementation with HA, synthetic bone graft substitutes, and stem cell therapy, in addition to demineralized bone matrix (DBM) and allograft. Our current product pipeline includes Sports Medicine solutions based on placental-based technologies (ReNu). There is a rapidly growing body of clinical and scientific evidence indicating the potential of these products, particularly orthobiologics, in surgical applications, resulting in increased adoption of these products.

Our Products

Advanced Wound Care

In the Advanced Wound Care (Chronic Wound) market, we focus on the development and commercialization of a broad portfolio of cellular and acellular wound care offerings that treat patients from the earliest indication of impaired healing to wound closure. Our suite of products helps treat a wide range of chronic wounds such as VLUs, DFUs, and pressure ulcers.

The breadth and depth of our portfolio allow physicians to tailor solutions to meet the needs of individual wound care patients. Wounds of all types normally progress through predictable phases of healing, starting with inflammation, progressing to cell proliferation, and finally remodeling to form normal skin. Wounds may stall during this process, typically in the inflammatory phase, for a variety of reasons. These reasons include biofilm or infection, uncontrolled inflammatory processes, shortages of cell types and growth factors secreted by cells that are critical to healing and disrupted cell signaling pathways.

It is increasingly recognized that addressing biofilm is an important step in healing any wound. Biofilm is generated by densely packed microbial communities that are attached to the wound surface and enclosed in a matrix of self-produced extracellular polymeric substance, or EPS. Biofilm is present in at least 78% of chronic wounds and can inhibit the healing of all wound types. We engage with the physician at the earliest indication of impaired healing with our PuraPly AM product, which helps control biofilm as an antimicrobial barrier via the broad-spectrum antimicrobial PHMB. If reduction of biofilm and control of the excessive inflammatory response is sufficient to result in healing, as is many times the case, PuraPly AM may be the only product required to achieve wound closure. If underlying healing issues persist, we offer an array of bioactive products and placental-based technologies tailored for a wide variety of wound sizes and types.

Our advanced wound care products are used in wound clinics that are located in an outpatient hospital setting as well as in physician offices and ASCs. The table below summarizes our comprehensive advanced wound care product suite:

Product (Launch Year)	Description	Regulatory Pathway	Clinical Application
Affinity (2014)† 	Fresh amniotic membrane in which viable cells, growth factors/cytokines, and ECM proteins in the native tissue are preserved.	361 HCT/P	Chronic and acute wounds
Novachor (2021) 	Fresh chorion membrane in which viable cells, growth factors/cytokines, and ECM proteins in the native tissue are preserved.	361 HCT/P	Chronic and acute wounds
Apligraf (1998) 	Bioengineered living cell therapy that contains two living cell types, keratinocytes, and fibroblasts, that produce a broad spectrum of cytokines and growth factors	PMA	VLUs; DFUs
Dermagraft (2001)* 	Bioengineered product with living human fibroblasts seeded on a bioabsorbable scaffold, that produces human collagen, ECM, proteins, cytokines, and growth factors	PMA	DFUs
NuShield (2010)† 	Dehydrated placental tissue preserved to retain the ECM scaffold and all layers of the native tissue including both the amnion and chorion membranes, with the epithelial layer and the spongy/intermediate layer intact	361 HCT/P	Chronic and acute wounds
PuraPly AM (2016) 	Antimicrobial barrier comprised of purified native collagen matrix scaffold with broad-spectrum polyhexamethylene biguanide, or PHMB, antimicrobial agent. Line extensions include PuraPly XT and PuraPly SX, which contains additional layers of collagen matrix scaffold and a higher level of PHMB. Extra-fenestrated (EF) versions of the products allow for added conformability and fluid drainage.	510(k)	Chronic and acute wounds (except 3rd degree burns)
CYGNUS Dual (2023) 	Dehydrated placental tissue preserved to retain the ECM scaffold. Contains two layers of amniotic tissue with the epithelial layer facing outward enabling omnidirectional application .	361 HCT/P	Chronic and acute wounds

† Launched by NuTech Medical; acquired by Organogenesis in 2017.
* Launched by Smith & Nephew; acquired by Organogenesis in 2014.

Affinity & Novachor

Affinity & Novachor are fresh, amnion & chorion placental allografts for application in the care of chronic and acute wounds as protective barriers and ECM scaffolds. We believe both products are one of only a few placental tissue products containing viable amniotic cells, and are unique in that they undergo our proprietary AlloFresh process that hypothermically stores the products in their fresh state, never dried or frozen, which retains their native benefits and structure. Regulated as human cells, tissues, and cellular and tissue-based product, or HCT/P, under Section 361 of the Public Health Service Act (the PHSA), these products are referred to as Section 361 HCT/Ps, or simply 361 HCT/Ps. Affinity was launched in 2014 by NuTech Medical and acquired by us in 2017. Novachor was launched in December 2021.

Apligraf

Apligraf is a bioengineered bi-layered skin substitute that is the only product that has, to date, received PMA approval for the treatment of both VLUs and DFUs. Launched in 1998, Apligraf drives faster healing and more complete wound closure through its tissue-engineered structure, which includes an outer layer of protective skin cells (human epidermal keratinocytes), and an inner layer of cells (human dermal fibroblasts) contained within a collagen matrix. Apligraf is the leading skin substitute product for the treatment of VLUs, and its effectiveness has been established based on an extensive clinical history with over one million units shipped. We believe Apligraf is also the first and only wound-healing therapy to demonstrate in a randomized controlled trial, or RCT, a significant change in patients' VLU wound tissue, showing a shift from a non-healing gene profile to a healing profile. Apligraf plays an active role in healing by providing the wound with living human skin cells, growth factors and other proteins produced by the cells, and a collagen matrix.

Dermagraft

Dermagraft is a dermal substitute grown from human dermal fibroblasts and has received PMA approval for the treatment of DFUs. Launched in 2001 by Smith & Nephew and acquired by us in 2014, this product helps to restore the compromised wound bed to facilitate healing. The living cells in Dermagraft produce many of the same proteins and growth factors that support the healing response in healthy skin. In addition to an FDA-monitored RCT demonstrating its superiority to conventional therapy in the healing of DFUs, studies based on real-world evidence and Medicare data have demonstrated its superior clinical efficacy and value as compared to competitive wound care products and conventional therapy. Dermagraft can be applied weekly (up to eight times) over a twelve-week period and contains a temporary mesh fabric that is dissolvable and becomes part of the body's own healing processes. Manufacturing of Dermagraft was suspended in the fourth quarter of 2021 and sales of Dermagraft were suspended in the second quarter of 2022 as part of our plan to transition our Dermagraft manufacturing to a new manufacturing facility or engage a third-party manufacturer, which we expect will result in substantial long-term cost savings. In the period when Dermagraft is not available, we expect that customers will be willing to substitute Apligraf for Dermagraft and that the suspension of Dermagraft sales will not have a material impact on our net revenue.

NuShield

NuShield is a dehydrated placental allograft and surgical barrier that is topically or surgically applied to the target tissue to provide a protective barrier and ECM scaffold to support native healing. Regulated as a 361 HCT/P, NuShield is processed using our proprietary LayerLoc process, which preserves the native structure of the amnion and chorion membranes, including the intermediate or spongy layer, and their native structural and regulatory proteins. NuShield is available in multiple sizes, can be used as a protective barrier and ECM scaffold to help support native healing of chronic and acute wounds of many sizes, and can be stored at room temperature with a five-year shelf life. NuShield was launched in 2010 by NuTech Medical and acquired by us in 2017.

PuraPly Antimicrobial

PuraPly Antimicrobial, or PuraPly AM, was developed to address the challenges posed by bioburden and excessive inflammation in the wound. Functioning as an antimicrobial barrier skin substitute, PuraPly AM is a purified native porcine type I collagen matrix embedded with polyhexamethylene biguanide, or PHMB, a localized broad-spectrum antimicrobial. PuraPly AM was launched in 2016 and has received 510(k) clearance for the management of multiple wound types, including partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds, trauma wounds, draining wounds, and first- and second-degree burns. The combination of PHMB with a native collagen matrix helps manage bioburden while supporting healing across a wide variety of wound types, regardless of severity or duration. Line extensions include PuraPly XT, which contains additional layers of collagen matrix and a higher level of PHMB. Extra-fenestrated (EF) versions of the products allow for added conformability and fluid drainage. We also developed and received 510(k) clearance for PuraPly without PHMB, which we refer to as "PuraPly," including a micronized version, PuraPly MZ, for those patients who do not require an antimicrobial agent.

CYGNUS Dual

CYGNUS Dual is a dual-layered amniotic tissue graft that can be stored at room temperature and has a five-year shelf life. It is manufactured in accordance with FDA regulations and American Association of Tissue Banks (AATB) standards using a methodology that helps maintain the inherent levels of key extracellular matrices, including carbohydrates, growth factors, and cytokines.

Surgical & Sports Medicine

In the Surgical & Sports Medicine market, we focus on the development and commercialization of products that support the healing of surgical/acute wounds, and musculoskeletal injuries including tendon repair and chronic degenerative conditions such as OA. Our products in this market are used predominantly in the inpatient and outpatient hospital and ASC settings. The table below summarizes the principal products in our Surgical & Sports Medicine product suite:

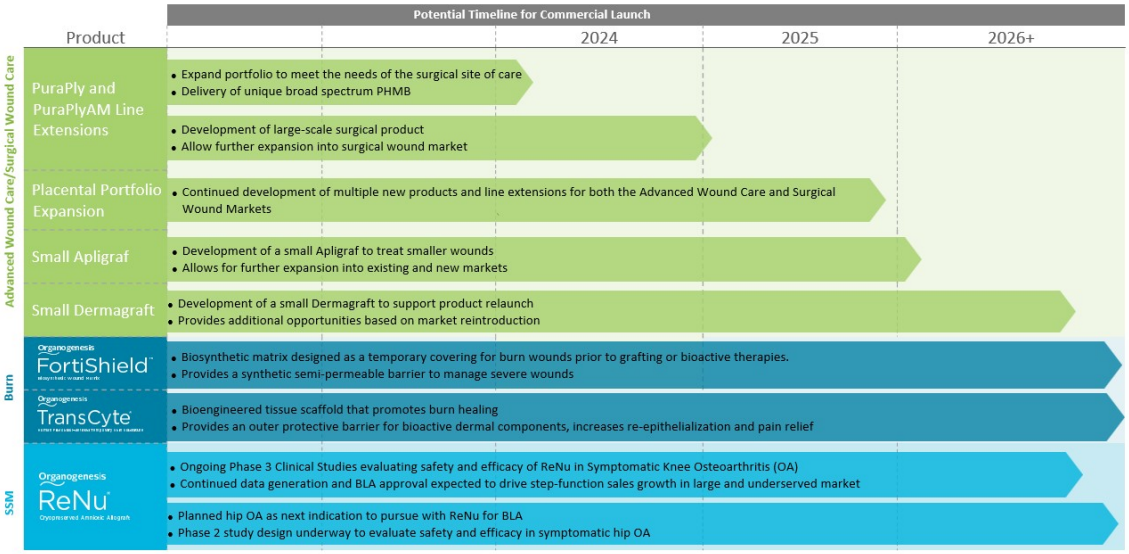
Product (Launch Year)	Description	Regulatory Pathway	Clinical Application
NuShield (2010) 	Dehydrated placental tissue barrier preserved to retain the ECM scaffold and all layers of the native tissue including both the amnion and chorion membranes, with the epithelial layer and the spongy/intermediate layer intact	361 HCT/P	Barrier membrane to support repair of tendon, ligament, and other soft tissue injuries
Affinity (2014) 	Fresh amniotic membrane in which viable cells, growth factors/cytokines, and ECM scaffold in the native tissue are preserved	361 HCT/P	Acute surgical wounds
Novachor (2021) 	Fresh chorion membrane in which viable cells, growth factors/cytokines, and ECM scaffold in the native tissue are preserved	361 HCT/P	Acute surgical wounds
PuraPly AM (2016) 	Purified native collagen matrix with broad-spectrum PHMB antimicrobial agent. Line extensions include PuraPly XT and PuraPly SX, which contains additional layers of collagen matrix and a higher level of PHMB. Extra-fenestrated (EF) versions of the products allow for added conformability and fluid drainage.	510(k)	Antimicrobial barrier for management of open wounds in the surgical setting
PuraForce (2019)	PuraForce is a bioengineered porcine collagen surgical matrix for use in soft tissue reinforcement applications that is intended for 510(k) indications for the reinforcement of all tendons in the body. PuraForce has high biomechanical strength per unit thickness, making it ideal for extremities applications	510(k)	Indicated for the reinforcement of soft tissues repaired by sutures or suture anchors during tendon repair surgery
PuraPly MZ (2022) 	PuraPly MZ is a micronized particulate version of PuraPly that allows application in powder or gel form to deep and tunneling wounds. PuraPly MZ is intended for indications for the management of open wounds in the surgical setting.	510(k)	Chronic and acute wounds (except 3rd degree burns)

NuShield, Affinity, Novachor, PuraPly AM, PuraPly SX, PuraForce, and PuraPly MZ

We market our NuShield product for surgical and orthopedic applications. NuShield may be used as a surgical barrier or as an on-lay or wrap barrier to support soft tissue repairs. When used as a barrier membrane, the native biological characteristics of this placental tissue may help support the healing of soft tissue defects, particularly in difficult-to-heal locations or challenging patient populations. We market our Affinity and Novachor products as placental allografts for acute surgical wounds and our PuraPly AM and PuraPly SX products as antimicrobial barriers for the management of open wounds in the surgical setting. PuraForce is a bioengineered porcine collagen surgical matrix for use in soft tissue reinforcement applications. PuraPly MZ is a micronized particulate version of PuraPly that allows application in powder or gel form for the management of open wounds in the surgical setting.

Product Pipeline

We have a robust pipeline of products under development for both the Advanced Wound Care and Surgical & Sports Medicine markets. We believe our pipeline efforts will deepen our comprehensive portfolio of offerings as well as allow us to address additional clinical applications. The following table summarizes our pipeline products and potential timeline for their commercial launch:



PuraPly and PuraPlyAM Line Extensions

The PuraPly portfolio is comprised of a purified native collagen matrix.PuraPly AM and PuraPly SX are native collagen scaffolds that also provide an antimicrobial barrier utilizing a broad spectrum antimicrobial agent (PHMB). The design objective of line extensions in development is to leverage our knowledge and expertise to develop products to specifically meet the needs of current additional sites of care.

Placental Portfolio Expansion

We have placental products under development. The design objective is to develop a larger graft to meet the needs of the advanced wound care and surgical wound markets. Our R&D team continues to research and develop additional product concepts from our placental technology platform, as well as to collaborate with our Business Development team to assess additional product in-licensing or acquisition opportunities.

Apligraf and Dermagraft Line Extensions

We have two development projects underway to develop additional sizes of Apligraf and Dermagraft. The objective is to develop at least one additional smaller size of each product to optimize clinical utilization for smaller wounds such as DFUs. These types of changes to living cell-based products require significant development and validation work and will require FDA PMA Supplement approval for the changes. Therefore, we expect the duration of the development projects to be several years before commercial products will be available. Manufacturing of Dermagraft line extensions is dependent on the completion of manufacturing and supply capabilities for the product.

FortiShield

FortiShield is a biosynthetic wound matrix made from a semi-permeable silicone membrane bonded to a kitted nylon fabric and coated with collagen, to provide a flexible dressing that is designed to adhere to the application site, provide a barrier to the external environment, and allow for excess exudate drainage. FortiShield is intended for use as a temporary protective covering, and to provide a moist wound healing environment on cleanly debrided wounds after hemostasis has been established. The primary indication for the product is as a transitional wound matrix for second degree burns. There are additional chronic and acute wound applications. The product received 510(k) clearance in May 2023. Commercial launch is dependent upon the completion of manufacturing and supply capabilities for the product.

TransCyte

TransCyte is a bioengineered tissue scaffold that promotes burn healing, and has received PMA approval for the treatment of deep second- and third-degree burns. We acquired the product from Shire, and it was previously marketed by Smith & Nephew. TransCyte complements our portfolio to address all severities of burn wounds. TransCyte is a flexible, durable product that provides bioactive dermal components, an outer protective barrier, increased re-epithelialization and pain relief for patients suffering from burns. We believe TransCyte will address a sizable market opportunity with limited competition, with only two other PMA approved products that would be directly competitive to TransCyte currently on the market, and only one competitor product containing a biosynthetic barrier to protect wounds. We conducted a clinical experience program with burn surgeons in 2022 with a limited supply of product manufactured at the closed La Jolla facility. Full launch is dependent on the completion of manufacturing capabilities.

ReNu

ReNu is a cryopreserved suspension derived from human amniotic membrane and cells derived from amniotic fluid, formulated for office use. It has been used to support healing of soft tissues, particularly in degenerative conditions such as OA and joint and tendon injuries such as tendinosis and plantar fasciitis. The initial target indication for ReNu is for the management of symptoms associated with knee OA. A clinical study of ReNu for knee OA has been published, which we believe may indicate signs of its safety and suggest potential efficacy for a period of at least a year. On May 31, 2021, we suspended commercial distribution of ReNu in connection with the end of the FDA's enforcement grace period for certain products that previously were marketed as 361 HCT/Ps. We are continuing to conduct clinical studies of ReNu to support BLA approval for the management of symptoms associated with knee OA, and are in the planning stages to conduct clinical studies of ReNu to support the management of symptoms associated with Hip OA. We believe ReNu may have potential as a treatment for additional OA and tissue regeneration applications, which would need to be clinically evaluated further before any such approved uses. ReNu was launched in 2015 by NuTech Medical and acquired by us in 2017.

Ongoing Clinical Studies

We believe gathering robust and comprehensive clinical and real-world outcomes data is an essential component of developing a competitive product portfolio and driving further penetration in the markets where we compete. We have three ongoing prospective trials and six comparative effectiveness studies. We continue to invest in generating clinical data for our Advanced Wound Care and Surgical & Sports Medicine products, and believe such data enhance sales efforts with physicians and reimbursement dynamics with payers over time. The tables below summarize the status of our recent clinical studies for our Advanced Wound Care and Surgical & Sports Medicine products. As used herein, p value is a measure of statistical significance. The lower the p value, the more likely it is that the results of a clinical trial or study are statistically significant rather than an experimental anomaly. Generally, to be considered statistically significant, such results must have a p value <0.05.

Advanced Wound Care

Product	Wound Type	Design	Completion Date	Data Presentation Date[4]
Organogenesis PuraPly AM	Diabetic Foot Ulcers (DFU)	Comparative Effectiveness Analysis (CEA), NetHealth EMR Database of PPAM vs Theraskin (NI)	Q1 2020[3]	Q2 2020 ISPOR[6] Q1 2024 Accepted for Publication
	DFU	Health Economics and Outcomes Research (HEOR)- Comparative Effectiveness Analysis (CEA), Medicare Claims, PPAM vs SOC	Q4 2022[3]	Q4 2021-SAWC[5] Fall, Q2 2023-SAWC[5] Spring
Organogenesis Apligraf	PRI	Comparative Effectiveness Analysis (CEA), NetHealth EMR Database of Apligraf vs Primatrix	Q4 2019[3]	Q3 2020 SAWC[5] Spring Published Q1 2024
	PRI	Comparative Effectiveness Analysis (CEA), NetHealth EMR Database of Apligraf vs Epifix	Q1 2020[3]	Q2 2020 ISPOR[6]
Organogenesis NuShield	DFU	Prospective Multicenter RCT, NuShield vs SOC	Q1 2023[2]	Q3 2024[4]
	DFU	Health Economics and Outcomes Research (HEOR)- Comparative Effectiveness Analysis (CEA), Medicare Claims, NuShield vs SOC	Q4 2022[3]	Q2 2023-SAWC[5] Spring
Organogenesis Affinity	VLU[1]	Prospective, Multicenter RCT Affinity vs SOC	Q1 2025[2]	Q4 2025[4]
	DFU	Health Economics and Outcomes Research (HEOR) - Comparative Effectiveness Analysis (CEA), Medicare Claims, Affinity vs SOC	Q4 2022[3]	Q2 2023-SAWC[5] Spring

(1) In development or actively enrolling
(2) Based on last patient last visit in the study
(3) Date analysis complete
(4) First external presentation of primary data: actual date for data presented, estimated date for data expected to be presented in future quarters
(5) SAWC: Symposium of Advanced Wound Care.
(6) ISPOR: Int Soc for Pharmacoeconomics and Outcomes

Sports Medicine

Product	Indication	Design	Completion Date[1]	Estimated Data Presentation Date[2]
Organogenesis ReNu	Knee OA	A Phase 3 Prospective, Multicenter, Double-Blind, Randomized, Placebo-Controlled Study To Evaluate The Efficacy Of Amniotic Suspension Allograft (ASA) In Patients With Osteoarthritis Of The Knee (N=474)	Q1 2024	Q3 2024
	Knee OA	A Phase 3 Prospective, Multicenter, Double-Blind, Randomized, Placebo-Controlled Study To Evaluate The Efficacy Of Amniotic Suspension Allograft (ASA) In Patients With Osteoarthritis Of The Knee (N=474)	Q4 2025	Q3 2026

(1) Based on last patient last visit in the study
(2) Estimated date of first external presentation of primary data

Selected Published Clinical Studies

PuraPly AM

In a published prospective, multicenter, cohort study of 307 patients on the use of PuraPly AM in cutaneous wounds including acute and chronic wounds (RESPOND Registry), 52, 62, and 73% of all wounds achieved closure at week 20, 26, and 32 respectively, with a median time to wound closure of 17 weeks. The wounds studied included 67 (22%) venous leg ulcers, 62 (20%) diabetic foot ulcers, 45 (15%) pressure ulcers, 54 (18%) post-surgical wounds, and 79 (26%) other wounds. For all 307 wounds, the incidence of achieving greater than a 60% reduction in baseline area and depth was 81 and 71% respectively. In addition, the incidence of wounds demonstrating greater than a 75% reduction in baseline volume was 85%.

Two subgroup analyses from the PuraPly AM multicenter, cohort study of 307 patients were published. In the venous leg ulcer (n=67) cohort, wound closure frequencies were 33%, 42%, 45%, 53%, and 73% at weeks 8, 12, 16, 24, and 32, respectively. The median time to closure was 22 weeks. Incidences of achieving a greater than 60% reduction in baseline area and depth were 78% and 70%, respectively, with 87% showing a reduction of greater than 75% in volume.

In the pressure injury (n=45) cohort, wound closure frequencies were 5%, 39%, 49%, and 62% at weeks 4, 16, 24, and 32 weeks, respectively. The median time to wound closure for all wounds was 32 weeks. Incidences of achieving a greater than 60% reduction in baseline area and depth were 78% and 64%, respectively, with approximately 82% of wounds showing a reduction in volume greater than 75%.

In a published study analyzing pooled data from a population of 3 combined registries on the use of PuraPly AM in acute and chronic wounds, 51, 56, 62 and 72% of all wounds achieved closure at week 20, 24, 28 and 48, respectively, with a median time to wound closure of 19 weeks. The populations were pooled from a single-center study of 41 patients, a single-center study of 86 patients, and the RESPOND Registry of 307 patients treated at 28 centers. This cohort study of 434 patients included 95 venous leg ulcers, 78 diabetic foot ulcers, 90 pressure injuries, 73 post-surgical wounds, and 98 other wounds.

Affinity

In a published randomized controlled clinical trial of Affinity for use in diabetic foot ulcers comparing the use of Affinity and the standard of care (n=38) to the use of the standard of care alone (n=38), 60% of wounds in the Affinity and standard of care group achieved wound closure at 12 weeks compared to 38% of wounds in the standard of care group (p=0.04) and 63% of wounds in the Affinity and standard of care group achieved wound closure at 16 weeks compared to 38% of wounds in the standard of care group (p=0.04). In addition: 82% of wounds in the Affinity and standard of care group achieved a greater than 60% reduction in wound area as compared to 58% of wounds in the standard of care group (p=0.02); 65% of wounds in the Affinity and standard of care group achieved a greater than 60% reduction in wound depth as compared to 39% in the standard of care group (p=0.04); and 81% of wounds in the Affinity and standard of care group achieved a greater than 75% reduction in wound volume as compared to 58% in the standard of care group.

In a 50 patient, multicenter, retrospective case series reporting on the outcomes of DFUs managed with Affinity, 52% attained complete wound closure (CWC) by week 8 and 78% attained CWC by week 12. A greater than 60% wound area reduction was attained in 96.0% of DFUs by week 12, with a median time to CWC of 55 days.

NuShield

In a published clinical study of clinical experience using NuShield for the management of 50 wounds (VLUs (n=14), DFUs (n=24) and other wounds (n=12)), 45 (90%) of the wounds had wound closure percentages between 60% to 100%. The median time to complete wound closure (or healing) for all wounds was 102 days (14.6 weeks), and the percent healing rate of all wounds healed at 16 and 24 weeks was 56% and 73%, respectively. For DFUs treated with NuShield, the median time to healing was 120 days (17.1 weeks) and the percent healing rates at 16 and 24 weeks were 43% and 59%, respectively. For VLUs treated with NuShield, the median time to healing was 90 days (12.9 weeks), with percent healing rates of 56% and 85% at 16 and 24 weeks, respectively. For all other wounds treated with NuShield (including pressure ulcers, nonhealing surgical, ischemic, mixed etiology, and nonhealing amputation), the median time to healing was 48 days (6.9 weeks), with percent healing rates of 57% and 100% at 16 and 24 weeks, respectively.

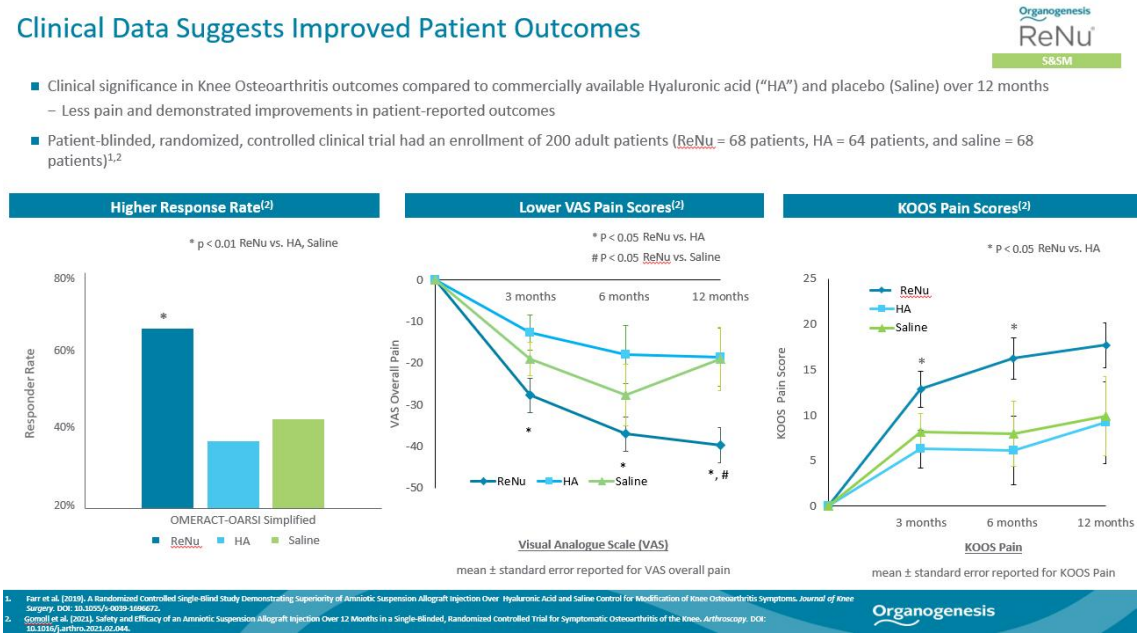
ReNu

In a 200-patient randomized controlled multicenter single-blind study comparing the treatment of knee OA symptoms with ReNu (n=68), a commercially available hyaluronic acid, or HA (n=64), and saline (n=68), patients treated with ReNu reported a clinically meaningful and statistically significant reduction in Visual Analogue Scale (VAS) pain and higher OMERACT-OARSI responder rate at 12 months follow-up compared to patients treated with HA or saline. Pain was also evaluated using the Knee Injury

and Osteoarthritis Outcome Score (KOOS) Pain score, and ReNu resulted in a statistically greater improvement in pain compared to HA at both 3 and 6 months.

A 474-patient Phase 3 prospective, multicenter, double-blind, placebo-controlled study recently completed last patient last visit and database lock and analysis is currently underway to evaluate the efficacy of ReNu (Amniotic Suspension Allograft, ASA) for the treatment of symptomatic knee OA (NCT04636229). Patients were randomly assigned in a 1:1 ratio to receive a single intra-articular (IA) injection of 2 mL of ASA (plus 2 mL of normal saline) or 4 mL of normal saline. The primary efficacy endpoint has been defined as the difference in change from baseline in WOMAC Pain scale at 6 months between ASA- and placebo-treated patients. The design and statistical methodology of the current Phase III multi-center trial were informed and optimized based on the results of the 200 patient study. In March 2023, we reported the positive outcome of a pre-specified interim analysis of the data from 50% of the 474 required patients in our Phase 3 clinical trial for management of symptoms associated with knee OA that focused on the 6-month primary endpoint for sample size re-estimation. Based on the interim analysis, the independent data monitoring committee (DMC) recommended that the trial proceed without modification and continue without change to sample size. The DMC also found the safety data to be consistent with the known safety profile for ReNu.

A second confirmatory Phase 3 prospective, multicenter, double-blind, placebo-controlled study was recently initiated to evaluate the efficacy of ReNu (ASA) for the treatment of symptomatic knee OA (NCT06000410). 474 patients will be randomly assigned in a 1:1 ratio to receive a single intra-articular (IA) injection of 2 mL of ASA (plus 2 mL of normal saline) or 4 mL of normal saline. The primary efficacy endpoint has been defined as the difference in change from baseline in WOMAC Pain scale at 6 months between ASA- and placebo-treated patients.



Previously Published Clinical Studies for FDA-Approved Products

We also have accumulated a significant body of clinical evidence demonstrating the efficacy of our FDA-approved products, Apligraf and Dermagraft. We continue to invest in generating similar data for other Advanced Wound Care and Surgical & Sports Medicine products, and believe such data enhance sales efforts with physicians and reimbursement dynamics with payers over time. Our product Apligraf is the only product that has obtained FDA approval for the treatment of both VLUs and DFUs. Our product Dermagraft has also received FDA approval for DFUs. Below is a summary of the primary data supporting each product, and a description of the clinical studies that are currently in progress. As used herein, p value is a measure of statistical significance. The lower the p value, the more likely it is that the results of a clinical trial or study are statistically significant rather than an experimental anomaly. Generally, to be considered statistically significant, such results must have a p value <0.05.

Apligraf

Two pivotal studies were initially conducted with Apligraf demonstrating the safety and efficacy of the product in the treatment of full- and partial-thickness VLUs and DLUs. As a result, Apligraf obtained FDA approval for these indications. We have conducted a number of additional studies that provide further clinical evidence of the safety and efficacy of the product, including recent comparative effectiveness, cost effectiveness, and mechanism of action studies.

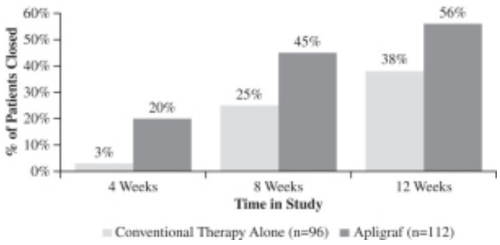
Pivotal FDA Registration Trials

For the DFU indication, a multi-center prospective RCT of Apligraf for the treatment of DFUs versus standard of care was conducted. Two hundred eight patients with Type 1 and 2 diabetes were enrolled, who had a plantar DFU of full- or partial-thickness. Patients with a chronic wound that exhibited less than 30% healing prior to treatment were eligible for the clinical trial. All patients' ulcers were off-loaded using either crutches or a wheelchair for the first six weeks, followed by customized pressure-relieving footwear for at least four weeks post closure. Mean ulcer size was 2.97 cm^2 and 2.83 cm^2 in the Apligraf and the control group, respectively. The mean duration of the ulcer was 12 months in the Apligraf group and 11 months in the control group.

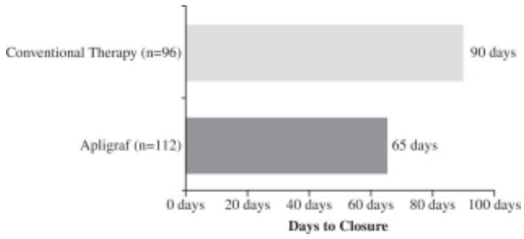
Apligraf was significantly more effective than conventional therapy for the incidence of complete wound closure over time. By 12 weeks of treatment, 56% (63 of 112 patients) of DFUs treated with Apligraf plus conventional therapy (debridement, saline dressings, total off-loading) were 100% closed, compared to 38% (36 of 96 subjects) of ulcers treated with conventional therapy alone (p=.0042). The median time to 100% wound closure was 65 days for DFUs treated with Apligraf plus conventional therapy versus 90 days for ulcers treated with conventional therapy alone (p=.0026).

Recurrence is an important measure of healing durability, and in the study, 96% of ulcers treated with Apligraf remained closed at six months versus 87% in the control group. An important outcome of the study was an observed reduction in the incidence of reported adverse events of osteomyelitis and amputations/resections. Patients receiving Apligraf had a statistically significant (p<.05) lower incidence of osteomyelitis at the study ulcer site (2.7% vs. 10.4%) compared to patients treated with conventional therapy at six months. Apligraf-treated patients required significantly fewer amputations or resections of the study limb (6.3% vs. 15.6%) (p <.05) compared to patients treated with conventional therapy at six months. The primary results of the study are presented in the figures below.

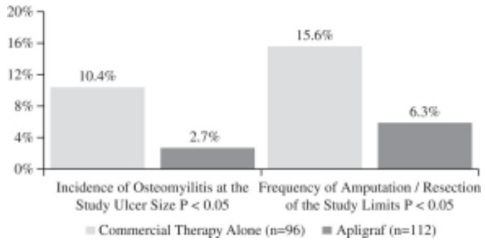
Incidence of 100% Wound Closure



Median Time to 100% Wound Closure



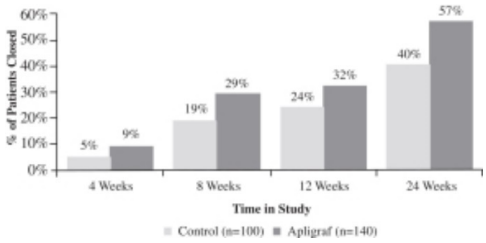
Reduction in Osteomyelitis and Amputation / Resection



For the VLU pivotal trial, the efficacy of Apligraf was evaluated in a prospective, parallel-group, randomized, controlled, multi-center study involving 240 patients with VLUs. Subjects receiving Apligraf in combination with compression therapy were compared with an active treatment concurrent control of zinc paste gauze and compression therapy. Apligraf plus compression

therapy was more effective in achieving complete wound closure by week 24 (57% vs 40%, *p*=.022). In patients with long-standing VLUs with greater than one year's duration (n=120), Apligraf plus compression therapy was more than twice as effective in achieving complete wound closure by week 24 (47% vs 19%, *p*=.002). The primary results of the study are presented in the figures below.

All Patients Achieving 100% Closure



Comparative Effectiveness and Economic Studies

We conducted four comparative effectiveness studies with Apligraf utilizing our proprietary access to data collected in Net Health's Wound Expert® Electronic Medical Record, or EMR, database. Net Health's wound care software is utilized by more than 1,000 wound care centers across the United States. In collaboration with statistical experts and leading clinicians, we analyzed outcomes of treatment with Apligraf versus other skin substitutes including EpiFix (owned by MiMedx), Theraskin (owned by Bioventus, Inc.), Oasis (owned by Smith & Nephew), and Primatrix (Owned by Integra). All four studies showed that Apligraf improved overall healing rates as well as time to healing. For example, patients treated with Apligraf showed a 53% relative improvement in healing over patients treated with EpiFix at 24 weeks. All four studies have been published in peer-reviewed journals.

The Analysis Group, a private economics consulting firm, conducted a study to evaluate the economic outcomes of Medicare patients receiving Apligraf and Dermagraft, assessing the real-world medical services utilization and associated costs compared to patients receiving conventional care. Data for 502 matched Apligraf and conventional care patient pairs and 222 matched Dermagraft and conventional care patient pairs were analyzed. Increased costs associated with outpatient service utilization relative to matched conventional care patients were offset by lower amputation rates, fewer days hospitalized and fewer emergency department visits among Apligraf and Dermagraft patients. Consequently, Apligraf and Dermagraft patients with DFUs had per-patient average healthcare costs during the 18-month follow-up period that were lower than their respective matched conventional care counterparts (Apligraf was $5,253 (*p*=0.49), lower per patient, while Dermagraft was $6,991 (*p*=0.84) lower). These findings suggest that use of Apligraf and Dermagraft for treatment of DFU may lower overall medical costs through reduced utilization of costly healthcare services.

Mechanism of Action Clinical Study

To elucidate the mechanisms through which Apligraf promotes healing of chronic VLUs, the University of Miami Miller School of Medicine Department of Dermatology & Cutaneous Surgery conducted an RCT in which 24 patients with non-healing VLUs were treated with either standard of care (compression therapy) or Apligraf together with standard of care. Tissue biopsies were collected from the VLU edge before and one week after treatment, and the samples underwent a comprehensive analysis of gene expression and protein analyses. The analyses conducted suggest that Apligraf induced a shift from a non-healing to a healing tissue response, involving modulation of inflammatory and growth factor signaling, keratinocyte activation, and attenuation of signaling involved in the chronic ulcer impaired state. In these ways, Apligraf application orchestrated a shift from the chronic non-healing ulcer microenvironment to a distinctive healing milieu resembling that of an acute, healing wound.

Dermagraft

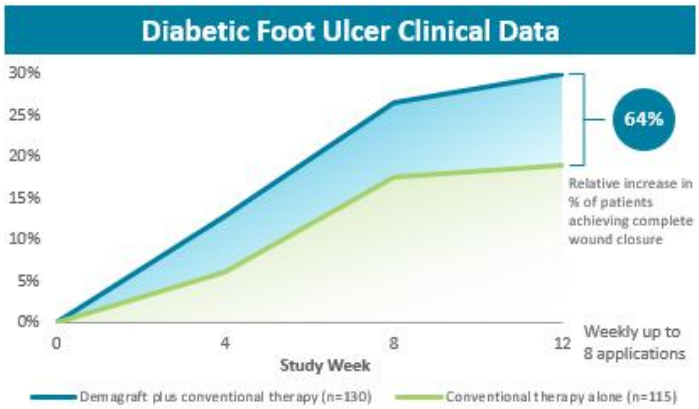
Dermagraft was approved as a Class III medical device for the treatment of DFUs based on the results of a large pivotal clinical trial. Three hundred fourteen patients were enrolled in a prospective RCT to evaluate the safety and efficacy of Dermagraft in conjunction with conventional therapy compared to a control arm of conventional therapy alone. Conventional therapy involved the sharp debridement and cleaning of the ulcer, application of a wet-to-dry gauze, and the use of therapeutic, pressure-reducing footwear. Patients were eligible to be screened for the trial if they had a plantar DFU on the heel or forefoot that was greater than 1cm^2 and less than 20cm^2. At the screening visit, the patients began receiving conventional therapy. If the DFU had not decreased in

size by more than 50% during the next two weeks and the patient met all other inclusion and exclusion criteria, the patient was randomized into one of two treatment groups: Dermagraft plus conventional therapy or conventional therapy alone. Patients in the Dermagraft group received a weekly application of Dermagraft and conventional therapy for up to eight weeks. The primary endpoint for the trial was superiority in complete DFU closure by 12 weeks.

Pivotal FDA Registration Trial

In the pivotal clinical trial, the weekly application of Dermagraft and conventional therapy for up to eight weeks increased the proportion of DFUs that achieved 100% closure at 12 weeks by 64%, when compared to the use of conventional therapy alone. Patients treated in the Dermagraft group were 1.7 times more likely to achieve 100% closure than patients receiving conventional therapy alone. These results demonstrated statistically significant improvements. The incidence of adverse events among the Dermagraft and control groups was generally consistent across both groups, with the most common adverse events being infection at the DFU site, infection not at the DFU site, accidental injury and skin dysfunction/blister. However, the percentage of patients who developed an infection at the DFU site was significantly lower in the Dermagraft treatment group as compared with the control group, 10.4% versus 17.9%, respectively. No adverse laboratory findings were associated with the use of Dermagraft and no adverse device effects were reported in the trial. In addition, no immunological responses or rejections from patients that received Dermagraft were reported in this trial or in patients treated to date. The primary healing data for the trial is presented in the figure below.

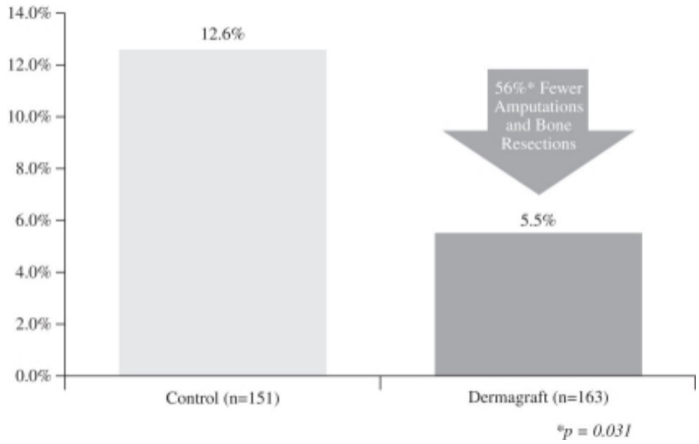
Percent of Patients with Complete Healing by 12 Weeks



In a post-hoc analysis, it was determined that in patients treated with Dermagraft, there was a significant reduction in incidence of amputations or bone resections, as compared to the control group (12.6% versus 5.5%, respectively, p=0.031). No adverse laboratory findings were associated with the use of Dermagraft and no adverse device effects were reported in the trial. In

addition, no immunological responses or rejections from patients that received Dermagraft were reported in this trial or in patients treated to date. The amputation or bone resection data is presented in the figure below.

Frequency of Patients Experiencing a Study Ulcer-Related Amputation or Bone Resection at 12 Weeks



Comparative Effectiveness and Economic Studies

We have conducted three comparative effectiveness studies with Dermagraft, which utilizes our proprietary access to data collected in the EMR database. In collaboration with statistical experts and leading clinicians, we analyzed outcomes of treatment with Dermagraft versus other skin substitutes including EpiFix (owned by MiMedx), Primatrix (owned by Integra), and Grafix (owned by Smith & Nephew). All three studies showed that Dermagraft improved overall healing rates as well as time to healing. In one study, patients treated with Dermagraft showed a 52% relative improvement in healing over EpiFix by week 24.

The economic study of Dermagraft in a Medicare population conducted by the Analysis Group is described under the heading "—Our Products—Previously Published Clinical Studies for FDA-Approved Products—Apligraf—Comparative Effectiveness and Economic Studies" above.

TransCyte

In a published study of the safety and efficacy of TransCyte for the treatment of partial thickness burns, the mean timing to achieve greater than 90% wound epithelialization was 11 days for patients treated with TransCyte as compared to 18 days for patients treated with silver sulfadiazine cream (p=0.002).

Platform Technologies

Our proven research and development capabilities and established technology platforms support a robust and adaptable product pipeline for future applications. The platform technologies in which we have deep experience include:

- ***Bioengineered Cultured Cellular Products:*** The development and production of bioengineered cultured cellular products have been a core competency of Organogenesis since its founding. Our Apligraf, Dermagraft, and TransCyte products all draw from our expertise in this area.

- ***Collagen Biomaterial Technology Platform:*** Our porcine collagen biomaterial technology platform incorporates proprietary tissue cleaning processes and allows us to bioengineer products for specific applications by controlling thickness, strength, and remodeling rates. We currently hold 510(k) clearances for a number of products in this platform with indications ranging from tendon reinforcement to plastic surgery and general surgery applications.

- ***Placental-Based Products:*** Our placental-based products are based on significant expertise in the processing of placental tissues and fluids to yield products with desirable characteristics. We have expertise using the full array of available tissue types and multiple processing methodologies, including our proprietary AlloFresh and LayerLoc processing methods. Our proprietary AlloFresh process hypothermically stores our Affinity product in its fresh state, never dried or frozen, which

retains its native benefits and structure. Our proprietary LayerLoc process preserves the native structure of the amnion and chorion membranes, optimized to provide excellent strength, flexibility, and handling.

• ***Antimicrobial Technology:*** Our Polyhexamethylene Biguanide (PHMB) antimicrobial technology provides clinical and competitive advantage for multiple wound indications. PHMB is a broad-spectrum effective antimicrobial that prevents biofilm reformation. We have developed multiple product versions incorporating PHMB that have demonstrated clinical benefit to control bioburden and support wound healing when used following wound debridement.

Commercial Infrastructure

Sales and Marketing

We have dedicated substantial resources to establish a multi-faceted sales capability in the United States. Our current Advanced Wound Care portfolio is sold throughout the United States via an experienced direct sales force, which focuses its efforts on wound care in various sites of care. We use a mix of direct sales representatives and independent agencies to service the Surgical & Sports Medicine market. As of December 31, 2023, we had approximately 260 direct sales representatives and approximately 160 independent agencies who have substantial medical device sales experience in our target end markets. These sales representatives are supported by teams of professionals focused on sales management, sales operations and effectiveness, ongoing training, analytics, and marketing.

We have historically focused our market development and commercial activities in the United States, but we have obtained marketing registrations, developed commercial and distribution capabilities, and are currently selling products in several countries outside of the United States. Our Apligraf product is currently distributed by our direct sales force in Switzerland, and through independent sales agents in Saudi Arabia and Kuwait. Our NuShield product is also distributed by our direct sales force in Switzerland, and through independent sales agents in Kuwait. We have obtained marketing registration for our Dermagraft product in Mexico, but we are not currently distributing it. Additionally, we are evaluating the regulatory pathways and market potential for our products in other major markets, including the European Union. Sales generated by our direct sales forces in the United States have represented, and we anticipate will continue to represent, a majority of our revenues.

Customer Support Services

We offer our customers in-house customer support services, including services provided by our experienced reimbursement support team, our medical and technical support team, and our field-based medical science liaison team. We believe that we have a competitive advantage by providing these essential support services in-house in that we are able to align the support services closely with our sales efforts as appropriate and improve the customer's overall experience.

Research and Development

Our research and development team has extensive experience in developing regenerative medicine products, and works to design products that are intended to improve patient outcomes, simplify techniques, shorten procedures, reduce hospitalization and rehabilitation times, and, as a result, reduce costs. We conduct research and development activities at our laboratory facilities in Canton, MA, Birmingham, AL, and San Diego, CA. We have recruited and retained staff with significant experience and skills, gained through both industry experience and training at leading colleges and universities with regenerative medicine graduate programs. In addition to our internal staff, our external network of development labs, testing labs, and expert clinicians aid us in our research and development process. We continue to build our clinical operations capabilities to effectively run multiple concurrent multicenter clinical trials, including trials intended for FDA regulatory submissions (e.g. BLA). We have significant regulatory affairs capabilities to prepare and manage our regulatory submissions for product approvals.

The majority of our product portfolio, including Apligraf, our PuraPly product family, our collagen biomaterial technology platform product family, and all of our placental-based products, was developed by our research and development team at our three facilities. We have proven competencies to bring products to market via a broad range of regulatory classifications, as evidenced by FDA approval or clearance of our products via PMA approval of a Class III medical device; BLA approval of a biologics product; and 510(k) clearance of a Class II medical device, in addition to our 361 HCT/P allograft products and several products for which we have obtained international registrations.

Manufacturing and Suppliers

We manufacture internally our primary non-placental-based products and use third-party manufacturers for our placental-based products. We have significant expansion capabilities in our in-house manufacturing facilities and we believe that our contract manufacturers are well positioned to support future expansion.

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 to monitor our quality control practices. We are registered with the FDA as a medical device manufacturing establishment and a HCT/P registered establishment. We are also accredited by the AATB and licensed with several states per their tissue banks regulations. All of our contract manufacturers are registered with the FDA as HCT/P establishments and are AATB accredited.

We utilize third-party raw material suppliers to support our internal manufacturing processes. We select all of 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 at pre-determined intervals. Historically, we have not experienced any significant difficulty locating and obtaining the suppliers or materials necessary to fulfill our production requirements. In the first quarter of 2019, however, we suspended production of our product Affinity due to production issues at one of our suppliers. As this was our sole supplier of Affinity, it resulted in a disruption of our production capabilities. We identified an alternate supplier and were able to resume commercial-scale production in the second quarter of 2020. Subsequently, we have added a second source to provide additional capacity and redundancy in supply.

The manufacture of our products is dependent on the availability of sufficient quantities of source tissue, which is the primary component of our products. Source tissue includes donated human tissue, porcine tissue, and bovine tissue. We acquire donated human tissue directly through institutional review board-approved protocols at multiple hospitals, as well as through tissue procurement firms engaged by us or by our contract manufacturers. We have two qualified porcine tissue suppliers, and currently one source of bovine tissue. Our processing of these tissues is, and our supplier sources are required to be, compliant with applicable FDA current Good Tissue Practice, or cGTP, regulations, AATB standards, and U.S. Department of Agriculture, or USDA, requirements.

License and Manufacturing Agreement with Vivex Biologics, Inc.

We enter into license and manufacturing agreements from time to time in the ordinary course of our business. In November 2023, we entered into a trademark license and manufacturing agreement with Vivex Biologics, Inc. (Vivex) to sell their CYGNUS Dual (Dual) and CYGNUS Matrix (Matrix) products. Vivex also granted us the right to purchase the license rights to sell their VIA Matrix product (VIA). We paid an upfront licensing fee to Vivex to sell Dual and Matrix, and also agreed to pay a fixed milestone payment for Dual in the event that the ASP is published by certain government agencies for a specified period of time. In addition, we are required to pay a low double-digit royalty and a high single-digit royalty on the Net Sales of Dual and Matrix, respectively, during the royalty term, as defined in the agreement with Vivex. The royalty term is commensurate with the initial term of the contract and will continue for each subsequent renewal period. The initial term of the agreement expires on December 31, 2026 and can be renewed for up to five additional one-year terms.

Reimbursement

Overview

Our customers primarily consist of hospitals, wound care centers, government facilities, ASCs, and physician offices, all of which rely on coverage and reimbursement for our products by Medicare, Medicaid, and other third-party payers. Governmental healthcare programs, such as Medicare and Medicaid, typically have published and defined coverage criteria and published reimbursement rates for medical products, services, and procedures that are established by law or regulation. Non-government payers have their own coverage criteria and often negotiate payment rates for medical products, services, and procedures. Many also require prior authorization as a prerequisite to coverage. In addition, in the United States, an increasing percentage of insured individuals are receiving their medical care through managed care programs, which monitor utilization and also may require prior authorization for the products and services that a member receives. Coverage and reimbursement from government and commercial payers are not assured and are subject to change.

Medicare, the federally funded program that provides healthcare coverage for senior citizens and people with disabilities, is the largest third-party payer in the United States. The Centers for Medicare and Medicaid Services (CMS) administers the Medicare program and, for Medicare Parts A and B (often referred to as "traditional Medicare") uses Medicare Administrative Contractors (MACs) to process claims, develop coverage policies and make payments within designated geographic jurisdictions. CMS does not have a national coverage determination related to skin substitutes. Coverage for our products falls under the jurisdiction of the Part A/B MACs. Medicare coverage for our products is determined by each MAC for its specific jurisdiction. Currently, all the MACs, even those without published local coverage determinations (LCDs), cover our products in the outpatient hospital, physician office, and ASC settings. Medicare Advantage (MA) Plans (Medicare Part C) are required to cover items and services that are covered by Medicare Parts A and B. However, if a MAC does not have an explicit coverage policy for an item or service, MA plans, if they

follow certain requirements and processes, are not required to cover items and services which are covered by Medicare Parts A and B. Therefore, it is possible that some MA plans may not cover one or more of our products.

Private payers often, but not always, follow the lead of Medicare or other governmental payers in making coverage and reimbursement determinations. Therefore, achieving favorable Medicare coverage and reimbursement can sometimes be a significant factor in obtaining favorable coverage and reimbursement for products by private payers. While most private payers currently cover Apligraf and Dermagraft, and some cover Affinity, most of those payers do not cover many of our other products, such as PuraPly, PuraPly AM, NuShield and CYGNUS.

Currently, Medicare makes a separate payment for our products when used in the physician office at a payment rate based on the average sales price (ASP) methodology, including ASP plus 6% for some products. In the outpatient hospital and ASC settings, Medicare payment for all our products is bundled into the payment for the application procedure.

All Medicare payment amounts, including separate payment for our products, are affected by sequestration. In 2020, legislation was enacted that temporarily discontinued the sequestration rate of 2% of the government portion, which was imposed under the Budget Control Act of 2011 (BCA); under 2% sequestration, the final payment rate for products paid based on ASP is ASP+4.3%. The sequestration began again on April 1, 2022 at a rate of 1%. Starting on July 1, 2022, the sequestration rate returned to 2%. Sequestration may also be ordered under the Statutory Pay-As-You-Go Act of 2010 (Statutory PAYGO), which requires deficit neutrality in most laws passed by Congress. The $1.9 trillion American Rescue Plan Act of 2021 was expected to trigger Statutory PAYGO at the end of the 2021 Congressional session, but Congress has delayed a Statutory PAYGO sequestration order until after 2024.

The proposed update to the Medicare Physician Fee Schedule (MPFS) for calendar year 2023 included a proposal to stop making separate payments for all skin substitutes, including all of our products, in 2024 or 2025. Instead of making separate payment for skin substitutes, Medicare would bundle the payment for skin substitutes into the payment made for the application procedure. As part of this proposal, Medicare would consider all skin substitutes to be supplies instead of biologicals and would require manufacturers of skin substitutes, including us, to apply for new HCPCS codes that would be effective starting in 2024. In the 2023 MPFS final rule, published on November 1, 2022, CMS did not finalize this bundling proposal and will consider more public input in the future; however, they may propose the same policy again or make other proposals in the future that could affect our business and our revenue.

All skin substitute products administered in the hospital outpatient department and ASC settings are bundled. No skin substitute products currently have pass-through status. Pursuant to the Appropriations Act, PuraPly AM and PuraPly had pass-through status from October 1, 2018 through September 30, 2020, at which time the pass-through status expired. As of October 1, 2020, payment for PuraPly and PuraPly AM is bundled into the payment rate for the application procedure.

Skin Substitutes Used for Wound Care

All of our Advanced Wound Care products are classified as "skin substitutes" for Medicare reimbursement purposes. In 2014, CMS instituted "bundled" payments in the hospital outpatient and ASC setting for skin substitutes using a two-tier payment system. The Medicare payment system bundles payment for our products (and all skin substitutes) into the payment for the application of the skin substitute, resulting in a single payment to the provider that includes both the application of the product and the product itself. There is one bundled payment amount for procedures that involve high-cost products, i.e., products whose cost exceeds a threshold amount, and another bundled payment amount for procedures that involve low-cost products that do not meet the threshold. The bundled payment rate is updated annually and is also geographically adjusted. Currently, all of our wound care products are assigned to the high-cost bundle; it is not possible to predict, however, whether those products will continue to be assigned to the high-cost bundle or the rates that will be paid for each bundle. Further, under the bundling policy, there is an inherent incentive to use the cheapest products available, even if those products are less effective.

The bundled payment rates are also geographically adjusted. This geographic adjustment may result in significant payment variations among regions; sixty percent of the hospital payment rate and fifty percent of the ASC payment is adjusted to take into account the region’s wage-index, which can vary widely from one region to another. The wage-index adjustment can increase or decrease the unadjusted payment amount and may result in reimbursement being insufficient to account for the cost of skin substitute products and sizes in one geographic area that are fully reimbursed in other geographic areas.

Medicare has signaled that it may revise its two-tiered bundled payment policy for skin substitutes. Medicare solicited comments in the calendar year 2019 proposed rule related to proposed updates and policy changes under the Medicare Hospital Outpatient Prospective Payment System (OPPS) and ASC Payment System. Medicare specifically solicited comments on whether it should eliminate the two-tiered bundle policy and establish a single bundle for all products. However, CMS has not implemented

any changes to its two-tiered payment structure for skin substitutes in response to those comments. In the calendar year 2023 proposed rule, CMS did not solicit comments on changes to its two-tiered payment structure. However, if CMS finalizes any revisions to its two-tiered payment policy, those changes could result in decreased reimbursement for our products which could decrease utilization and reduce our revenues. Moreover, any new policy could result in a financial incentive for hospitals and ASCs to use our competitor's products, thereby reducing our market share and revenue.

In the physician office setting, payment for skin substitutes is not bundled into the payment for the administration of the product. Skin substitutes are paid separately from the application procedure and the Medicare payment rate for all biological skin substitutes (including ours) is calculated based on the ASP methodology on a per square centimeter basis with the total payment for the product being the per square centimeter ASP-based payment rate multiplied by the total number of centimeters. In the physician office setting the Medicare payment rates for all biological skin substitutes (including ours) are updated quarterly based on the ASP methodology and are not geographically adjusted. All Medicare payment amounts, including separate payment for our products, are affected by sequestration. Under the BCA, sequestration reduces by two percent the federal portion of the Medicare payment amount; the beneficiary coinsurance amount of 20 percent is unaffected by sequestration. Congress had suspended sequestration during the COVID-19 public health emergency until April 1, 2022, at which time the reduction was one percent. Starting on July 1, 2022, the sequestration rate returned to two percent.

The ASP-based payment methodology applies only to physician offices and other sites of service where services are paid under the MPFS such as a patient's home and certain nursing facilities. However, in the future, it is possible, through legislation or regulation, that Medicare will institute bundled payment for skin substitutes in the physician office and these other settings. In fact, the proposed updates to the MPFS for calendar year 2023 included a proposal to stop making separate payment for all skin substitutes, including all of our products, in 2024 or 2025. Instead of making separate payment for skin substitutes, Medicare would bundle the payment for skin substitutes into the payment made for the application procedure. In the 2023 MPFS final rule, published on November 1, 2022, CMS did not finalize this bundling proposal and will consider more public input in the future; however, they may propose the same policy again or make other proposals in the future that could affect our business and our revenue.

Before calendar year 2022, Medicare did not require us to report ASP for some of our products because they are regulated by the FDA as medical devices; we voluntarily reported ASP data for most products. However, starting on April 30, 2022, we were required to report ASP for all our products because of a provision enacted in the Consolidated Appropriations Act of 2020, signed into law on December 27, 2020. CMS does not necessarily include all products that report ASP data in the quarterly ASP file. The local Part A/B MACs establish local payment for drugs and biologics whose ASP does not appear in the quarterly ASP file. MACs have the discretion to pay for such products based on invoices submitted by providers, Wholesale Acquisition Cost (WAC) + 3%, or they may contact CMS to determine if there are unpublished ASP data.

Section 90004 of the Infrastructure Investment and Jobs Act, enacted in November 2021, requires manufacturers to pay a refund to the federal government if more than a certain applicable percentage of their single-use product is not administered to a patient and is discarded ("wasted") by providers. Because there is a lack of consistency and uniformity in wound sizes, it is likely that some skin substitute product is discarded with every treatment. Providers are only required to report discarded product when the product is paid separately (not part of a bundled payment rate.) The rebate obligation took effect on January 1, 2023, and CMS proposed a methodology to implement the rebate in the MPFS rulemaking. The applicable percentage is required to be at least 10 percent of total allowed charges for the drug in a given calendar quarter. CMS has the authority to increase the applicable percentage that applies to refunds for discarded product if there are "unique circumstances". We submitted comments on the proposal noting the unique circumstances related to skin substitutes and asking CMS to apply a higher percentage. In the 2023 MPFS final rule, published on November 1, 2022, CMS did not apply a higher applicable percentage to any products other than the hydrogel example they used in the proposed rule and stated that they plan to collect additional information about products that may have unique circumstances such that an increased applicable percentage (higher than 10 percent) would apply. CMS estimated the wastage percentage for three of our products - Apligraf, Dermagraft, and PuraPly - based on 2020 data. In the calendar year 2023 rulemaking, CMS exempted skin substitutes from this refund requirement. This exemption is based on the possibility that CMS will, in future rulemaking, stop paying for skin substitutes using the ASP methodology and bundle payment into the payment for the application of the product. However, because we do not know if or when CMS will begin bundled payment under the MPFS, this exemption may be rescinded and we may be required to refund payments made for the discarded portions of our products. If that happens, we do not know if the refund amounts calculated in 2023 will be similar to these estimates but if they are, we may owe rebates, which could be material, on these products and possibly other products. The total amount of any potential discarded product rebate liability is not known at this time.

In the calendar year 2022 Final Rule for the MPFS, CMS established ten healthcare common procedure coding system (HCPCS), codes that describe synthetic skin substitutes, and more of these codes for synthetic skin substitutes have been established since. CMS has directed MACs to make separate payments for these codes when they are reported with the CPT codes for the application of skin substitutes. Because manufacturers of these products are not required to establish a WAC, or submit an ASP

(because they are not treated as drugs or biologics by Medicare), it is likely the Part A/B MACs will pay for these products based on invoices. We do not know what effect this will have on our business or revenue.

Commercial insurers contract with participating providers such as hospitals, wound care centers, government facilities, ASCs, and physician offices to establish agreed-upon payment rates for items and services, including skin substitutes. Usually, these rates are in the form of a fee-schedule but sometimes there is a bundled payment rate. In many cases, the fee schedules are based on Medicare payment rates, which are bundled in hospitals and ASCs, but not in physician offices. These rates may vary by insurer, by provider and by region.

Medicaid coverage and payment rates and policies as to the types of providers (e.g., podiatrists) who are allowed to apply our products are determined by each state's Medicaid program. Some states may bundle Medicaid payment for skin substitutes into the payment for the application procedure, like Medicare, while other states may pay separately. State Medicaid programs may reach different conclusions regarding the medical necessity of products used in treating Medicaid patients.

In 2023, three MACs (Novitas, FCSO, and CGS) issued final LCDs for skin substitutes for the treatment of DFUs and VSUs, eliminating coverage for over 130 products, including five of our commercially marketed products. These final LCDs also would have limited the number of skin substitutes that could be applied to a wound, and would have limited the ability to switch skin substitutes during a course of treatment. In addition, the LCDs would have required us to get certification from the FDA that our amniotic products are solely regulated under Section 361 of the Public Health Services Act. The final LCDs were scheduled to take effect on October 1, 2023. However, all three of the MACs withdrew these LCDs, and have indicated they intend to issue new proposed LCDs on the use of skin substitutes for DFUs and VSUs. To date, no such LCDs have been issued but they may be issued at any time in the future. If new LCDs are issued, they may eliminate coverage for some or all of our products, which could adversely impact utilization of any of our non-covered products and our revenue. In addition, future LCDs could limit the number of skin substitutes that can be applied to a wound, limit a provider's ability to switch skin substitutes during a course of treatment or require us to obtain FDA certification that our amniotic products are solely regulated under Section 361 of the Public Health Services Act. If such LCDs were finalized, we would aggressively dispute such conclusions, as we did at the time the 2023 LCDs were issued. However, if we were unsuccessful in disputing these LCDs, our business and revenue could be materially and adversely affected.

Surgical & Sports Medicine Products

Surgical & Sports Medicine products administered on an inpatient basis in a hospital are reimbursed by Medicare as part of a bundled payment based on the Medicare Severity Diagnosis Related Group (MS-DRG), to which a patient is assigned upon discharge from the hospital. MS-DRG assignment is determined according to the patient's primary diagnosis, but can also be affected by other secondary diagnoses and the provision of certain surgical procedures. Certain MS-DRGs account for complications and comorbidities, which may increase the reimbursement amount.

The MS-DRG payment rate is a consolidated prospective payment for all services provided by the hospital during the patient's hospitalization, based on the average cost of care calculated from Medicare claims data. With extremely few exceptions, the MS-DRG payment is inclusive of all services, products, and resources. Products administered during surgical procedures are not typically coded or paid separately when provided to a hospital inpatient. MS-DRG payments are case rates and hospitals profit when their costs for a particular patient are below the case rate and they are at risk of a loss if their costs are above the case rate.

Some private payers use the MS-DRG based system to reimburse facilities for inpatient services.

Competition

We operate in highly competitive markets that are subject to rapid technological change. Success in these markets depends primarily on product efficacy, ease of product use, product price, availability of 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 reputation offer us advantages over our competitors. In addition, we believe we are one of the few regenerative medicine companies offering PMA approved and 510(k) cleared products in addition to our 361 HCT/Ps.

Our products compete primarily with skin substitute products, placental-based technology products, orthobiologics products, other advanced wound care and traditional wound care products, among others. Our competitors include Arthrex, Inc., Bioventus Inc., Integra LifeSciences Holdings Corporation, MiMedx Group, Inc., Smith & Nephew plc, 3M, Incorporated, Coloplast A/S, DePuy Synthes (Johnson & Johnson), and Zimmer Biomet Holdings, Inc.

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.

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 on our ability to develop proprietary products that reach the market in a timely manner, receive adequate coverage and reimbursement, are cost effective, and are safe and effective.

Intellectual Property

Our success depends in part on our ability to protect our proprietary technology and intellectual property and operate without infringing the patents and other proprietary rights of third parties. We rely on a combination of trademark, trade secret, patents, copyright, and other intellectual property rights and measures to protect the intellectual property rights that we consider important to our business. We also rely on know-how and continuing technological innovation to develop and maintain our competitive position. Other than a license from Novartis Pharma AG for trademark and domain name rights to Apligraf and an exclusive license from RESORBA Medical GmbH, or Resorba, to a U.S. patent for a collagen-based wound dressing containing PHMB, we do not have any additional material licenses to any technology or intellectual property rights. Under the terms of the exclusive license from Resorba, we were obligated to make minimum royalty payments of $1.0 million in each of 2018 and 2019, and were subject to a $2.5 million minimum royalty payment in 2017, as part of an ongoing low single-digit royalty payment on net sales of PuraPly AM; the term of the license shall continue for the life of the patent, which expires in October 2026. We may also terminate the license upon written notice to Resorba in the event that (i) the patent is invalidated or (ii) we stop all activities that would require a license to the patent, and either party may terminate the license in the event of a material breach by the other party, subject to notice and an ability to cure. In addition, we were obligated to make upfront and maintenance payments totaling $0.6 million at specified periods prior to April 1, 2019, including a payment of $0.2 million that was made on July 1, 2018. The license is assignable but not sub-licensable.

As of December 31, 2023, we owned 36 issued patents globally, of which 15 were U.S. patents. As of December 31, 2023, we owned 19 pending patent applications, of which 9 were patent applications pending in the United States. Subject to payment of required maintenance fees, annuities, and other charges, many of our issued patents are currently expected to expire between 2027 and 2042. The expiration of these patents is not expected to have a material impact on our business. In addition, many of our products, including our Apligraf, Dermagraft, and NuShield products, are not covered by our issued patents or pending patent applications. Our issued patents are drawn to the following main areas: methods of making and using cultured tissue constructs, methods for preparing multi-layer stacks of living tissue, methods for treating recessed oral gingiva using cultured tissue constructs, methods of making and using osteogenic implants comprising a placental membrane sheet, wound treatment methods using amniotic stem cell solutions and placental membrane sheets, methods of generating cartilage in a skeletal joint using placental membrane preparations, hepatocyte growth factor- and hyaluronic acid-containing compositions and methods of using such compositions, methods making placental membrane preparations comprising hyaluronic acid, methods of harvesting or proliferating human prenatal stem cells, hypothermic morselized placental membrane storage methods, uses of human amniotic fluid for treating chronic wounds and joint diseases, and adjustable debridement curette apparatuses. Our pending patent applications encompass additional areas, including wound treating methods using morselized amnion tissue and amniotic-derived cells, methods of assessing native stem cell populations using cultured isolated stem cells and reference cell sources, viscosupplement compositions and musculoskeletal inflammatory treatment methods using same, wound care treatment and methods of making and using such treatment, model systems and methods to characterize anti-inflammatory activity, and porcine collagen compositions and methods of using such compositions. Our pending patent applications may not result in issued patents and we can give no assurance that any patents that have been issued or might be issued in the future will protect our current or future products or provide us with any competitive advantage. See the section titled "*Risk Factors—Risks Related to Our Intellectual Property*" for additional information.

Additionally, we own or have rights to trademarks or trade names that are used in our business and in conjunction with the sale of our products, including 16 U.S. trademark registrations and 12 foreign trademark registrations, as of December 31, 2023.

We also seek to protect our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with suppliers, employees, consultants, and others who may have access to our proprietary information.

Government Regulation

FDA Regulation of Product Registration, Manufacture, and Promotion

We market medical products in the United States that have either been approved or cleared by the FDA prior to marketing, or do not require FDA premarket review. Our marketed products that have received marketing authorization from the FDA have done so under one of the following agency pathways: 510(k) clearance for a Class II medical device or approval of a PMA for a Class III medical device. These medical products are regulated by the FDA under the PHSA or the FDCA along with the FDA's implementing regulations. These federal statutes and regulations govern, among other things, the following activities that we perform or are performed on our behalf and will continue to perform or have performed on our behalf: the production, research, development, testing, manufacture, quality control, packaging, labeling, storage, approval, advertising, and promotion, distribution of our products into interstate commerce, record keeping, service and surveillance, complaint handling, repair or recall of products, adverse event reporting and other field safety corrective actions.

FDA Regulatory Review and Approval Process

Unless an exemption applies or the product is a Class I device, each medical device that we market must first receive either 510(k) clearance or PMA approval from the FDA. In addition, certain modifications made to marketed devices also may require 510(k) clearance or approval of a PMA supplement. We maintain necessary clearances and approvals for products derived from porcine, bovine, and human tissues that are regulated by the FDA. PuraPly, PuraPly AM, PuraPly XT, PuraPly SX, PuraPly MZ, and PuraForce are medical devices that have been cleared for marketing under a number of 510(k)s for uses such as wound dressing, intraoral barrier, and surgical mesh. We also maintain medical device approvals for the Apligraf (P950032) and Dermagraft (P000036) devices, both approved by the FDA as chronic wound treatments.

With respect to the manufacture of medical devices and biologics, the FDA regulates and inspects equipment, facilities, laboratories, and processes used in the manufacturing and testing of products prior to providing approval to market products. After receiving approval from the FDA, additional regulatory review or inspection may be required if we make a material change in manufacturing equipment, location or process. Our manufacturing processes must comply with the FDA's Quality System Regulation, or QSR, for our medical device products. The QSR requires that each device manufacturer establish and implement a quality system under which the manufacturer monitors the manufacturing process and maintains records that show compliance with FDA regulations and the manufacturer's written specifications and procedures relating to the devices. Among other things, these regulations require that manufacturers establish performance requirements before production and follow requirements applicable to design controls, testing, record keeping, documentation, manufacturing standards, labeling, complaint handling, and management review.

Manufacturers of biologics must comply with applicable cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Manufacturers and others involved in the manufacture and distribution of such products also must register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Concurrent with clinical trials, companies usually complete additional preclinical studies and must also develop additional information about the physical characteristics of the biologic product candidate, as well as finalize a process for manufacturing the product candidate in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents or of causing other adverse events with the use of biologic products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other requirements, the sponsor must develop methods for testing the identity, strength, quality, potency, and purity of the final biologic product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biologic product candidate does not undergo unacceptable deterioration over its shelf life.

The FDA conducts periodic visits, both announced and unannounced, to re-inspect our equipment, facilities, laboratories, and processes to confirm regulatory compliance. These inspections may include the manufacturing facilities of subcontractors. Following an inspection, the FDA may issue a report, known as a 483, listing instances where the manufacturer has failed to comply with applicable regulations and/or procedures or, if observed violations are severe and urgent, a warning letter. If the manufacturer does not adequately respond to a 483 or warning letter, the FDA may take enforcement action against the manufacturer or impose other sanctions or consequences, which may include:

- cease and desist orders;
- injunctions, or consent decrees;
- civil monetary penalties;

- recall, detention, or seizure of our products;
- operating restrictions, partial or total shutdown of production facilities;
- refusal of or delay in granting our requests for 510(k) clearance or PMA or BLA approval of new products or modified products;
- withdrawing 510(k) clearance or PMA/BLA approvals that are already granted;
- refusal to grant export approval or export certificates for our products; and
- criminal prosecution.

In addition, we must comply with medical device reporting regulations and corrections and removal reporting regulations. Medical device reporting regulations require that manufacturers report to the FDA if their devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. Corrections and removal reporting regulations 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 may also order a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death.

Certain human cells, tissues, and cellular and tissue-based products, or HCT/Ps, are regulated under Section 361 of the PHSA and are referred to as "Section 361 HCT/Ps" or simply "361 HCT/Ps," while other HCT/Ps are subject to the FDA's regulatory requirements for medical devices and/or biologics. A product that is regulated as a 361 HCT/P may be commercially distributed without prior FDA clearance or approval. Pursuant to 21 CFR 1271.10, in order to be regulated as a 361 HCT/P, and hence exempt from premarket review, an HCT/P must be minimally manipulated, intended for homologous use, and manufactured without being combined with another article (except for water, crystalloids, or sterilizing, preserving, or storage agents). The HCT/P must also either have no systemic effect and not be dependent upon the metabolic activity of living cells for its primary function or, if it has a systemic effect, be intended for autologous use, for allogeneic use in a first-degree or second-degree blood relative or for reproductive use. We believe that Affinity and NuShield generally fulfill the relevant criteria under 21 CFR 1271.10. In light of the 361 HCT/P Guidance, our labeling and marketing claims for Affinity and NuShield clarify that they are intended for use as protective barriers, and thus qualify as Section 361 HCT/Ps. However, the FDA could disagree with our conclusion and require premarket approval or clearance for Affinity, NuShield, or any placental-based sheet product we presently have or may have in the future market, which would disrupt the marketing of these products, potentially expose us to regulatory sanctions, and have a material adverse effect on our business, financial condition and results of operations. Section 361 HCT/Ps are subject to specific FDA regulations that include cGTPs, donor eligibility determination requirements, adverse event reporting, and advertising and labeling requirements. cGTP regulations govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, including but not limited to all steps in recovery, donor screening, donor testing, processing, storage, labeling, packaging, and distribution.

Before testing any biologic product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, potency, toxicity, and formulation, as well as in vivo studies to assess the potential safety and activity of the product candidate and to establish a rationale for therapeutic use. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. Concurrent with clinical trials, companies usually must complete some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final drug product.

The clinical trial sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature, and a proposed clinical protocol, to the FDA as part of the Investigational New Drug Application (IND). The FDA may impose clinical holds on a biologic product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, clinical trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to commence, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biologic product candidate to volunteers or patients under the supervision of qualified investigators who generally are physicians not employed by, or under, the control of the trial sponsor. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety, including stopping rules that assure a

clinical trial will be stopped if certain adverse events should occur. Each protocol and certain amendments to the protocol must be submitted to the FDA as part of the IND. Submission of an IND may or may not result in the FDA allowing clinical trials to commence. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an Institutional Review Board (IRB) at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers items such as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject, or their legal representative, reviews and approves the trial protocol, and must monitor the clinical trial until completed.

Human clinical trials are typically conducted in three sequential phases that may overlap, be combined, or be bifurcated into two parts:

- Phase 1. The biological product candidate is initially introduced into healthy human subjects and tested for safety. In the case of some product candidates for severe or life-threatening diseases, especially when the product candidate may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

- Phase 2. The biological product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases, and to determine dosage tolerance, optimal dosage, and dosing schedule.

- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product candidate and provide an adequate basis for product approval and labeling. In January 2021, we announced that the first patient was enrolled in the pivotal Phase 3 clinical trial evaluating the safety and efficacy of ReNu for the management of symptoms associated with knee OA.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. Sometimes approval for a product is conditional upon the completion of post-marketing clinical studies.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, the IRB, and the investigators for: serious and unexpected suspected adverse reactions; any findings from other trials; findings from animal or in vivo laboratory tests or in vitro testing that suggest a significant risk for human subjects; or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report as soon as possible, but in no case later than 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but no later than seven calendar days after the sponsor's initial receipt of the information.

The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biologic product candidate has been associated with unexpected serious harm to patients.

Expedited Development and Review Programs

The FDA is authorized to expedite the review of BLAs in several ways. Under the Fast Track program, the sponsor of a biologic product candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the filing of the IND. Biologic products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track BLA before the application is complete, a process known as rolling review.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as breakthrough therapy designation, regenerative medicine advance therapy designation, priority review and accelerated approval.

- Breakthrough therapy designation. To qualify for the breakthrough therapy program, product candidates must be intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence must indicate that such product candidates may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives intensive guidance on an efficient drug development program; intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review; and a rolling review.

- Regenerative Medicine Advance Therapy (RMAT) designation. RMAT was introduced as a new designation under the 21st Century Cures Act for the development and review of certain regenerative medicine therapies. As set forth in section 506(g)(8) of the FDCA, the term "regenerative medicine therapy" is defined to include cell therapy, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except for those regulated solely under section 361 of the PHSA. To receive RMAT designation, a regenerative medicine product candidate must be intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition with preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs. RMAT designation does not require evidence to indicate that the drug may offer a substantial improvement over available therapies, as breakthrough designation requires. Similar to breakthrough designation, an RMAT product candidate receives intensive guidance on an efficient drug development program; involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review; and a rolling review. Regenerative medicine therapies that qualify for RMAT designation may also qualify for other FDA expedited programs, including Fast Track designation, breakthrough therapy designation, accelerated approval, and priority review designation, if they meet the criteria for such programs. In January 2021, we announced ReNu received the RMAT designation from the FDA for the management of symptoms associated with knee OA.

- Accelerated approval. Drugs or biologic products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval. Accelerated approval means that a product candidate may be approved on the basis of adequate and well-controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefits, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, FDA may require that a sponsor of a drug or biologic product candidate receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify the predicted clinical benefit. In addition, for accelerated approval products FDA typically requires pre-dissemination submission of promotional materials to FDA for the agency's consideration. A drug approved under the accelerated approval pathway may have its approval revoked on several grounds including if a required post-approval trial fails to verify clinical benefit or does not demonstrate sufficient clinical benefit to justify the risks associated with the drug.

Fast Track designation, breakthrough therapy designation, RMAT designation and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Post-approval Requirements

FDA regulation of biologic products continues after approval, particularly with respect to cGMP requirements, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biologic products include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information and complying with electronic record and signature requirements. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal actions and adverse publicity. These actions could include refusal to approve pending applications or supplemental applications, withdrawal of an approval, clinical hold, suspension or termination of a clinical trial by an IRB, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines or other monetary penalties, refusals of government contracts, mandated corrective advertising or communications with healthcare providers, debarment, restitution, disgorgement of profits or other civil or criminal penalties.

Medical Product Marketing and Promotion

Advertising, marketing and promotional activities for devices and biologics are also subject to FDA oversight and must comply with the statutory standards of the FDCA, and the FDA's implementing regulations. The FDA's oversight authority review of marketing and promotional activities encompasses, but is not limited to, direct-to-consumer advertising, healthcare provider-directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving electronic media. The FDA also regulates industry-sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context. A sponsor also must comply with the FDA's advertising and promotion requirements, such as the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as off-label use). The FDA may take enforcement action against a company for promoting unapproved uses of a product or for other violations of its advertising and labeling laws and regulations. Enforcement actions may include product seizures, injunctions, civil or criminal penalties or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals.

Government Advocacy

We engage in public policy advocacy with policymakers and continue to work to demonstrate that our therapeutic products provide value to patients and to those who pay for health care. We advocate with government policymakers to encourage a long-term approach to sustainable health care 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 health care spending, we encourage those governments to increase their investments and adopt market reforms in order to improve their citizens' access to appropriate health care.

Regulations Governing Reimbursement/Fraud and Abuse

Within the United States, our products and our customers are subject to extensive regulation by a wide range of federal and state agencies. These agencies regulate the coverage and reimbursement of our products, and prohibit activities that might result in health care fraud and abuse against patients and insurance programs. Internationally, other governments also impose regulations in connection with their health care reimbursement programs and the delivery of health care items and services.

U.S. federal health care fraud and abuse laws generally apply to our activities because our products are covered under federal healthcare programs such as Medicare and Medicaid. The principal U.S. federal health care fraud and abuse laws applicable to us and our activities include: (1) the Anti-Kickback Statute, which prohibits the knowing and willful offer, solicitation, payment or receipt of anything of value in order to generate business reimbursable by a federal health care program; (2) the False Claims Act, which prohibits the submission of false or otherwise improper claims for payment to a federally funded health care program, including claims resulting from a violation of the Anti-Kickback Statute; and (3) health care fraud statutes that prohibit false statements and fraudulent and abusive claims made to any third-party payer.

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 health care programs, such as the Medicare and Medicaid programs. Depending on the circumstances, almost any financial interaction with a healthcare provider, patient or customer could implicate the Anti-Kickback Statute. Statutory exceptions and regulatory safe harbors protect certain interactions from prosecution if all specified requirements are met. However, most safe harbors or exceptions require, among other things, fair market value exchanges. The government can exercise enforcement discretion in taking action against unprotected activities. Many types of interactions in which we commonly engage, such as customer support services, could implicate the Anti-Kickback Statute, are not protected by a safe harbor or exception and have been the subject of government scrutiny and enforcement action when not structured appropriately. If the government determines that these activities are abusive, we could be subject to enforcement action. Other companies that manufacture wound care products have been subject to government scrutiny and enforcement action. For example, in early 2017, Shire Pharmaceuticals LLC and other subsidiaries of Shire plc agreed to pay $350 million to settle federal and state False Claims Act allegations that Shire and the company that Shire acquired in 2011, Advanced BioHealing, employed kickbacks and other unlawful methods to induce clinics and physicians to use or overuse its product Dermagraft (a product we subsequently acquired). Penalties for Anti-Kickback Statute violations may include both criminal penalties such as imprisonment and civil sanctions such as fines and possible exclusion from Medicare, Medicaid, and other federal health care programs. Exclusion would mean that our products would no longer be eligible for reimbursement under federal healthcare programs.

There are similar state false claims, anti-kickback, and insurance laws that apply to state-funded Medicaid and other health care programs as well as to commercial third-party payers. Insurance companies may also bring a private cause of action for treble damages against a manufacturer for a pattern of causing false claims to be filed under the federal Racketeer Influenced and Corrupt Organizations Act, or RICO. In addition, the Foreign Corrupt Practices Act, or FCPA, may be used to prosecute companies in the United States for arrangements with physicians, or other parties outside the United States if the physician or party is a government official of another country and the arrangement violates the laws of that country.

In addition to receiving scrutiny and providing potential grounds for action under the Anti-Kickback Statute, pricing, sales and marketing practices of medical device and pharmaceutical manufacturers are also subject to tightly focused regulation at the federal and state levels. Federal law and regulation, for example, establish pricing methodologies for government health insurance programs and require regular reporting of sales information to CMS in support of manufacturer price calculations. In recent years, the federal government and a growing number of states have introduced new drug price transparency requirements that can require extensive information disclosures to agencies or potential purchasers relating to drug price increases. Health care laws and regulations generally limit financial interactions between manufacturers and health care providers; require pharmaceutical and medical device companies to comply with voluntary compliance standards issued by industry associations and the relevant compliance guidance promulgated by the U.S. federal government; and/or require disclosure to the government and/or public of financial interactions (so-called "sunshine laws"). Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Manufacturers must adopt reasonable interpretations of requirements if there is ambiguity and those interpretations could be challenged. Given the lack of clarity in laws and their implementation, our activities could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

The healthcare laws and regulations applicable to us, including those described above, are subject to evolving interpretations and enforcement discretion. If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, we and our officers and employees could be subject to severe criminal and civil financial penalties, including, for example, exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid. Any failure to comply with laws and regulations relating to reimbursement and health care goods and services could adversely affect our reputation, business, financial condition and cash flows. To help ensure compliance with the laws and regulations governing the provision of health care goods and services, we have implemented a comprehensive compliance program based on the HHS Office of Inspector General's Seven Elements of an Effective Compliance Program. Despite our compliance program, we cannot be certain that we have always operated in full compliance with all applicable healthcare laws.

Our profitability and operations are subject to risks relating to changes in legislative, regulatory, and reimbursement policies and decisions as well as changes to private payer reimbursement coverage and payment decisions and policies. Implementation of further legislative or administrative reforms to reimbursement systems, or adverse decisions relating to our products by administrators of these systems in coverage or reimbursement, could significantly reduce reimbursement or result in the denial of coverage, which could have an impact on the acceptance of and demand for our products and the prices that our customers are willing to pay for them.

Seasonality

Revenues during our fourth quarter tend to be stronger than other quarters because many hospitals increase their purchases of our products during the fourth quarter to coincide with the end of their budget cycles in the United States. Satisfaction of deductibles through the course of the year also results in increased revenues later in the year. In general, our first quarter usually has lower revenues than the preceding fourth quarter, the second and third quarters have higher revenues than the first quarter, and the fourth quarter revenues are the highest in the year.

Human Capital Resources

As of December 31, 2023, we had approximately 862 employees worldwide. None of our employees are represented by a collective bargaining agreement. We have never experienced a work stoppage. We believe our employee relations are good.

In managing our business, we focus on a number of measures and objectives with respect to the attraction, development, and retention of our employees that we believe are important to our business, including diversity, communication, compensation, tenure, professional development, and health, well-being and safety:

• We are proud to be an equal opportunity employer. We seek to attract a diverse slate of candidates, including from historically underrepresented groups. We believe that diversity and inclusion in the workplace enhance employee engagement and stimulate innovation, and that people in diverse groups work better, share information more broadly and consider a wider range of views.

We pride ourselves on our diverse workforce, which we believe has been and will continue to be a major contributor to our growth and innovation, and intend to continue to make diversity and inclusion a focus of our efforts regarding our workforce.

• We aim to maintain an "open door" culture, and encourage employees to voice their concerns, questions, suggestions and comments. We strive to foster an atmosphere where employees openly share ideas and where people are treated with dignity and respect. Our goal is to provide a productive working environment based on mutual respect and the highest level of ethical and lawful conduct. We have also established a hotline for employees to report suspected violations of law and concerns related to accounting, auditing, compliance and ethical violations.

• We provide our employees a competitive wage and evaluate our compensation programs to ensure that our employees are paid fairly for the valuable work they are doing. We are also committed to achieving internal pay equity and rewarding outstanding performance. We offer our employees competitive benefits and are proud that we have not raised employee contributions to our healthcare benefits for 8 years running.

• We aim to foster a culture where learning is continuous, and we strive to promote from within. We believe in our people and their ability to accept new responsibilities and challenges and to grow with us to contribute to our success. Growth is fostered through professional development and learning programs as well as practical experience. Employees receive regular performance reviews to support their progress and development.

• We recognize the benefits of a healthy workforce and offer our employees the opportunity to participate in wellness activities and programs throughout the year. We also support the mental health of our employees by offering Mental Health and Wellness training for managers and employees. We also provide an employee assistance program for employees and their families that provides free counseling sessions and offers other resources for employees. Additionally, our healthcare benefit allows for reimbursement for fitness and weight loss programs.

• We prioritize the health and safety of our employees. Guided by an Environmental Health & Safety (EHS) manual that is regularly reviewed, we have a dedicated EHS team, who seek to prevent and reduce workplace risks and injuries through various programs, training, projects, services, and assistance, such as ergonomic evaluation, hazard reporting, risk assessment, and first aid training. We require all work-related injuries or illnesses to be reported. This information is reviewed bi-monthly by our EHS Team and Safety Committee for analysis and trending.

Available Information

Our Internet website address is http://www.organogenesis.com. Through our website, we make available, free of charge, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as well as proxy statements, and, from time to time, other documents as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or SEC. These SEC reports can be accessed through the "Investors" section of our website. The information found on our website is not part of this or any other report we file with or furnish to the SEC.

TEM 1A. RISK FACTORS

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our Class A common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Form 10-K and our other filings with the SEC before making an investment decision regarding our Class A common stock.

• Our operating results may fluctuate significantly as a result of a variety of factors, many of which are outside of our control.

• We have incurred significant losses in past years, and, notwithstanding our reported net income since the year ended December 31, 2020, we may incur losses in the future.

• Our success will depend in part on the extent to which coverage and adequate reimbursement for the costs of our products and related services will be available from government payers, private health insurers, and other third-party payers and we do not know whether such reimbursement will be available or, if such reimbursement is available, the rate at which it will be available. The rate of reimbursement and coverage for the use of our products has been and may continue to be unstable, unpredictable and subject to changes in government and private payer policies (including the adoption of new LCDs) that could adversely affect our business, results of operations, and financial condition. Currently, not all of our products are covered by all payers.

• If Medicare reproposes and finalizes a policy to stop making separate payment for skin substitutes under the Medicare Physician Fee Schedule in calendar year 2025 or thereafter, reimbursement for our products may not be adequate and our business may be negatively affected.

• If Medicare Part A/B Administrative Contractors finalize policies that do not cover some or all of our products, or limit the use of our products, our business could be adversely affected. In addition, MA plans typically follow Medicare Part A/B LCDs and would not cover the same products as Part A/B.

• Many existing and potential customers for our products are members of GPOs and/or IDNs, including accountable care organizations or public-based purchasing organizations, and our business is partly dependent on major contracts with these organizations. Cost-containment efforts of our customers, GPOs, IDNs, third-party payers, and governmental organizations could adversely affect our business, results of operations, and financial condition.

• Medicare, which is the major source of revenue for most of our customers, reimburses the same amounts for most of our products and the products of our competitors targeting the same indications in the hospital outpatient setting. Because in some sites of care the reimbursement amount is not based on the cost we charge our customers for our products or the cost our competitors charge for products targeting the same indication, our customers may elect to use products cheaper than ours in order to increase their margins, which could have a material adverse effect on our business, results of operations, and financial condition.

• As of January 1, 2022, we began reporting ASP for all our skin substitute products that are paid separately as biologics. The first such ASP report was made on April 30, 2022 for Q1 2022. If we do not report ASP or if we incorrectly report ASP, we may have to restate ASP for prior quarters or may face penalties, including statutory and regulatory sanctions.

• Section 90004 of the Infrastructure Investment and Jobs Act, enacted in November 2021, requires manufacturers to pay a refund to the federal government if more than a certain applicable percentage of their single-use product is not administered to a patient and is discarded ("wasted") by providers. Because there is a lack of consistency and uniformity in wound sizes, it is likely that some skin substitute product is discarded with every treatment. The rebate obligation took effect January 1, 2023 and CMS proposed a methodology to implement the rebate in the MPFS rulemaking. The applicable percentage is required to be at least 10 percent of total allowed charges for the drug in a given calendar quarter. CMS has the authority to increase the applicable percentage that applies to refunds for discarded product if there are "unique circumstances." We submitted comments on the proposal noting the unique circumstances related to skin substitutes and asking CMS to apply a higher percentage. In the 2023 MPFS final rule, published on November 1, 2022, CMS did not apply a higher applicable percentage to any products other than the hydrogel example they used in the proposed rule and stated that they plan to collect additional information about products that may have unique circumstances such that an increased applicable percentage (higher than 10 percent) would apply. CMS estimated the wastage percentage for three of our products - Apligraf, Dermagraft, and PuraPly - based on 2020 data. In the calendar year 2023 rulemaking, CMS exempted skin substitutes from this refund requirement. This exemption is based on the possibility that CMS will, in future rulemaking, stop paying for skin substitutes using the ASP methodology and bundle payment into the payment for the application of the product. However, because we do not know if or when CMS will begin bundled payment under the MPFS, this exemption may be rescinded and we may be required to refund payments made for the discarded portions of our products. If that happens, we do not know if the refund amounts calculated in 2023 will be similar to these estimates but if they are then we may owe rebates, which could be material, on these products and possibly other products. The total amount of any potential discarded product rebate liability is not known at this time.

• We have identified a material weakness in our internal control over financial reporting, and our management has concluded that our disclosure controls and procedures are not effective. While we have remediated one of the previously reported material weaknesses, we are continuing to work on remediating the remaining internal control deficiencies that collectively are aggregating to form the remaining material weakness in our internal controls over financial reporting that exists as of December 31, 2023. However, we cannot guarantee that additional material weaknesses or significant deficiencies will not occur in the future. If our internal control over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results or prevent fraud, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.

• We face significant and continuing competition, which could adversely affect our business, results of operations, and financial condition.

• Rapid technological change could cause our products to become obsolete, and if we do not enhance our product offerings through our research and development efforts, we may be unable to effectively compete.

• To be commercially successful, we must convince physicians that our products are safe and effective alternatives to existing treatments and that our products should be used in their procedures.

• Our failure to comply with regulatory obligations could result in negative effects on our business.

• The FDA may determine that certain of our products that are, or are derived from, human cells or tissues, such as Affinity, Novachor, and NuShield, do not qualify for regulation solely under Section 361 of the Public Health Services Act, or PHSA. To the extent that any of these products are deemed not to be HCT/Ps or Section 361 HCT/Ps, the FDA may require that we revise our labeling and marketing claims for these products or that we suspend sales of such products until FDA approval is obtained, which could adversely affect our business, results of operations, and financial condition.

• The FDA may determine that our suspension of NuCel and ReNu commercialization on May 31, 2021 was not conducted in a timely or otherwise proper manner. To the extent that our suspension of any of these products is determined not to comply with the 361 HCT/P Guidance, we may be subject to regulatory sanctions, which could adversely affect our business, results of operations, and financial condition.

• Because we depend upon a limited group of suppliers and manufacturers for our products, including Apligraf, Affinity, CYGNUS, Novachor, NuShield and PuraPly Antimicrobial products, we may incur significant product development costs or experience material delivery delays if there is an interruption in supply from any one of these suppliers or manufacturers, which could materially impact sales of our products.

• We are dependent on the proper functioning of our and third-party manufacturing facilities, our supply chain and our sales force, all of which could be negatively impacted by public health emergencies, including the global COVID-19 pandemic, or other factors, in a manner that could materially adversely affect our business, financial condition or results of operations.

• Uncertainty and adverse changes in the general economic conditions, including recent turmoil in the global banking system, may negatively affect our business.

• Significant disruptions of our information technology systems or breaches of information security could adversely affect our business, results of operations, and financial condition.

• Our patents and other intellectual property rights may not adequately protect our products.

• We engage in transactions with related parties and the transactions present possible conflicts of interest that could have an adverse effect on our business, results of operations, and financial condition.

• The Inflation Reduction Act of 2022 (IRA), signed into law on August 16, 2022, includes several provisions to lower prescription costs for people with Medicare and reduce health care spending by the federal government. Among these is a requirement for manufacturers to pay a rebate to the federal government if prices for single-source biologicals covered under Medicare Part B, such as our products, increase faster than the rate of inflation.

Risk Factors

You should carefully consider the risks and uncertainties described below, together with the information included elsewhere in this Annual Report on Form 10-K and other documents we file with the SEC. The risks and uncertainties described below are those that we have identified as material, but are not the only risks and uncertainties facing us. Our business is also subject to general risks and uncertainties that affect many other companies, such as overall U.S. and non-U.S. economic and industry conditions including a global economic slowdown, geopolitical events, changes in laws or accounting rules, fluctuations in interest and exchange rates, terrorism, international conflicts, major health concerns, natural disasters or other disruptions of expected economic and business conditions. Additional risks and uncertainties not currently known to us or that we currently believe are immaterial also may impair our business operations and liquidity.

Risks Related to Organogenesis and its business

Our operating results may fluctuate significantly as a result of a variety of factors, many of which are outside of our control.

We are subject to the following factors, among others, that may negatively affect our operating results:

• the announcement or introduction of new products by our competitors;

• failure of government healthcare programs and private health plans to cover our products or to timely and adequately reimburse the users of our products;

• the rate of reimbursement by government and private insurers for use of our products;

• any change in Medicare payment policy which provides a competitive advantage to our competitor's products;

- any change in government healthcare programs' and private health plans' policies regarding sales and reimbursement of durable medical equipment (DME), including a prohibition on physician-owned DME supplier entities;
- whether our products or our competitors' products are granted pass-through reimbursement status or included in the "bundled" reimbursement structure;
- our ability to upgrade and develop our systems and infrastructure to accommodate growth;
- our ability to attract and retain key personnel in a timely and cost-effective manner;
- our ability to offer our wound care and surgical products and supplies using our existing sales force and distribution network;
- 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;
- cost containment initiatives or policies developed by government and commercial payers 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;
- discovery of product defects during the manufacturing process;
- initiation of a government investigation into potential non-compliance with laws or regulations;
- issuance of government advisory opinions or program bulletins that could negatively affect one or more of our sales models;
- sanctions imposed by federal or state governments due to non-compliance with laws or regulations;
- recall of one or more of our products by the FDA due to noncompliance with FDA requirements; and
- general economic conditions as well as economic conditions specific to the healthcare industry.

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

We have identified a material weakness in our internal control over financial reporting, and our management has concluded that our disclosure controls and procedures are not effective.

A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. We did not design and maintain effective controls over information technology general controls and proper segregation of duties to support the proper initiation and recording of transactions and the resulting impact on business process controls and applications that rely on such data.

While we have remediated one of the previously reported material weaknesses, we are continuing to work on remediating the remaining internal control deficiencies that collectively aggregate to form the remaining material weakness in our internal controls over financial reporting that exists as of December 31, 2023. However, we cannot assure you that additional material weaknesses or significant deficiencies will not occur in the future. If our internal control over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results or prevent fraud, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.

Although we have made certain progress in remediating the remaining material weakness, we concluded that the material weakness described above continued to exist as of December 31, 2023. We have taken actions to remediate the deficiencies in our

internal controls over financial reporting and implemented additional processes and controls designed to address the underlying causes of the above-mentioned remaining material weakness. If we do not successfully remediate the material weakness described above, or if other material weaknesses or other deficiencies arise in the future, we may be unable to accurately report our financial results, which could cause our financial results to be materially misstated and require restatement.

Rapid technological change could cause our products to become obsolete, and if we do not enhance our product offerings through our research and development efforts, we may be unable to effectively compete.

The technologies underlying our products are subject to rapid and profound technological change. 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 services, products, or processes with significant advantages over the products, services, and processes that we offer or are seeking to develop. Any such occurrence could have a material and adverse effect on our business, results of operations, and financial condition.

We plan to enhance and broaden our product offerings in response to changing customer demands and competitive pressure and technologies, but we may not be successful. The success of any new product offering or enhancement to an existing product will depend on numerous factors, including our ability to:

- properly identify and anticipate physician and patient needs;
- develop and introduce new products or product enhancements in a timely manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the safety and efficacy of new products, including through the conduct of additional clinical trials;
- obtain the necessary regulatory clearances or approvals for new products or product enhancements;
- achieve adequate coverage and reimbursement for our products; and
- compete successfully against other skin substitutes and other modalities for treating wounds such as negative-pressure wound therapy and hyperbaric oxygen.

If we do not develop and, when necessary, obtain regulatory clearance or approval for new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our results of operations will suffer. 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, material or other innovation. In addition, even if we are able to successfully develop enhancements or new generations of our products, these enhancements or new generations of products may not be covered or reimbursed by government healthcare programs such as Medicare or private health plans, may not produce sales in excess of the costs of development and/or may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

To be commercially successful, we must convince physicians that our products are safe and effective alternatives to existing treatments and that our products should be used in their procedures.

We believe physicians 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 conventional methods. Physicians also are more interested in using cost-effective products and may practice in settings like Accountable Care Organizations, or ACOs, or Medical Homes, where they face considerable cost-containment pressure. In general, physicians may be slow to change their medical treatment practices and use of our products for the following reasons, among others:

- their lack of experience using 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;
- limited availability of coverage and/or reimbursement from third-party payers; and
- the time that must be dedicated to training.

The degree of market acceptance of our products will continue to depend on a number of factors, including:

- the 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;
- product labeling or product insert requirements of the FDA or other regulatory authorities, including any limitations or warnings contained in approved labeling;
- the cost of, and relative reimbursement rate for, using our products relative to the use of our competitors' products or alternative treatment modalities;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the quality of the service and support provided to our customers;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- our reputation and the reputation of the products;
- the shelf life of our products and our ability to manage the logistics of the end-user supply chain; and
- sufficient and readily accessible third-party insurance coverage and reimbursement.

In addition, we are currently conducting clinical studies for some of our products that were brought to market as 361 HCT/Ps to generate efficacy data in various clinical applications. Unfavorable results from these 361 HCT/P clinical trials such as lack of clinical efficacy or serious treatment-related side effects could negatively affect the use and adoption of our products by physicians and hospitals, thereby compromising our market acceptance.

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), physicians and hospitals may not use our products, which would significantly reduce our ability to achieve expected revenue and would prevent us from sustaining profitability.

In the course of conducting our business, we must comply with regulatory quality requirements, and adequately address quality issues that may arise with our products, as well as defects in third-party components included in our products. Although we have established internal procedures to minimize risks that may arise from quality issues, we may not be able to eliminate or mitigate these risks and quality issues may arise in which case we would be subject to liability. If the quality of our products does not meet the expectations of regulators, physicians, or patients, then we could be subject to regulatory sanctions and our brand and reputation could suffer and our business, results of operations, and financial condition could be adversely impacted.

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 tissue products. We are, and may in the future be, subject to product liability claims and lawsuits, including potential class actions or mass tort claims, alleging that our products have resulted or could result in an unsafe condition or injury. Product liability claims may be made by patients and their families, healthcare providers, or others selling our products. Defending a lawsuit, 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 defense 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.

Although we have product liability insurance that we believe is adequate, this insurance is subject to deductibles and coverage limitations and we may not be able to maintain this insurance. Also, it is possible that claims could exceed the limits of our coverage or be excluded from coverage under our policy. 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 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 cause our stock price to decline and, if our liability exceeds our insurance coverage, could adversely affect our business, results of operations, and financial condition.

Interruptions in the supply of our products or inventory loss may adversely affect our business, results of operations, and financial condition.

Our products are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials, and other production constraints. The complexity of these processes, as well as strict company and government standards for the manufacture and storage of our products, subjects us to production risks. In addition to ongoing production risks, process deviations or unanticipated effects of approved process changes may result in non-compliance with regulatory requirements including stability requirements or specifications. Most of our products must be stored and transported within a specified temperature range. For example, 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. These deviations may go undetected. The occurrence of actual or suspected production and distribution problems can lead to lost inventories, and in some cases recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can cause production delays and result in substantial additional expenses. Production of our Affinity product, for example, was suspended in the first quarter of 2019 due to production issues at one of our suppliers. As a result, we identified an alternate supplier, and were only able to resume commercial-scale production in the second quarter of 2020. Subsequently, we have added a second source to provide additional capacity and redundancy in supply. This disruption in supply resulted in reduced Affinity revenue. Although we were able to partially offset the lost Affinity revenue by increasing production of our other products, there can be no assurance that we will be able to do so in the event of any future suspensions or failures in the storage or manufacturing of Affinity, Dermagraft or our other products. Any future failure in the storage or manufacture of our products or loss in supply could result in a loss of our market share and negatively affect our revenues and operations.

As noted above, manufacturing of Dermagraft was suspended in the fourth quarter of 2021, and sales of Dermagraft were suspended in the second quarter of 2022. We plan to transition our Dermagraft manufacturing to a new manufacturing facility or engage a third-party manufacturer, which we expect will result in substantial long-term cost savings. In the period when Dermagraft is not available, we expect that customers will be willing to substitute Apligraf for Dermagraft and that the suspension of Dermagraft sales will not have a material impact on our net revenue. However, if we do not realize the expected substantial long-term cost savings or if customers are unwilling to substitute Apligraf for Dermagraft during the period in which Dermagraft is unavailable, it could have an adverse effect on our net revenue and results of operations.

Because we depend upon a limited group of suppliers and manufacturers for our products, including our Apligraf, Affinity, CYGNUS, Novachor, NuShield and PuraPly Antimicrobial products, we may incur significant product development costs and experience material delivery delays if we lose any significant supplier, which could materially impact sales of our products.

We obtain some of the components for our products from a limited group of suppliers. These suppliers must be able to provide us with these 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. Manufacturing disruptions experienced by our suppliers may jeopardize our supply of these components. Due to the stringent regulations and requirements of the FDA regarding the manufacture of our products, we may not be able to quickly establish additional or replacement sources for certain components or 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. A reduction or interruption in manufacturing (including the current suspension of Dermagraft manufacturing pending its transition to a new manufacturing facility or engagement of a third-party manufacturer), or an inability to secure alternative sources of raw materials or components, could have a material effect on our business, results of operations, and financial condition. In addition, one or more of our suppliers may refuse to extend us credit with respect to our purchasing or leasing 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, results of operations, and financial condition. Any casualty, natural disaster, other disruption of any of our sole-source suppliers' operations, or any unexpected loss of any existing exclusive supply contract, could have a material adverse effect on our business, results of operations, and financial condition.

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

Many of the products that we manufacture require that we obtain human tissue. The success of our business depends upon, among other factors, the availability of tissue from human donors. Any failure to obtain tissue from our sources will interfere with our ability to effectively meet the demand for our products incorporating human tissue. The processing of human tissue for our products is very labor-intensive and it is therefore difficult to maintain a steady supply stream. The availability of donated tissue could also be adversely impacted by regulatory changes, public opinion of the donor process as well as our own reputation in the industry. The challenges we may face in obtaining adequate supplies of human tissue involve several risks, including limited control over the availability, quality, and delivery schedules. In addition, any interruption 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 in a reasonable time period or on commercially reasonable terms, if at all, which would have a material adverse effect on our business, results of operations, and financial condition.

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

Our profitability is affected by the prices of the raw materials used in the manufacture of our products. These prices may fluctuate based on a number of factors beyond our control, including changes in supply and demand, general economic conditions, labor costs, fuel-related 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 payers, we may be unable to pass along cost increases for key components or raw materials through higher prices to our customers. If the cost of key components or raw materials increases, and we are unable fully to 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, due to inflation or otherwise, that cannot be recovered through productivity gains, price increases or other methods could adversely affect our business, results of operations, and financial condition.

We continue to invest significant capital to maximize our sales and marketing infrastructure, and there can be no assurance that these efforts will result in significant increases in sales.

We are committed to maximizing our internal sales and marketing capabilities, including by optimizing our sales force to further support the marketing and sales of the products acquired in connection with our 2017 acquisition of NuTech Medical and our 2020 acquisition of CPN Biosciences. As a result, we continue to invest in sales and marketing resources for our products to allow us to reach new customers and potentially increase sales. These expenses impact our operating results, and there can be no assurance that we will continue to be successful in significantly increasing the sales of our products.

The impairment or termination of our relationships with independent sales agencies, whom we do not control, could materially and adversely affect our ability to generate revenues and profits. We intend to develop additional relationships with independent sales agencies in order to increase revenue from certain of our products; our inability to do so may prevent us from increasing sales.

We derive a portion of our revenues through our relationships with independent sales agencies. The impairment or termination of these relationships for any reason could materially and adversely affect our ability to generate revenues and profits. Because the independent sales agency often controls the customer relationships within its territory, there is a risk that if our relationship with the independent sales agency ends, our relationship with the customer will be lost. Also, because we do not control an independent sales agency's field sales agents, there is a risk we will be unable to ensure that our sales processes, regulatory compliance, and other priorities will be consistently communicated and executed by the distributor. If we fail to maintain relationships with our key independent sales agencies, or fail to ensure that our independent sales agencies adhere to our sales processes, regulatory compliance, and other priorities, this could have an adverse effect on our business, results of operations, and financial condition. We may have liability for the actions of independent sales agencies in marketing our products and our lack of control over their activities impedes our ability to prevent, detect or address such non-compliance.

We intend to develop relationships and arrangements with additional independent sales agencies in order to increase our sales with respect to certain of our products. However, we may fail to develop such relationships, in which case we may not be able to increase our sales. Our success is partially dependent upon our ability to retain and motivate our independent sales agencies and their representatives to sell our products in certain territories. They may not be successful in implementing our marketing plans. Some of our independent sales agencies may not sell our products exclusively and may offer similar products from other companies. Our independent sales agencies may terminate their contracts with us, may devote insufficient sales efforts to our products, or may focus their sales efforts on other products that produce greater commissions for them, which could have an adverse effect on our business, results of operations, and financial condition. We also may not be able to find additional independent sales agencies who will agree to market and/or distribute those products on commercially reasonable terms, if at all. If we are unable to establish new independent sales agency relationships or renew current sales agency agreements on commercially acceptable terms, our business, results of operations, and financial condition could be materially and adversely affected. In addition, because we do not control these independent sales agencies as closely as our employees, while we may take steps to mitigate the risks associated with noncompliance by independent sales agencies, there remains a risk they do not comply with regulatory requirements or our requirements or our policies which could also adversely affect our business.

We will need to continue to expand our organization, and managing growth may be more difficult than expected.

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 management, operational and financial resources. To manage the expected growth of our operations, 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.

In addition to expanding our organization, we are expanding our manufacturing capabilities, which requires significant capital expenditures. If these capital expenditures are higher than expected, it may adversely affect our financial condition and capital resources. In addition, if the expansion of our manufacturing facilities is delayed, for regulatory or other reasons, it may limit our ability to expand the size of our organization and to meet our corporate goals. Even if we are able to expand our manufacturing facilities as we plan, we may not realize the full expected benefit of our investment.

We may expand our business through acquisitions, similar to our acquisitions of NuTech Medical and CPN Biosciences, licenses, investments, and other commercial arrangements in other companies or technologies. Such acquisitions or commercial arrangements may entail significant risks.

We periodically evaluate strategic opportunities to acquire companies, divisions, technologies, products, and rights through licenses, distribution agreements, investments, and outright acquisitions to grow our business, such as our acquisitions of NuTech Medical and CPN Biosciences and our License and Manufacturing Agreement with Vivex Biologics, Inc. In connection with one or more of those transactions, we may:

- issue additional equity securities that would dilute our stockholders' value;
- use cash that we may need in the future to operate our business;
- incur debt that could have terms unfavorable to us or that we might be unable to repay;
- structure the transaction in a manner that has unfavorable tax consequences, such as a stock purchase that does not permit a step-up in the tax basis for the assets acquired;
- be unable to realize the anticipated benefits, such as increased revenues, cost savings, economies of scale or synergies from additional sales of existing or newly acquired products;
- be unable to successfully integrate, operate, maintain, and manage our newly acquired operations;
- be unable to sell all of the products we are required to purchase under the Vivex agreement;
- divert management's attention from the existing business to integrate, operate, maintain, and manage our newly acquired operations and personnel;
- acquire unknown liabilities that could subject us to government investigations and/or litigation or other actions that make it impossible to realize the anticipated benefits of the transaction;
- be unable to secure the services of key employees related to the acquisition; and
- be unable to succeed in the marketplace with the acquisition.

Any of these items could materially and adversely affect our revenues, financial condition, and profitability. Our November 2023 license and manufacturing agreement with Vivex to sell their Dual and Matrix products expanded our product Advanced Wound Care and Surgical & Sports Medicine product portfolio. However, we are required to pay a royalty on the net sales of the licensed products during the royalty term, and to meet certain minimum purchase commitments. If we are not able to sell sufficient quantities of the licensed products, we may not be able to sell all of the products we are required to purchase under the agreement, achieve economies of scale for this product line, or in general realize the full anticipated benefit of our investment in the arrangement with Vivex. Business acquisitions also involve the risk of unknown liabilities associated with the acquired business, which could be material. Our acquisition of NuTech Medical and CPN Biosciences expanded our wound care portfolio and our acquisition of NuTech Medical broadened our addressable market to include the Surgical & Sports Medicine market. We may not realize the increased revenues, cost savings, and synergies that we anticipate from this acquisition in the near term or at all due to many factors, including delays in the integration process, an inability to successfully penetrate the amniotic category of the wound care market or an inability to obtain necessary regulatory approvals. Additional liabilities related to acquisitions could include a lack of compliance with government regulations that could subject us to investigation and civil and criminal sanctions. 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 realize the anticipated benefits of an acquisition could materially and adversely affect our business and we may lose our entire investment or be unable to recover our initial investment, which could include the cost of acquiring licenses or distribution rights, acquiring products, purchasing initial inventory, or investments in early-stage companies. Inability to recover our investment, or any write off of such investment, associated goodwill, or assets, could have a material and adverse effect on our business, results of operations, and financial condition.

We have incurred significant losses in past years and, notwithstanding our reported net income for the fiscal years since the year ended December 31, 2020, we may incur losses in the future.

To date, we have financed our operations primarily through debt and equity financings, and, with the exception of the fiscal years since the year ended December 31, 2020, we have incurred losses from operations in many years since our inception. In the years ended December 31, 2023, 2022, and 2021, we reported net income of $4.9 million, $15.5 million and $94.2 million, respectively, As of December 31, 2023, we had an accumulated deficit of $41.0 million. Our prior losses, and the possibility of potential future losses, may have an adverse effect on our business, results of operations, and financial condition.

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

From time to time, we may implement or may acquire new lines of business, such as our Surgical & Sports Medicine products that were acquired in connection with our acquisition of NuTech Medical, or we may offer new products and services within existing lines of business. 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 marketing 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 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, results of operations, and financial condition.

Significant disruptions of information technology systems or breaches of information security could adversely affect our business, results of operations, and financial condition.

Our business depends on the availability, reliability, and security of our information systems, networks, data, and intellectual property. In the ordinary course of business, we collect, store, and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property). Any disruption, compromise, or breach of our systems or data due to a cybersecurity threat or incident could adversely affect our operations, customer service, product development, sales, competitive position, and privacy and confidentiality of our stakeholders. Such a breach could expose us to business interruption, lost revenue, ransom payments, remediation costs, liabilities to affected parties, cybersecurity protection costs, lost assets, litigation, regulatory scrutiny and actions, reputational harm, customer dissatisfaction, harm to our vendor relationships, or loss of market share.

Cyberattacks have become increasingly more prevalent and much harder to detect, defend against or prevent. As the frequency of cyberattacks and resulting breaches reported by other businesses and governments increases, we expect to continue to devote significant resources to improve and maintain our information technology (IT) infrastructure. We have incurred and may in the future incur significant costs in order to implement, maintain and/or update security systems we believe are necessary to protect our IT infrastructure. As the techniques used to obtain unauthorized access or to sabotage systems change frequently and are often not recognized until launched against a target, we may be unable to anticipate these techniques or to implement adequate preventive measures. A breakdown in existing controls and procedures around our cyber-security environment may prevent us from detecting, reporting or responding to cyber incidents in a timely manner and could have a material adverse effect on our financial position and

value of our stock. We cannot guarantee that our implemented processes for IT and risk mitigation measures will be effective for IT systems under our control.

We also have outsourced significant elements of our operations to third parties, including significant elements of our information technology infrastructure and, as a result, we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our information technology and information security systems, and those of our third-party vendors with whom we contract (and the large amounts of confidential information that is present on them), make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from malicious attacks by third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. While we have invested significantly in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. For example, in August 2020, our information technology (IT) systems were exposed to a ransomware attack, which partially impaired certain IT systems for a short period of time. We finished investigating the incident, together with legal counsel and other incident response professionals. We did not experience any material losses related to the ransomware attack and were able to recover all data quickly, with only a minimal and temporary interruption to our business. While we have implemented measures to protect our data security and information technology systems, such measures may not prevent these events. Although we have cyber-insurance coverage that may cover certain events described above, this insurance is subject to deductibles and coverage limitations and we may not be able to maintain this insurance. Also, it is possible that claims could exceed the limits of our coverage.

If a breach of our measures protecting personal data covered by HIPAA, the HITECH Act, or the CCPA occurs, we may incur significant liabilities.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the HITECH Act, and the regulations that have been issued under it, impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of protected health information. The requirements and restrictions apply to "covered entities" (which include health care providers and insurers) as well as to their business associates that receive protected health information from them in order to provide services to or perform certain activities on their behalf. The statute and regulations also impose notification obligations on covered entities and their business associates in the event of a breach of the privacy or security of protected health information. We occasionally receive protected health information from our customers in the course of our business. As such, we believe that we are business associates and therefore subject to HIPAA’s requirements and restrictions with respect to handling such protected health information, and have executed business associate agreements with certain customers.

In addition, California has enacted the California Consumer Privacy Act (CCPA), which came into effect on January 1, 2020. Pursuant to the CCPA, certain businesses are required, among other things, to make certain enhanced disclosures related to California residents regarding the use or disclosure of their personal information, allow California residents to opt-out of certain uses and disclosures of their personal information without penalty, provide Californians with other choices related to personal data in our possession, and obtain opt-in consent before engaging in certain uses of personal information relating to Californians under the age of 16. The California Attorney General may seek substantial monetary penalties and injunctive relief in the event of our non-compliance with the CCPA. The CCPA also allows for private lawsuits from Californians in the event of certain data breaches. Aspects of the CCPA remain uncertain, and we may be required to make modifications to our policies or practices in order to comply. Aside from California, Texas and several other major states impose rigorous local medical privacy requirements.

It is possible the data protection laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country and state to state, and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Further, compliance with data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. We can provide no assurance that we are or will remain in compliance with diverse privacy and security requirements in all of the jurisdictions in which we do business. If we fail to comply or are deemed to have failed to comply with applicable privacy protection laws and regulations such failure could result in government enforcement actions and create liability for us, which could include substantial civil and/or criminal penalties, as well as private litigation and/or adverse publicity that could negatively affect our operating results and business.

We engage in transactions with related parties and such transactions present possible conflicts of interest that could have an adverse effect on our business, results of operations, and financial condition.

We have entered into a significant number of transactions with related parties. Related party transactions create the possibility of conflicts of interest with regard to our management, including that:

- we may enter into contracts between us, on the one hand, and related parties, on the other, that are not as a result of arm's-length transactions;
- our executive officers and directors that hold positions of responsibility with related parties may be aware of certain business opportunities that are appropriate for presentation to us as well as to such other related parties and may present such business opportunities to such other parties; and
- our executive officers and directors that hold positions of responsibility with related parties may have significant duties with, and spend significant time serving, other entities and may have conflicts of interest in allocating time.

Such conflicts could cause an executive officer or a director to seek to advance his or her economic interests or the economic interests of certain related parties above ours. Conversely, we may not be able to enter into transactions with third parties on terms as favorable as the terms of existing transactions with related parties. Further, the appearance of conflicts of interest created by related party transactions could impair the confidence of our investors. It is possible that a conflict of interest could have a material adverse effect on our business, results of operations, and financial condition.

Our financial performance may be adversely affected by medical device tax provisions in healthcare reform laws.

The Patient Protection and Affordable Care Act (the PPACA) imposed, among other things, an excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States. Under these provisions, the Congressional Research Service predicted that the total cost to the medical device industry may be up to $20 billion over a decade. The Internal Revenue Service issued final regulations implementing the tax in December 2012, which required, among other things, bi-monthly payments and quarterly reporting. The Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed into law in December 2015, included a two-year moratorium on the medical device excise tax. A second two-year moratorium on the medical device excise tax was signed into law in January 2018 as part of the Extension of Continuing Appropriations Act, 2018 (Pub. L. 115-120), extending the moratorium through December 31, 2019. On December 20, 2019, President Trump signed into law a permanent repeal of the medical device tax under the PPACA, but there is no guarantee that Congress will not reverse course in the future. If such an excise tax on sales of our products in the United States is enacted, it could have a material adverse effect on our business, results of operations, and financial condition.

We could incur asset impairment charges related to certain leasehold improvements and construction in progress, which could adversely affect our business, results of operations, and financial condition.

Our long-term assets include property and equipment of $116.2 million and $102.5 million, of which $60.8 million and $37.6 million represents the value of improvements to our leased assets, and of which $59.1 million and $65.6 million represents construction in progress (each as described more fully in Note 8, *Property and Equipment, Net*, to our audited consolidated financial statements included in this Annual Report on Form 10-K), as of December 31, 2023 and 2022, respectively. We review our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If an asset is determined to be impaired, the asset is written down to fair value, which is determined based on appraised value. Any such impairment could result in a non-cash charge equal to the full value of these improvements. During the years ended December 31, 2023, 2022, and 2021, we did not recognize an impairment charge with respect to our long-lived assets. Changes in our assumptions with respect to our expected use of these assets may result in an impairment charge in the future, which could adversely affect our business, results of operations, and financial condition.

We may be required to record a significant charge to earnings if our goodwill and other amortizable intangible assets, or other assets become impaired.

We are required under generally accepted accounting principles in the United States (GAAP) to test goodwill for impairment at least annually and to review our goodwill, amortizable intangible assets, and other assets acquired through merger and acquisition activity, for impairment when events or changes in circumstance indicate the carrying value may not be recoverable. Factors that could lead to impairment of goodwill, amortizable intangible assets, and other assets acquired via acquisitions include significant adverse changes in the business climate and actual or projected operating results (affecting our company as a whole or affecting any particular segment) and declines in the financial condition of our business. We may be required in the future to record additional charges to earnings if our goodwill, amortizable intangible assets, or other investments become impaired. Any such charge would adversely impact our financial results.

Our ability to use our net operating loss carryforwards may be subject to certain limitations.

As of December 31, 2023, we had approximately $11.7 million of federal net operating loss carry-forwards available for the reduction of future years' federal taxable income, all of which can be carried forward indefinitely. Under the Internal Revenue Code of 1986, as amended, or the Code, the deductibility of the net operating loss-carry-forward as of December 31, 2023 and all future net operating loss-carry-forwards is limited to 80% of taxable income, limiting or delaying in part the use of net operating loss-carry-forwards. As of December 31, 2023, we also had state net operating loss carry-forwards of approximately $9.4 million expiring from the year ended December 31, 2031 through 2038. It is uncertain whether and to what extent applicable state tax laws will conform to the federal rule, though we are already subject to limitations in net operating loss utilization in certain states.

In addition, our ability to utilize our federal net operating loss carryforwards may be limited under Section 382 of the Code. In the event of an "ownership change", Section 382 imposes an annual limitation on the amount of post-ownership change taxable income that may be offset with pre-ownership change net operating losses of the loss corporation experiencing the ownership change. An "ownership change" is defined by Section 382 as a cumulative change in ownership of our company of more than 50% within a three-year period. As of December 31, 2021, we performed a study and determined that there is no limitation on our federal net operating losses. Current or future changes in our stock ownership may trigger an "ownership change," some of which may be outside our control. Accordingly, our ability to utilize our net operating loss carryforwards to offset federal taxable income, if any, could be limited by Section 382, which could potentially result in increased future tax liability to us.

We are dependent on the proper functioning of our and third-party manufacturing facilities, our supply chain, and our sales force, all of which could be negatively impacted by public health emergencies, including the COVID-19 pandemic, or other factors, in a manner that could materially adversely affect our business, financial condition or results of operations.

We manufacture our non-placental-based products and use third-party manufacturers for our placental-based products and we use third-party raw material suppliers to support our internal manufacturing processes. If our manufacturing capabilities or the manufacturing capabilities of our suppliers are impacted as a result of a public health emergency, including a resurgence of the COVID-19 pandemic, it may not be possible for us to timely manufacture relevant products at the required levels or at all. While the COVID-19 pandemic has not had a material adverse effect on our business to date, a reduction or interruption in any of our manufacturing processes as a result of a public health emergency in the future (including a resurgence of the COVID-19 pandemic) could have a material adverse effect on our business, results of operations, financial condition and cash flows.

We also may be unable to obtain the raw materials necessary to support our internal manufacturing processes due to the additional constraints on suppliers. The manufacture of our products is dependent on the availability of sufficient quantities of source tissue, which is the primary component of our products. Source tissue includes donated human tissue, porcine tissue, and bovine tissue. We acquire donated human tissue directly through institutional review board-approved protocols at multiple hospitals, as well as through tissue procurement firms engaged by us or by our contract manufacturers. Any failure to obtain tissue from our sources, including any failures related to public health emergencies, like the COVID-19 pandemic, will interfere with our ability to effectively meet the demand for our products. Any interruption in the supply of source tissue 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 in a reasonable time period or on commercially reasonable terms, if at all, which would have a material adverse effect on our business, results of operations, and financial condition.

Our current Advanced Wound Care portfolio is sold throughout the United States via an experienced direct sales force, which focuses its efforts on wound care in various sites of care. We use a mix of direct sales representatives and independent agencies to service the Surgical & Sports Medicine market. These sales representatives are supported by teams of professionals focused on sales management, sales operations and effectiveness, ongoing training, analytics and marketing. Our direct sales force functions by meeting in person with physicians and health care providers to discuss our products. Public health emergencies, like COVID-19, may negatively affect demand for our products by limiting the ability of our sales personnel to maintain their customary contacts with physicians and health care providers. In such case, we cannot assure you that our direct sales representatives or independent agencies will increase or maintain our current sales levels, which could have a material adverse effect on our business, results of operations, financial condition and cash flows. We may also experience significant and unpredictable reductions in demand for

certain of our products if patients are unable to access certain advanced therapies due to stay-at-home orders or other governmental actions taken to address a public health emergency.

Risks Related to Regulation of Our Products and Other Government Regulations

Our products are subject to the Infrastructure Investment and Jobs Act and rebate obligations that took effect on January 1, 2023, and we may owe rebates, which could be material, on our Apligraf, Dermagraft, and PuraPly products and possibly other products.

Section 90004 of the Infrastructure Investment and Jobs Act, enacted in November 2021, requires manufacturers to pay a refund to the federal government if more than a certain applicable percentage of their single-use product is not administered to a patient and is discarded ("wasted") by providers. Because there is a lack of consistency and uniformity in wound sizes, it is likely that some skin substitute product is discarded with every treatment. The rebate obligation took effect January 1, 2023, and CMS proposed a methodology to implement the rebate in the MPFS rulemaking. The applicable percentage is required to be at least 10 percent of total allowed charges for the drug in a given calendar quarter. CMS has the authority to increase the applicable percentage that applies to refunds for discarded product if there are "unique circumstances." We submitted comments on the proposal noting the unique circumstances related to skin substitutes and asking CMS to apply a higher percentage. In the 2023 MPFS final rule, published on November 1, 2022, CMS did not apply a higher applicable percentage to any products other than the hydrogel example they used in the proposed rule and stated that they plan to collect additional information about products that may have unique circumstances such that an increased applicable percentage (higher than 10 percent) would apply. CMS estimated the wastage percentage for three of our products - Apligraf, Dermagraft, and PuraPly - based on 2020 data. In the calendar year 2023 rulemaking, CMS exempted skin substitutes from this refund requirement. This exemption is based on the possibility that CMS will, in future rulemaking, stop paying for skin substitutes using the ASP methodology and bundle payment into the payment for the application of the product. However, because we do not know if or when CMS will begin bundled payment under the MPFS, this exemption may be rescinded and we may be required to refund payments made for the discarded portions of our products. If that happens, we do not know if the refund amounts calculated in 2023 will be similar to these estimates but if they are then we may owe rebates, which could be material, on these products and possibly other products. The total amount of any potential discarded product rebate liability is not known at this time.

We may encounter substantial delays or difficulties in our clinical trials.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates. Clinical testing is expensive, time-consuming and uncertain as to the outcome. We have limited experience with clinical trials. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- the FDA may require additional clinical trials in connection with the approval of product candidates;
- delays in reaching a consensus with the FDA or other regulatory authorities on trial design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in opening clinical trial sites or obtaining required IRB or independent ethics committee approval at each clinical trial site;
- our decision or the requirement of regulators or IRBs to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements, a finding that the participants are being exposed to unacceptable health risks, or the imposition of a clinical hold as a result of a serious adverse event or after an inspection of our clinical trial operations or clinical trial sites;
- delays in recruiting suitable patients to participate in our future clinical trials, including, but not limited to challenges associated with any resurgence of COVID-19;
- failure by us, any CROs we engage or any other third parties to adhere to clinical trial or regulatory requirements;
- failure by us, any CROs we engage or any other third parties to perform in accordance with Good Clinical Practice, or GCP, cGMPs, or applicable regulatory guidelines in the United States and other international markets;
- failure by physicians to adhere to delivery protocols leading to variable results;

- delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical trial sites, including delays by third parties with whom we have contracted to perform certain of those functions due to COVID-19 or other reasons;
- insufficient or inadequate supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates;
- delays in having patients complete participation in a clinical trial or return for post-treatment follow-up;
- clinical trial sites or patients dropping out of a clinical trial at a rate higher than we anticipate;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- receipt of negative or inconclusive clinical trial results;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- occurrence of serious adverse events in clinical trials of the same class of agents conducted by other sponsors; and
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;

ReNu is in Phase 3 clinical development for the management of symptoms associated with knee OA. Our anticipated timeline for these and other trials and studies on our clinical trial candidates may be subject to delays due to factors such as those discussed above.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory, development and commercialization milestones and royalties. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

Success in research and preclinical studies or early clinical trial results may not be indicative of results obtained in later trials. Likewise, preliminary, initial or interim data from clinical trials should be considered carefully and with caution since the final data may be materially different from the preliminary, initial or interim data, particularly as more patient data become available.

Results from preclinical studies or early clinical trials, including feasibility studies, or earlier conducted clinical trials are not necessarily predictive of future clinical trial results, and interim results of a clinical trial are not necessarily indicative of final results. Our clinical trial candidates, including ReNu, may fail to show the desired safety and efficacy in clinical development despite demonstrating positive results in preclinical studies or having successfully advanced through initial or earlier clinical trials or preliminary stages of clinical trials. From time to time, we have and may in the future publish or report preliminary, initial or interim data. Preliminary, initial or interim data from our clinical trials and those of our partners may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and/or more patient data become available. In this regard, such data may show initial evidence of clinical benefit, but as patients continue to be followed and more patient data becomes available, there is a risk that any therapeutic effects will not be durable in patients and/or will decrease over time, or cease entirely. Preliminary, initial or interim data also remain subject to audit and verification procedures that may result in the final data being materially different from such preliminary, initial or interim data. As a result, preliminary, initial or interim data should be considered carefully and with caution until the final data are available.

There is no guarantee that any of our clinical trials will be successful. In addition, there is a high failure rate for drugs, biologic products and cell therapies proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. Any such setbacks could adversely affect our business, financial condition, results of operations and prospects.

Obtaining the necessary regulatory approvals or clearances for certain of our products will be expensive and time-consuming and may impede our ability to fully exploit our technologies or otherwise limit our ability to meet other business objectives.

As biological products and medical devices, many of the products that we market require regulatory approvals or clearances from the FDA, or from similar regulatory authorities outside of the United States, before they may legally be distributed in commerce. In particular, such products may require FDA approval of Biologics License Applications, or BLAs, under Section 351 of the PHSA, Premarket Approval, or PMA, submissions under Section 515 of the Federal Food, Drug, and Cosmetic Act, or FDCA, or may require clearance under Section 510(k) of the FDCA. Although we believe that we have all necessary regulatory approvals or clearances legally required for the products that we currently market, the introduction of new or modified products, or new or modified FDA regulatory rules, may require us to secure new approvals or clearances. Additionally, the FDA may take the position that some of the products that we currently market without premarket approval or clearance in fact require such approval or clearance. The process of obtaining an approved BLA or PMA requires the expenditure of substantial time, effort and financial resources and may take years to complete. Although obtaining clearance under section 510(k) is somewhat less burdensome, it is also associated with significant costs and resource commitments. The fee for filing a BLA, PMA or 510(k) notification, and the annual user fees for any establishment that manufactures biologics or medical devices, as well as product fees applicable to each approved product are substantial.

In January 2021, we announced that the first patient was enrolled in the pivotal Phase 3 clinical trial evaluating the safety and efficacy of ReNu for the management of symptoms associated with knee OA. There are significant costs associated with conducting clinical trials to support approvals that cannot necessarily be estimated with any accuracy until investigational plans have been developed. Moreover, data obtained from clinical activities may show a lack of safety or efficacy or may be inconclusive or susceptible to varying interpretations, any of which could delay, limit or prevent regulatory approval. Failure or delay can occur at any time during the clinical trial process. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. Even product candidates in later stages of clinical trials may fail to show the required safety profile or meet the efficacy endpoints despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. We cannot be certain that we will not face similar setbacks. Even with positive clinical trial results, there may be other barriers to approval or clearance, and the FDA may not grant approval or clearance on a timely basis, or at all. Even if the FDA clears or approves our products, the clinical data submitted to the FDA may not be sufficient for payers to cover and/or adequately reimburse our customers for use of our products. Additionally, the FDA may limit the indications for use in an approval or clearance, or place other conditions on an approval, that could restrict the commercial application of the products.

Regenerative medicine advanced therapy, or RMAT, designation for our product candidates may not lead to faster development or regulatory processes nor does it increase the likelihood that such product candidates will receive marketing approval.

RMAT was introduced as a new designation under the 21st Century Cures Act for the development and review of certain regenerative medicine therapies. To receive RMAT designation, a regenerative medicine product candidate must be intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition with preliminary clinical evidence indicating that the drug has the potential to address the unmet medical needs. RMAT designation does not require evidence to indicate that the drug may offer a substantial improvement over available therapies, as breakthrough designation requires.

An RMAT product candidate receives intensive guidance on an efficient product development program; involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review; and a rolling review. Regenerative medicine therapies that qualify for RMAT designation may also qualify for other FDA expedited programs, including fast track designation, breakthrough therapy designation, accelerated approval and priority review designation, if they meet the criteria for such programs. However, RMAT designation does not assure that marketing approval will be granted and, if granted, that the approval process would be any faster than it would have otherwise been.

In January 2021, we announced RMAT designation for ReNu for the management of symptoms associated with knee OA. However, there is no guarantee that the receipt of RMAT designation will result in a faster development process, review or approval for ReNu for the management of symptoms associated with knee OA or increase the likelihood that ReNu will be granted marketing approval for the management of symptoms associated with knee OA. Likewise, any future RMAT designation or other expedited review status such as breakthrough therapy designation for any of our other product candidates neither guarantees a faster development process, review or approval nor improves the likelihood of the grant of marketing approval by FDA for any such product candidate compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may withdraw any RMAT or other expedited review status at any time. We may seek RMAT or breakthrough therapy designation for our other product candidates, but the FDA may not grant this status to any such product candidates.

We may seek fast track designation by the FDA for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process.

If a product is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet needs for this condition, the treatment sponsor may apply for FDA fast track designation. Even if we receive fast track designation, fast track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular time frame. We may not experience a faster development, regulatory review or approval process with fast track designation compared to conventional FDA procedures. Additionally, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

A breakthrough therapy designation by the FDA for a product candidate may not lead to a faster development or regulatory review or approval process, and it would not increase the likelihood that the product candidate will receive marketing approval.

We may seek a breakthrough therapy designation for one or more product candidates. A breakthrough therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the new drug application.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened.

We must comply with applicable post-marketing regulatory obligations, which could include obtaining new regulatory approvals or clearances.

Following approval or clearance, some types of changes to the approved or cleared product, such as adding new indications or additional labeling claims or introducing manufacturing changes, are subject to FDA review and approval, which may require further nonclinical or clinical testing. The costs and other resource burdens associated with obtaining new regulatory approvals or clearances for existing or future products may limit the resources available to us to fully exploit our technologies or may otherwise limit our ability to carry out other business activities. Depending on the nature of the change, we may determine that the change may be carried out without obtaining premarket approval or clearance. The FDA or another regulatory body could disagree with our conclusion and require such premarket approval or clearance, which would disrupt the marketing of these products, potentially expose us to regulatory sanctions, and have a material adverse effect on our business, financial condition and results of operations.

The FDA may determine that certain of our products that are, or are derived from, human cells or tissues, such as Affinity, Novachor, and NuShield, do not qualify for regulation solely under Section 361 of the Public Health Services Act, or PHSA, and may require that we revise our labeling and marketing claims for these products or that we suspend sales of such products until FDA approval is obtained, which could adversely affect our business, results of operations, and financial condition.

Certain of the products that we manufacture, process and distribute are, or are derived from, human cells or tissues, including amniotic tissue. The FDA has specific regulations governing human cells, tissues and cellular and tissue-based products, or HCT/Ps. In particular, HCT/Ps that meet certain criteria set forth in the FDA's regulations at 21 C.F.R. § 1271.10 are regulated solely under Section 361 of the PHSA, so-called "Section 361 HCT/Ps", and are not subject to any premarket clearance or approval requirements. They are also subject to less stringent post-market regulatory requirements than products regulated under Section 351 of the PHSA and/or under Sections 505, 510 or 515 of the FDCA. The Company has believed that certain of our HCT/Ps, including our products derived from amniotic membrane, qualify for regulation as Section 361 HCT/Ps. However, the regulatory classification of an HCT/P as a Section 361 HCT/P depends in part on the purposes for which the product is intended and in part on the processing to which an HCT/P is subject. On November 16, 2017, the FDA issued a final guidance document entitled, "Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use", or 361 HCT/P Guidance, which provides FDA's current thinking on how to apply the existing regulatory criteria for regulation as a Section 361

HCT/P. These include, in addition to other requirements, requirements that an HCT/P be both minimally manipulated and intended for homologous use. In general, "minimal manipulation" is a standard referring to the degree to which the original characteristics of an HCT/P have been altered by processing and "homologous use" refers to the requirement that an HCT/P perform the same basic function in the donor as in the recipient. Any action by the FDA to apply the principles set forth in the 361 HCT/P Guidance to the HCT/Ps that we distribute could have adverse consequences for us and make it more difficult or expensive for us to conduct our business.

In light of the 361 HCT/P Guidance, our labeling and marketing claims for our placental-based membrane products, including our Affinity, NuShield, and Novachor products, clarify that they are intended as protective barriers, and thus meet the homologous use requirement to qualify as Section 361 HCT/Ps. However, the FDA could disagree with our conclusion and require premarket approval or clearance for Affinity, NuShield, or any placental-based sheet product we market, which would disrupt the marketing of these products, potentially expose us to regulatory sanctions, and have a material adverse effect on our business, financial condition and results of operations. Further, we believe it is necessary to obtain FDA approval of a BLA for NuCel and ReNu because those products may be deemed to be more than minimally manipulated, not for homologous use, or otherwise not regulated as Section 361 HCT/Ps. We continue to conduct clinical studies of ReNu to support FDA approval of a BLA for the management of symptoms associated with knee OA and, based on favorable feasibility studies that are subject to further evaluation, we believe ReNu has potential as a treatment for additional OA and tissue regeneration applications. We have discontinued clinical development of NuCel. If we obtain BLA approval for ReNu or NuCel, compliance with applicable post-market regulatory requirements will involve significant time and substantial costs. Even for those products that remain regulated as Section 361 HCT/Ps, increasing regulatory scrutiny within the industry in which we operate could lead to heightened requirements, compliance with which could be costly. The costs and other resource burdens associated with any of these regulatory outcomes may limit the resources available to us to fully exploit our technologies or may otherwise limit our ability to carry out other business activities.

The 361 HCT/P Guidance originally indicated that the FDA was providing a 36-month enforcement grace period to allow time for distributors of HCT/Ps to make any regulatory submissions and obtain any premarket approvals necessary to comply with the guidance. In July 2020, the FDA announced that the enforcement grace period would be extended until May 31, 2021 as a result of the challenges presented by the COVID-19 public health emergency. On April 21, 2021, the FDA reaffirmed that the enforcement grace period would end on May 31, 2021, at which time we ceased commercial distribution of ReNu and NuCel. Although we believe our suspension of ReNu and NuCel commercialization was timely and proper, the FDA and other regulators may disagree with how or when such commercialization practices were conducted, which could expose us to regulatory sanctions, and have a material adverse effect on our business, financial condition and results of operations.

To the extent that the FDA may determine that certain of our products that are, or are derived from, human cells or tissues do not qualify for regulation solely under Section 361 of the PHSA, the introduction of new tissue products would become more expensive, expansion of our tissue product offerings could be significantly delayed, and we could be subject to additional post-market regulatory requirements or suspension of product sales until FDA approval is obtained.

As stated above, in light of the 361 HCT/P Guidance, the FDA may determine that the types of cell- and tissue-based products that we distribute—and in particular, products derived from allografts consisting of human skin or amniotic tissue—are subject to premarket clearance or approval requirements. Should the FDA make such a determination, products of this type, including future products that we seek to introduce, will be much more costly to commercialize, as we will likely have to carry out preclinical work in animals and/or clinical trials in humans to support approval. Such preclinical work and clinical trials are expensive and time-consuming with no guarantee of success. In addition, these products will be subject to more stringent post-market regulatory requirements than those that currently apply, including but not limited to more stringent restrictions on advertising and promotion of these products, as well as more extensive adverse event reporting. In the future, we may also wish to market our existing HCT/P products for new intended uses that may render them ineligible for regulation as Section 361 HCT/Ps and cause them to require premarket clearance or approval and comply with post-market regulations under the medical device or biological product provisions of the FDCA and/or PHSA instead. Compliance with these requirements will involve significant time and substantial costs and could limit the resources available to us to fully exploit our technologies, including limiting our ability to introduce new allograft-derived products.

We conduct a range of nonclinical, as well as clinical trials, comparative effectiveness, economic and other studies of our products. Unfavorable results from these trials or studies or from similar trials or studies conducted by others may negatively

affect the use or adoption of our products by physicians, hospitals, and payers, which could have a negative impact on the market acceptance of these products and their profitability.

We conduct a variety of nonclinical and clinical trials, comparative effectiveness studies and economic and other studies of our products, including our ongoing clinical trial for ReNu, in an effort to generate comprehensive clinical and real-world outcomes data and cost-effectiveness data in order to obtain product approval and drive further penetration in the markets we serve. In the event that these trials and studies, or similar trials and studies conducted by others, yield unfavorable results, those results could negatively affect the use or adoption of our products by physicians, hospitals, and payers, thereby compromising market acceptance and profitability.

Our business is subject to continuing and evolving significant regulatory obligations by the FDA and other authorities, compliance with which is expensive and time-consuming and may impede our ability to fully exploit our technologies or otherwise limit our ability to meet other business objectives.

Aside from the obligation to obtain regulatory approvals or clearances, companies such as ours have ongoing regulatory obligations that are expensive and time-consuming to meet. In particular, the production and marketing of our products are subject to extensive regulation and review by the FDA and numerous other governmental authorities both in the United States and abroad. As noted above, some of the products that we distribute are considered Section 361 HCT/Ps. The FDA's regulation of HCT/Ps includes requirements for registration and listing of products; donor screening and testing; processing and distribution, known as "Current Good Tissue Practices," or cGTP; labeling; record keeping and adverse-reaction reporting; and inspection and enforcement. Moreover, it is likely that the FDA's regulation of HCT/Ps will continue to evolve in the future. Complying with any such new regulatory requirements may entail significant time delays and expense, which could have a material adverse effect on our business, results of operations, and financial condition.

Our other products are regulated as biologics and medical devices, which are subject to even more stringent regulation by the FDA. As noted above, these products are subject to rigorous premarket review processes, and an approval or clearance may place substantial restrictions on the indications for which the product may be marketed or the population for whom it may be marketed, may require warnings to accompany the product or may impose other restrictions on the sale and/or use of the product. In addition, most of our products are subject to continuing obligations to comply with other substantial regulatory requirements, including the FDA's cGTP regulations, the FDA's Current Good Manufacturing Practices (cGMP) regulations, adverse event reporting, FDA inspections, and the FDA's QSR, and the regulatory expectations for these types of regulatory obligations may evolve over time. For example, on January 31, 2024, the FDA issued a final rule amending the QSR for medical devices. This final rule is intended to more closely align the FDA QSR with the international consensus standard for device quality management and will become effective on February 2, 2026. We may need to dedicate considerable resources to come into compliance with the new QSR by the final rule's effective date. The costs and other resource burdens associated with maintaining regulatory approvals or clearances for our products and otherwise meeting our regulatory obligations may limit the resources available to us to fully exploit our technologies or may otherwise limit our ability to carry out other business activities.

In some states, the manufacture, storage, or distribution of HCT/Ps requires a license or permit to operate as a tissue bank or tissue distributor. We believe that we have all required state licenses or permits applicable to the distribution of HCT/Ps, but there is a risk that there may be state or local license or permit requirements of which we are unaware or with which we have not complied. In the event that such noncompliance exists in a given jurisdiction, we could be precluded from distributing HCT/Ps in that jurisdiction and also could be subject to fines or other penalties. If any such actions were to be instituted against us, it could adversely affect our business and/or financial condition.

The American Association of Tissue Banks, or AATB, has issued operating standards for tissue banking. Compliance with these standards is a requirement in order to become an accredited tissue bank. In addition, some states have their own tissue banking regulations. In addition, procurement of certain human organs and tissue for transplantation is subject to the restrictions of the National Organ Transplant Act, or NOTA, which prohibits the transfer of certain human organs, including skin and related tissue for valuable consideration, but permits the reasonable payment associated with the removal, transportation, implantation, processing, preservation, quality control and storage of human tissue and skin. We reimburse tissue banks, hospitals, and physicians for their services associated with the recovery, storage, and transportation of donated human tissue. Although we have independent third-party appraisals that confirm the reasonableness of the service fees we pay, if we were to be found to have violated NOTA's prohibition on the sale or transfer of human tissue for valuable consideration, we, our officers, or employees, would potentially be subject to criminal enforcement sanctions, which could materially and adversely affect our business, results of operations, and financial condition.

Many of the products we manufacture and process are derived from human tissue and therefore have the potential for disease transmission.

The utilization of human tissue creates the potential for transmission of communicable diseases, including, but not limited to, human immunodeficiency virus, or HIV, viral hepatitis, syphilis and other viral, fungal or bacterial pathogens. We are required to comply with federal and state regulations intended to prevent communicable disease transmission.

Although we maintain strict quality controls over the procurement and processing of our tissue, there is no assurance that these quality controls will be adequate. In addition, negative publicity concerning disease transmission from other companies' improperly processed donated tissue could have a negative impact on the demand for our products. If any of our products are implicated in the transmission of any communicable disease, our officers, employees and we could be subject to government sanctions including but not limited to recalls, and civil and criminal liability, with sanctions that include exclusion from doing business with the federal government. We could also be exposed to product liability claims from those who used or received our products as well as loss of our reputation.

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 that could erode our competitive advantage and market share and materially adversely affect our reputation, business, results of operations, and financial condition.

Quality is extremely important to us and our customers due to the serious and costly consequences of product failure. Quality and safety issues may occur with respect to any of our products, and our future operating results will depend on our ability to maintain an effective quality control system and effectively train and manage our workforce with respect to our quality system. The development, manufacture, and control of our products are subject to extensive and rigorous regulation by numerous government agencies, including the FDA and similar foreign agencies. Compliance with these regulatory requirements, including but not limited to the FDA's QSR, GMPs, and adverse events/recall reporting requirements in the United States and other applicable regulations worldwide, is subject to continual review and is monitored rigorously through periodic inspections by the FDA and foreign regulatory authorities. The FDA and foreign regulatory authorities may also require post-market testing and surveillance to monitor the performance of approved products. Our manufacturing facilities and those of our suppliers and independent sales agencies are also subject to periodic regulatory inspections. If the FDA or a foreign authority were to conclude that we have failed to comply with any of these requirements, it could institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions, such as product recalls or seizures, withdrawals, monetary penalties, consent decrees, injunctive actions to halt the manufacture or distribution of products, import detentions of products made outside the United States, export restrictions, restrictions on operations or other civil or criminal sanctions. Civil or criminal sanctions could be assessed against our officers, employees, or us. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing, and selling our products.

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, results of operations, and financial condition.

We may implement a product recall or voluntary market withdrawal, which could significantly increase our costs, damage our reputation and disrupt our business.

The manufacturing, marketing, and processing of our products involve an inherent risk that our products or processes may not meet manufacturing specifications, applicable regulatory requirements or quality standards. In that event, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority. A recall or market withdrawal of one of our products would be costly and would divert management resources. A recall or withdrawal of one of our products, or a similar product processed by another entity, also could impair sales of our products as a result of confusion concerning the scope of the recall or withdrawal, or as a result of the damage to our reputation for quality and safety.

We are subject to various governmental regulations relating to the labeling, marketing, and sale of our products.

Both before and after a product is commercially released, we have ongoing responsibilities under regulations promulgated by the FDA, the Federal Trade Commission, and similar U.S. and foreign regulations governing product labeling and advertising, distribution, sale, and marketing of our products.

Manufacturers of medical devices and biological products are permitted to promote products solely for the uses and indications set forth in the approved or cleared product labeling. Traditionally, many of our wound dressing products have been marketed and, in some cases, specifically cleared, for use in "wound management;" however, the FDA is currently reconsidering whether wound dressings may continue to use that term in device labeling and promotional materials. On November 30, 2023, the FDA issued a proposed rule that would prohibit wound dressings from using the term "wound management," a generally well-understood and accepted term in the healthcare community that describes a context of use. If the rule is finalized, we will be required to update the labeling and promotional material for many of our wound dressings which may make it more difficult to distinguish our wound dressings from competing wound care products.

In addition, a number of enforcement actions have been taken against manufacturers that promote products for off-label uses (i.e., uses that are not described in the approved or cleared labeling), including actions alleging that claims submitted to government healthcare programs for reimbursement of products that were promoted for off-label uses are fraudulent in violation of the Federal False Claims Act or other federal and state statutes and that the submission of those claims was caused by off-label promotion. The failure to comply with prohibitions on off-label promotion can result in significant monetary penalties, revocation or suspension of a company's business license, suspension of sales of certain products, product recalls, civil or criminal sanctions, exclusion from participating in federal healthcare programs, or other enforcement actions. In the United States, allegations of such wrongful conduct could also result in a corporate integrity agreement with the U.S. government that imposes significant administrative obligations and costs.

We and our employees and contractors are subject, directly or indirectly, to federal, state and foreign healthcare fraud and abuse laws, including false claims laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Our operations are subject to various federal, state, and foreign fraud and abuse laws. These laws may constrain our operations, including the financial arrangements and relationships through which we market, sell, and distribute our products.

U.S. federal and state laws that affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering, or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for, the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- the federal physician self-referral law, which prohibits a physician from referring a patient to an entity with which the physician (or an immediate family member) has a financial relationship, for the furnishing of certain designated health services for which payment may be made by Medicare or Medicaid, unless an exception applies;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other government payers that are false or fraudulent;

- 18 U.S.C. § 1347, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or from making false or fraudulent statements to defraud any healthcare benefit program (i.e., public or private);

- federal transparency laws, including the Physician Payments Sunshine Act which requires the tracking and disclosure to the federal government by pharmaceutical and medical device manufacturers of payments and other transfers of value to physicians and teaching hospitals as well as ownership and investment interests that are held by physicians and their immediate family members; and

- state law equivalents of each of these federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical and medical device companies to comply with their industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict certain payments that may be made to healthcare providers and other potential referral sources; state laws that require drug and medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that prohibit giving gifts to licensed healthcare professionals; and state laws governing the

privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances, such as specific disease states.

Activities and arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, waste, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of activities or other arrangements related to the development, marketing, or promotion of products, including pricing and discounting of products, provision of customer incentives, provision of reimbursement support, other customer support services, provision of sales commissions or other incentives to employees and independent contractors and other interactions with healthcare practitioners, other healthcare providers and patients.

Because of the breadth of these laws and the narrow scope of the statutory or regulatory exceptions and safe harbors available, our business activities could be challenged under one or more of these laws. Relationships between medical product manufacturers and health care providers are an area of heightened scrutiny by the government. We engage in various types of activities, including the conduct of speaker programs to educate physicians, the provision of reimbursement advice and support to customers, and the provision of customer and patient support services, that have been the subject of government scrutiny and enforcement action within the medical device industry.

Government expectations and industry best practices for compliance continue to evolve and our past activities may not always be consistent with current industry best practices. Further, there is a lack of government guidance as to whether many varied industry practices comply with these laws, and government interpretations of these laws continue to evolve, all of which create compliance uncertainties. Any non-compliance could result in regulatory sanctions, criminal or civil liability, and serious harm to our reputation. Although we have a comprehensive compliance program designed to ensure that our employees' and commercial partners' activities and interactions with healthcare professionals and patients are appropriate, ethical, and consistent with all applicable laws, regulations, guidelines, policies, and standards, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in preventing such conduct, mitigating risks, or reducing the chance of governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations.

If a government entity opens an investigation into possible violations of any of these laws (which may include the issuance of subpoenas or civil investigative demands), we would have to expend significant resources to defend ourselves against the allegations. Allegations that we, our officers, or our employees violated any one of these laws can be made by individuals called "whistleblowers" who may be our employees, customers, competitors, or other parties. Government policy is to encourage individuals to become whistleblowers and file a complaint in federal court alleging wrongful conduct. The government is required to investigate all of these complaints and decide whether to intervene. If the government intervenes and we are required to pay money back to the government, the whistleblower, as a reward, is awarded a percentage of the collection. If the government declines to intervene, the whistleblower may proceed on their own and, if they are successful, they will receive a percentage of any judgment or settlement amount the company is required to pay. The government may also initiate an investigation on its own. Such actions could have a significant impact on our business, including the imposition of significant fines, and other sanctions that may materially impair our ability to run a profitable business. In particular, if our operations are found to be in violation of any of the laws described above or if we agree to settle with the government without admitting to any wrongful conduct or if we are found to be in violation of any other governmental regulations that apply to us, we, our officers and employees may be subject to sanctions, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, the curtailment or restructuring of our operations and the imposition of a corporate integrity agreement, any of which could adversely affect our business, results of operations, and financial condition.

We could be subject to legal exposure if we do not report the average sales prices, or ASP, to government agencies or if our reporting is not accurate and complete.

Our products are reimbursed by Medicare in physician office settings at a rate of ASP plus 6%. All Medicare payments, including payments based on the ASP methodology, are subject to sequestration. Congress previously suspended sequestration imposed under the BCA, and there was no sequestration through March 31, 2022. On April 1, 2022, there was a 1% sequestration and beginning on July 1, 2022, the sequestration returned to 2%. Sequestration applies to the government's payment portion, which is 80% of the total payment amount. Additionally, in future years, it is possible that an up-to 4% Medicare sequestration could be ordered under Statutory PAYGO, which requires deficit neutrality in most laws passed by Congress. Until January 2022, we were not required to report ASP for all our skin substitute products that are paid separately as biologics because they are regulated as medical devices by the FDA, although we chose to report ASP for some of our products. Starting with the reporting deadline for the first quarter of 2022, we were required to report ASP for all our skin substitute products that are paid separately as biologics as a result of provisions included in the Consolidated Appropriations Act of 2020. As of January 1, 2022, we began reporting ASP for all our skin substitute products that are paid separately as biologics. The first such ASP report was made on April 30, 2022 for Q1

2022. Government price reporting requirements are complex. If we do not report ASP correctly, we may have to restate ASP for prior quarters and we could be subject to civil monetary penalties and/or, if the violation is knowing or reckless, be subject to False Claims Act liability. In the case of very serious or repeated violations, we could be excluded from doing business with the Medicare program and other federal healthcare programs.

We face significant uncertainty in the industry due to government healthcare reform and other legislative action.

There have been and continue to be laws enacted by the federal government, state governments, regulators, and third-party payers to control healthcare costs, and generally, to reform the healthcare system in the United States. For example, the PPACA and the Medicare Access and CHIP Reauthorization Act of 2015 substantially changed the way healthcare is delivered and financed by both governmental and private insurers. These changes included the creation of demonstration programs and other value-based purchasing initiatives that provide financial incentives for physicians and hospitals to reduce costs, including incentives for furnishing low-cost therapies for chronic wounds even if those therapies are less effective than our products. There were extensive efforts recently to modify or repeal all or part of PPACA. Tax reform legislation was passed that includes provisions that impact healthcare insurance coverage and payment such as the elimination of the tax penalty for individuals who do not maintain health insurance coverage (the so-called "individual mandate"). Such actions or similar actions could have a negative effect on the utilization of our products. We expect such efforts to continue and that there may be additional reform proposals at federal and state levels. On December 18, 2019, the United States Court of Appeals for the Fifth Circuit upheld a lower court's determination in *California v. Texas* (orig. *Texas v. Azar*, 4:18-cv-00167), that the individual mandate was unconstitutional and remanded the case to the lower court for further analysis as to whether PPACA as a whole is unconstitutional because the individual mandate is not severable from other provisions of the law. The United States Supreme Court agreed to review the case and on June 17, 2021, ordered that the Fifth Circuit's decision be reversed and that the case be dismissed.

Additionally, on August 16, 2022, Congress passed legislation to limit the price of drugs and biologicals under the Medicare program. The IRA establishes a Drug Price Negotiation Program that requires the Secretary of Health and Human Services to negotiate the price of certain high expenditure Medicare drugs that do not have generic or biosimilar competition. The law also establishes Medicare Part B inflationary rebates, effective Q1 2023. Generally, manufacturers of Part B drugs with an ASP+6% that exceeds the inflation-adjusted payment amount from Q3 2021 will be required to pay a rebate to the Medicare program. These and similar drug pricing reforms could increase pricing pressure on our products.

General legislative action may also affect our business. For example, the Budget Control Act of 2011 included provisions to reduce the federal deficit. The Budget Control Act, as amended, resulted in the imposition of reductions of up to 2% in Medicare payments to providers which began in April 2013 and are scheduled to remain in effect through the first six months of 2032. The Coronavirus Aid, Relief, and Economic Security (CARES) Act and subsequent legislation suspended the payment adjustment from May 1, 2020 through March 31, 2022. There was 1% Medicare sequestration from April 1 to June 30, 2022, and the 2% Medicare sequester was reinstated on July 1, 2022. Additionally, under Statutory PAYGO, a 4% Medicare sequester could be ordered at the end of the 2024 Congressional session. These or other similar reductions in government healthcare spending could result in reduced demand for our products or additional pricing pressure.

Bills currently before the United States Congress may also affect our business, if enacted. For example, during the 117th Congressional session, the Cures 2.0 Act, H.R. 6000, 117th Cong. (2021) was introduced into the United States House of Representatives. If reintroduced in a similar form, it may contain provisions that could result in legal and regulatory changes that affect our business. These changes may include a new payment pathway for breakthrough medical devices that are FDA approved or cleared on or after a certain date. The enactment of Cures 2.0 (or similar legislation) may also accelerate FDA timelines for designation of breakthrough and RMAT therapies and also result in new requirements for the use of patient experience data and real-world evidence in regulating certain FDA products. If enacted, these changes could make it easier for our competitors to bring comparable or more advanced products to market quickly, resulting in reduced demand for our products.

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

We are currently selling into foreign markets and plan to expand such sales. Managing a global organization is difficult, time-consuming, and expensive. Conducting international operations subjects us to risks that could be different from those faced by us in the United States. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subject us to extensive U.S. and foreign governmental trade, import and export and customs regulations and laws, including but not limited to, the Export Administration Regulations and trade sanctions against embargoed countries, which are administered by the Office of Foreign Assets Control within the Department of the Treasury, as well as the laws and regulations administered by the Department of Commerce. These regulations limit our ability to market, sell, distribute, or otherwise transfer our products or technology to prohibited countries or persons.

Compliance with these regulations and laws is costly, and failure to comply with applicable legal and regulatory obligations could adversely affect us in a variety of ways that include, but are not limited to, significant criminal, civil, and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and

restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities.

These risks may limit or disrupt our expansion, 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 resources.

We could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws.

The U.S. Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act of 2010, and similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business. Our policies mandate compliance with these anti-bribery laws, including the requirements to maintain accurate information and internal controls. We operate in many parts of the world that have experienced governmental corruption to some degree and in certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices. There is no assurance that our internal control policies and procedures will protect us from acts committed by our employees or agents. If we are found to be liable for FCPA or other violations (either due to our own acts or our inadvertence, or due to the acts or inadvertence of others), we could suffer from civil and criminal penalties or other sanctions, including contract cancellations or debarment, and loss of reputation, any of which could have a material adverse impact on our business, financial condition, and results of operations.

Risks Related to Reimbursement for our Products

The rate of reimbursement and coverage for the purchase of our products by government and private insurance is subject to change.

Sales of almost all of our products depend partly on the ability of our customers to obtain reimbursement for the cost of our products under government healthcare programs such as Medicare and Medicaid and from other global government authorities. Government healthcare programs and private health plans continuously seek to reduce healthcare costs. For example, in 2014, Medicare established a policy to stop making separate payment for our products in certain clinical settings. This policy required us to reduce prices for our products which caused significant reduction in our revenue.

Our success will depend in part on the extent to which coverage and adequate reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers, and other third-party payers and we do not know whether such reimbursement will be available. For example, currently most private payers provide limited coverage for our PuraPly AM, PuraPly, Novachor, and NuShield products and as a result, there is limited use of these products for patients covered by private payers.

The continuing efforts of government agencies, private health plans, and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the availability of our products due to restricted coverage;
- the ability of our customers to pay for our products;
- our ability to maintain pricing so as to generate revenues or achieve or maintain profitability; and
- our ability to access capital.

The proposed updates to the MPFS for calendar year 2023 included a proposal to stop making separate payments for all skin substitutes, including all of our products, in 2024 or 2025. Instead of making separate payment for skin substitutes, Medicare would bundle the payment for skin substitutes into the payment made for the application procedure. As part of this proposal, Medicare would consider all skin substitutes to be supplies instead of biologicals and would require manufacturers of skin substitutes, including us, to apply for new HCPCS codes that would be effective starting in 2024. In the 2023 MPFS final rule, published on November 1, 2022, CMS did not finalize this bundling proposal and will consider more public input in the future; however, they may propose the same policy again or make other proposals in the future that could affect our business and our revenue. If Medicare reproposes and finalizes a policy to stop making separate payment for skin substitutes in calendar year 2024 or calendar year 2025, reimbursement for our products may not be adequate and our business, results of operations, and financial condition may be negatively affected.

Payers are increasingly attempting to contain healthcare costs by limiting both the breadth of coverage and the level of reimbursement, particularly for new therapeutic products generally or specifically for new therapeutic products that target an indication that is perceived to be well served by existing treatments. Specifically, the Patient Protection and Affordable Care Act, or

PPACA, enacted in 2010, contains provisions for Medicare demonstration programs that create financial incentives to treat patients with chronic wounds conservatively and not use our products. Furthermore, all our products are not paid separately in the outpatient hospital setting which is our largest customer base. This payment policy has created incentives to use our competitors' products. Accordingly, even if coverage and reimbursement are provided, market acceptance of our products has been and will be adversely affected if access to coverage is administratively burdensome to obtain and/or use of our products is administratively burdensome or unprofitable for healthcare providers or less profitable than alternative treatments. In addition, Medicare, which is the major source of revenue for most of our customers, reimburses the same amounts for most of our products and the products of our competitors targeting the same indications in the hospital outpatient setting. Because in some sites of care, the reimbursement amount is not based on the cost we charge our customers for our products or the cost our competitors charge for products targeting the same indication, our customers may elect to use products cheaper than ours in order to increase their margins, which could have a material adverse effect on our business, results of operations, and financial condition.

Reimbursement from Medicare, Medicaid, and other third-party payers is usually adjusted yearly as a result of legislative, regulatory, and policy changes as well as budgetary pressures. In fact, Medicare has signaled that it may discontinue its two-tier bundling policy when it solicited comments on alternatives in its calendar year 2019 rulemaking. Changes in the policy could occur as early as calendar year 2024 and could include the establishment of a single bundle for all products which could place our products at a significant competitive disadvantage. Possible reductions in, or eliminations of, coverage or reimbursement by third-party payers, or the denial of, or provision of uneconomical reimbursement for new products, as a result of these changes may affect our customers' revenue and ability to purchase our products. Any changes in the healthcare regulatory, payment, or enforcement landscape relative to our customers' healthcare services also have the potential to significantly affect our operations and revenue. In addition, Medicare uses regional contractors called Medicare Administrative Contractors, or MACs, to process claims, develop coverage policies and make payments within designated geographic jurisdictions. While our products are currently covered by most MACs, we cannot be certain they will be in the future.

Wound care supplies, such as our product line acquired from CPN Biosciences, are subject to coding verification from CMS's Pricing, Data Analysis and Coding contractor (the PDAC). The PDAC is responsible for verifying the HCPCS Level II DMEPOS Codes for all wound care supplies. Our current wound care supplies sold through CPN have received coding verification from the PDAC and all products have HCPCS Level II codes. Additional wound care supplies that we develop or acquire will also be subject to the PDAC coding verification process. We cannot guarantee the outcome of the PDAC coding verification process. If we are unsuccessful in receiving verification of the applicable HCPCS codes for our products, our wound care supplies could be ineligible for reimbursement or reimbursed at a lower rate than appropriate for our supplies.

While we cannot predict the outcome of current or future legislation, we anticipate, particularly given the recent focus on healthcare reform legislation, that governmental authorities will continue to introduce initiatives directed at lowering the total cost of healthcare and restricting coverage and reimbursement for our products. If we are not successful in obtaining adequate reimbursement for our products from third-party payers, the market's acceptance of our products could be adversely affected. Inadequate reimbursement levels also likely would create downward price pressure on our products. Even if we do succeed in obtaining widespread reimbursement for our products, future changes in reimbursement policies could have a negative impact on our business, financial condition and results of operations.

The rate of reimbursement and coverage for the purchase of our products by government and private insurance (including by Medicare Administrative Contractors) is subject to uncertainty.

Our products are subject to varying forms of governmental and private payor reimbursement, and fluctuations in these forms of payment may adversely affect our business. For example, in sites of service where payment for skin substitutes is based on the ASP methodology, Medicare pays for skin substitutes separately from the application procedure. In this case, the Medicare payment rate for all skin substitutes (including ours) is calculated on a per square centimeter basis. These rates are adjusted quarterly based on manufacturer ASP reporting, and the payment amount is ASP plus 6% when Medicare includes our ASP in its quarterly ASP file; when ASP data is not available in the quarterly ASP file, MACs may ask CMS what the ASP is or they may reimburse at WAC plus 3%, or invoice pricing. All Medicare payment amounts, including separate payments under the ASP methodology, are subject to sequestration. The Medicare sequestration of 2%, under the BCA, was temporarily suspended and that suspension continued through March 31, 2022. On April 1, 2022, the sequestration became 1% and it returned to 2% as of July 1, 2022. Additionally, under Statutory PAYGO, a 4% Medicare sequester could be ordered at the end of the 2024 Congressional session. Before January 2022, the Medicare statute did not require us to report ASP for our products because they are regulated by the FDA as medical devices. However, starting with the reporting deadline for the first quarter of 2022, we were required to report ASP for our products based on a provision within the Consolidated Appropriations Act of 2020, signed into law on December 27, 2020.

When ASP data are not available in the quarterly ASP file published by CMS (for instance our Affinity product in the fourth quarter of 2021), the Part A/B MACs establish payment for drugs and biologics in their jurisdiction(s). In these situations, MACs

can update their reimbursement methodology as frequently as quarterly, without notice. MACs also have the discretion to establish coverage policies for all skin substitute products (including ours). Accordingly, even if coverage and reimbursement are provided, market acceptance of our products has been and will be adversely affected if access to coverage is administratively burdensome to obtain, use of our products is administratively burdensome, or is unprofitable for healthcare providers or less profitable than alternative treatments.

Furthermore, Medicare has signaled that it may revise its two-tiered bundled payment policy for skin substitutes. Medicare solicited comments in rulemaking for calendar year 2019 related to proposed updates and policy changes under the Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center Payment System. Medicare specifically solicited comments on whether it should eliminate the two-tiered bundle policy and establish a single bundle for all products. However, Medicare did not make any changes to its two-tiered payment policy in response to those comments. If CMS proposes and finalizes any revisions to its two-tiered payment policy, those changes could result in decreased reimbursement for our products which could decrease utilization and reduce our revenues. Moreover, any new policy could result in a financial incentive for hospitals and ASCs to use our competitor's products, thereby reducing our market share and revenue.

Three MACs recently withdrew LCDs for skin substitutes and/or CTPs for the treatment of DFUs and VLUs in the Medicare population that would have eliminated coverage for certain of our products as of October 1, 2023. Had these LCDs taken effect or if new LCDs are adopted and take effect in the future that eliminate or reduce coverage for our products, it could have a material adverse effect on utilization of our products, our business and our revenue.

On August 3, 2023, three MACs (Novitas, First Coast Services, and CGS) published final LCDs for skin substitutes and CTPs for the treatment of DFUs and VLUs in the Medicare population that would have eliminated coverage for our PuraPly, Novachor, TransCyte, Affinity and NuShield products as of October 1, 2023. These LCDs were withdrawn by the MACs on September 28, 2023 and our products remain covered. Had coverage for these products been eliminated, it would have presented a significant amount of uncertainty regarding (i) future revenue for the affected products in the applicable regions and (ii) the potential impact on demand for our products when used for treatment of non-DFU/VLU wounds. While in this case the LCDs were ultimately withdrawn before they took effect, there is no guarantee that the MACs will not adopt new LCDs in the future that could eliminate or reduce coverage for our products. If new LCDs are adopted in the future that eliminate or reduce coverage for our products and we are unable to convince the MACs to withdraw them, it could materially and adversely impact utilization of our products, our business, and our revenue.

Cost-containment efforts of our customers, purchasing groups, third-party payers, and governmental organizations could adversely affect our business, results of operations, and financial condition.

Many existing and potential customers for our products within the United States are members of GPOs and/or IDNs, including accountable care organizations or public-based purchasing organizations, and our business is partly dependent on major contracts with these organizations. 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. At any given time, we are typically at various stages of responding to bids and negotiating and renewing GPO and IDN agreements, including agreements that would otherwise expire. 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. Failure to be included in certain of these agreements could have a material adverse effect on our business, financial condition and results of operations. In addition, while having a contract with a major purchaser, such as a GPO or IDN, for a given product category can facilitate sales, sales volumes of those products may not be maintained. For example, GPOs and IDNs are increasingly awarding contracts to multiple suppliers for the same product category. Even when we are the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN generally are free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause upon 60 to 90 days' notice. The healthcare industry has been consolidating, and the consolidation among third-party payers into larger purchasing groups will increase their negotiating and purchasing power. Such consolidation may result in greater pricing pressure on us due to pricing concessions and may further exacerbate the risks described above.

Risks Related to Our Intellectual Property

Our patents and other intellectual property rights may not adequately protect our products.

Our ability to compete effectively will depend, in part, on our ability to maintain the proprietary nature of our technology and manufacturing processes. We rely on manufacturing and other know-how, patents, trade secrets, trademarks, license agreements, and contractual provisions to establish our intellectual property rights and protect our products. These legal means, however, afford

only limited protection and may not adequately protect our rights. The failure to obtain, maintain, enforce, or defend such intellectual property rights, for any reason, could allow third parties to make competing products or impact our ability to develop, manufacture and market our own products on a commercially viable basis, or at all, which could have a material adverse effect on our revenues, financial condition or results of operations.

In particular, we rely primarily on trade secrets, know-how, and other unpatented technology, which are difficult to protect. Although we seek such protection in part by entering into confidentiality agreements with our vendors, employees, consultants, and others who may have access to proprietary information, we cannot be certain that these agreements will not be breached, adequate remedies for any breach would be available or our trade secrets, know-how, and other unpatented proprietary technology will not otherwise become known to or be independently developed by our competitors. If we are unsuccessful in protecting our intellectual property rights, sales of our products may suffer and our ability to generate revenue could be severely impacted.

We have filed applications to register various trademarks for use in connection with our products in various countries and also, with respect to certain products, rely on the trademarks of third parties. These trademarks may not afford adequate protection. We or these third parties also may not have the financial resources to enforce the rights under these trademarks which may enable others to use the trademarks and dilute their value. Additionally, our marks may be found to conflict with the trademarks of third parties. In such a case, we may not be able to derive any value from such trademarks or, even, may be required to cease using the conflicting mark. The value of our trademarks may also be diminished by our own actions, such as failing to impose appropriate quality control when licensing our trademarks. Any of the foregoing could impair the value of, or ability to use, our trademarks and have an adverse effect on our business.

Most of the key patents related to our marketed products are expired. We have no patent protection covering, for example, our Apligraf, Dermagraft, or NuShield products. However, in addition to trade secrets, trademarks, know-how, and other unpatented technology, we have pursued and plan to continue to pursue patent protection where we believe that doing so offers potential commercial benefits. However, we may be incorrect in our assessments of whether or when to pursue patent protection. Moreover, patents may not issue from any of our pending patent applications. Even if we obtain or in-license issued patents, such patent rights may not provide valid patent protection sufficiently broad to prevent any third party from developing, using, or commercializing products that are similar or functionally equivalent to our products or technologies, or otherwise provide any competitive advantage. In addition, these patent rights may be challenged, revoked, invalidated, infringed, or circumvented by third parties. Laws relating to such rights may in the future be changed or withdrawn in a manner adverse to us.

Additionally, our products or the technologies or processes used to formulate or manufacture our products may now, or in the future, infringe the patent rights of third parties. It is also possible that third parties will obtain patent or other proprietary rights that might be necessary or useful for the development, manufacture, or sale of our products. In such cases, we may need or choose to obtain licenses for intellectual property rights from others and it is possible that we may not be able to obtain these licenses on commercially reasonable terms, if at all.

Pending and future intellectual property litigation could be costly and disruptive and may have an adverse effect on our business, results of operations, and financial condition.

We operate in an industry characterized by extensive intellectual property litigation. Defending intellectual property litigation is expensive and complex, takes significant time and diverts management's attention from other business concerns, and the outcomes are difficult to predict. We have in the past been subject to claims that our products or technology violate a third party's intellectual property rights, and we may be subject to such assertions in the future. Any pending or future intellectual property litigation may result in significant damage awards, including treble damages under certain circumstances, and injunctions that could prevent the manufacture and sale of affected products or could force us to seek a license and/or make significant royalty or other payments in order to continue selling the affected products. Such licenses may not be available on commercially reasonable terms, if at all. We have in the past and may in the future choose to settle disputes involving third-party intellectual property by taking a license. Such licenses or other settlements may involve, for example, upfront payments, yearly maintenance fees and royalties. At any given time, we may be involved as either a plaintiff or a defendant in a number of intellectual property actions, the outcomes of which may not be known for prolonged periods of time. A successful claim of patent or other intellectual property infringement or misappropriation against us could materially adversely affect our business, results of operations, and financial condition.

We may be subject to damages resulting from claims that we, our employees, or our independent contractors have wrongfully used or disclosed alleged trade secrets, proprietary or confidential information of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Some of our employees were previously employed at other medical device, pharmaceutical, or biotechnology companies. We may also hire additional employees who are currently employed at other medical device, pharmaceutical, or biotechnology

companies, including our competitors. Additionally, consultants or other independent agents with whom we may contract may be or have been in a contractual arrangement with one or more of our competitors. Although no claims are currently pending, we may be subject to claims that we, our employees, or our independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail to defend such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. There can be no assurance that this type of litigation will not occur, and any future litigation or the threat thereof may adversely affect our ability to hire additional direct sales representatives, or other personnel. A loss of key personnel or their work product could hamper or prevent our ability to market existing or new products, which could severely harm our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming, and ultimately unsuccessful.

Competitors may infringe or misappropriate the patents or other intellectual property that we own or license. In response, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us, such as alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent that we own or license is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or conclude that there is no infringement. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to the patents or patent applications that we own or license. An unfavorable outcome could require us to cease using the invention or attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

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

We seek to protect our proprietary technology and processes, in part, by entering into confidentiality and assignment of inventions agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Despite our efforts, agreements may be breached and security measures may fail, and we may not have adequate remedies for any breach or failure. In addition, our trade secrets and know-how may otherwise become known or be independently discovered by competitors. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We may be subject to claims challenging the inventorship or ownership of the patents and other intellectual property that we own or license.

We may be subject to claims that former employees, collaborators, or other third parties have an ownership interest in the patents and intellectual property that we own or license. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements obligating them to assign such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own; our licensors may face similar obstacles. We could be subject to ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against any claims challenging inventorship or ownership. If we fail in defending any such claims, we may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could adversely impact our business, results of operations, and financial condition.

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

Periodic maintenance fees, renewal fees, annuity fees, and other fees on patents and patent applications will be due to be paid to the U.S. Patent and Trademark Office and similar foreign agencies in several stages over the lifetime of the patents and patent applications. We rely on our outside counsel to pay these fees due to foreign patent agencies. The U.S. Patent and Trademark Office and various foreign patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent application process. We employ law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market, which could have a material adverse effect on our business, results of operations, and financial condition.

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

Success in the biopharmaceutical industry is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both technological and legal complexity, and therefore obtaining and enforcing pharmaceutical patents is costly, time-consuming, and inherently uncertain.

Recent patent reform legislation could increase the uncertainties and costs of prosecuting patent applications and enforcing and defending patents. Enacted in 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, made significant changes to U.S. patent law, including provisions that affect the prosecution of patent applications and also affect patent litigation. The U.S. Patent and Trademark Office 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, including the first to file provisions, only became effective in March 2013. The full impact of the Leahy-Smith Act on our business is not yet clear, but it could result in increased costs and more limited patent protection, either of which could adversely affect our business, results of operations, and financial condition.

Moreover, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty regarding our ability to obtain patents in the future, this combination of events has created uncertainty regarding the value of any patents we do obtain. Depending on decisions by the U.S. Congress, the federal courts, and the U.S. Patent and Trademark Office, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce any current or future patents that we may own or license.

Risks Related to Our Indebtedness

Our indebtedness could have a material adverse effect on our business, results of operations, and financial condition.

As of December 31, 2023, we had approximately $66.6 million of aggregate principal amount of indebtedness outstanding under our 2021 Credit Agreement. Our 2021 Credit Agreement requires that we comply with certain financial covenants that include Consolidated Fixed Charge Coverage Ratio and Consolidated Total Net Leverage Ratio, tested quarterly. If we are unable to meet these financial covenants, the borrowings under the 2021 Credit Agreement may become due and payable immediately unless we obtain an amendment from our lenders and we would be prohibited from making any borrowings under the Revolving Facility (see "*Indebtedness - 2021 Credit Agreement*"). There can be no assurance that our lenders would agree to any such amendment on acceptable terms, or at all. In addition, our indebtedness increases the risk that we may be unable to generate cash sufficient to pay amounts due in respect of our indebtedness and could have other important consequences to our debt holders and significant effects on our business. For example, it could:

- increase our vulnerability to adverse changes in general economic, industry, and competitive conditions;
- require us to dedicate a substantial portion of our cash flow from operations to making payments on our indebtedness, thereby reducing the availability of our cash flow to fund working capital, capital expenditures, and other general corporate purposes;
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;
- expose us to the risk of increased interest rates as certain of our borrowings are at variable rates, and we may not be able to enter into interest rate swaps and any swaps we enter into may not fully mitigate our interest rate risk;
- restrict us from capitalizing on business opportunities;

- make it more difficult to satisfy our financial obligations, including payments on our indebtedness;
- place us at a competitive disadvantage compared to our competitors that have less debt; and limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy, or other general corporate purposes.

In addition, the credit agreements governing our senior secured credit facilities collateralize substantially all of our personal property and assets, including our intellectual property, and contain restrictive covenants that limit our ability to engage in activities that may be in our long-term best interests. Our failure to comply with those covenants could result in an event of default that, if not cured or waived, could result in the acceleration of all of our indebtedness.

Despite our current level of indebtedness, we may incur substantially more debt. This could further exacerbate the risks associated with our substantial leverage.

We may incur significant additional indebtedness in the future. Although the credit agreements governing our senior secured and subordinated credit facilities limit our ability and the ability of our present and future subsidiaries to incur additional indebtedness, the terms of the senior secured and subordinated credit facilities permit us to incur significant additional indebtedness under certain circumstances. In addition, the credit agreements governing our senior secured and subordinated credit facilities 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 risk associated with our substantial indebtedness described above, including our potential inability to service our debt, will increase.

We will require a significant amount of cash to service our debt, and our ability to generate cash depends on many factors beyond our control, and any failure to meet our debt service obligations could materially adversely affect our business, results of operations, and financial condition.

Our ability to make payments on and to refinance our indebtedness and to fund working capital needs and planned capital expenditures will depend on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, business, legislative, regulatory, and other factors that are beyond our control.

If our business does not generate sufficient cash flow from operations or if future borrowings are not available to us in an amount sufficient to enable us to pay our indebtedness or to fund our other liquidity needs, we may need to refinance all or a portion of our indebtedness on or before the maturity thereof, sell assets, reduce or delay capital investments or seek to raise additional capital, any of which could have a material adverse effect on our business, results of operations, and financial condition. In addition, we may not be able to effect any of these actions, if necessary, on commercially reasonable terms or at all. Our ability to restructure or refinance our indebtedness will depend on the condition of the capital markets and our financial condition at such time. Any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. The terms of existing or future debt instruments, including the credit agreements governing our senior and subordinated secured credit facilities, may limit or prevent us from taking any of these actions. In addition, any failure to make scheduled payments of interest and principal on our outstanding indebtedness would likely result in a reduction of our credit rating, which could harm our ability to incur additional indebtedness on commercially reasonable terms or at all. Our inability to generate sufficient cash flow to satisfy our debt service obligations, or to refinance or restructure our obligations on commercially reasonable terms or at all, would have an adverse effect, which could be material, on our business, results of operations, and financial condition, as well as on our ability to satisfy our obligations in respect of the senior and subordinated secured credit facilities and our other indebtedness.

Our failure to comply with the agreements relating to our outstanding indebtedness, including as a result of events beyond our control, could result in an event of default that could materially adversely affect our business, results of operations, and financial condition.

If there were an event of default under any of the agreements relating to our outstanding indebtedness, the holders of the defaulted debt could cause all amounts outstanding with respect to that debt to be due and payable immediately. We cannot guarantee that our assets or cash flow would be sufficient to fully repay borrowings under our outstanding debt instruments if accelerated upon an event of default. Further, if we are unable to repay, refinance or restructure our indebtedness under our secured debt, the holders of such debt could proceed against the collateral securing that indebtedness. In addition, any event of default or declaration of acceleration under one debt instrument could also result in an event of default under one or more of our other debt instruments. As a result, any default by us on our indebtedness could have a material adverse effect on our business, results of operations, and financial condition.

The credit agreements governing our senior secured credit facility and our subordinated credit facility restrict our current and future operations, particularly our ability to respond to changes or to take certain actions.

The credit agreements governing our senior secured credit facility and our subordinated credit facility are collateralized by substantially all of our assets, including our intellectual property, and impose significant operating and financial restrictions and limit our ability and our other restricted subsidiaries' ability to, among other things:

- incur additional indebtedness for borrowed money and guarantee indebtedness;
- pay dividends or make other distributions in respect of, or repurchase or redeem, capital stock;
- enter into any new line of business not reasonably related to our existing business;
- prepay, redeem or repurchase certain debt;
- make loans and investments;
- sell or otherwise dispose of assets;
- incur liens;
- enter into transactions with affiliates; and
- enter into agreements restricting our subsidiaries' ability to pay dividends; and consolidate, merge or sell all or substantially all of our assets.

As a result of these covenants and restrictions, we are and will be limited in how we conduct our business, and we may be unable to raise additional debt or equity financing to compete effectively or to take advantage of new business opportunities. In addition, our senior secured credit facility requires us to comply with a minimum consolidated revenue covenant (measured on a trailing twelve-month basis) and a minimum monthly liquidity ratio (measured as of the last day of each month). The operating and financial restrictions and covenants in the senior secured credit facility, as well as any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. Our ability to comply with these covenants may be affected by events beyond our control, and we may not be able to meet those covenants. For example, in the past, we have not been in compliance with certain financial covenants in our debt agreements, which may occur again in the future. We cannot guarantee that we will be able to maintain compliance with these covenants in the future and, if we fail to do so, that we will be able to obtain waivers from the lenders and/or amend the covenants.

Our failure to comply with the restrictive covenants described above as well as others contained in our future debt instruments from time to time could result in an event of default, which, if not cured or waived, could result in our being required to repay these borrowings before their due date. If we are forced to refinance these borrowings on less favorable terms, our business, results of operations, and financial condition could be adversely affected.

Risks Related to Our Class A Common Stock

The Significant Stockholder Group exercises significant control over us, and their interests may conflict with yours in the future.

Alan A. Ades, Albert Erani, Glenn H. Nussdorf, Dennis Erani, Starr Wisdom, and certain of their respective affiliates, including Organo PFG LLC, Organo Investors LLC, Dennis Erani 2012 Issue Trust, Alan Ades as Trustee of the Alan Ades 2014 GRAT, Albert Erani Family Trust dated 12/29/2012, GN 2016 Family Trust u/a/d August 12, 2016, GN 2016 Organo 10-Year GRAT u/a/d September 30, 2016 and RED Holdings, LLC, who we refer to collectively as the Significant Stockholder Group, control a significant amount of the voting power of the outstanding Class A common stock. As of February 26, 2024, the Significant Stockholder Group collectively beneficially owns approximately 46% of the Company's Class A common stock. As a result of this voting control, the Significant Stockholder Group collectively can effectively determine the outcome of all matters requiring stockholder approval, including, but not limited to, the election and removal of the Company's directors (including the right to designate four of our directors pursuant to the terms of an agreement between the Company and the Significant Stockholder Group), as well as other matters of corporate or management policy (such as potential mergers or acquisitions, payment of dividends, asset sales, and amendments to the Company's certificate of incorporation and bylaws). This concentration of ownership may delay or deter possible changes in control and limit the liquidity of the trading market for the Company's Class A common stock, which may reduce the value of an investment in its Class A common stock. This voting control could also deprive stockholders of an opportunity to receive a premium for their shares of Class A common stock as part of a potential sale of the Company. So long as the Significant Stockholder Group and their affiliates continue to own a significant amount of the Company's combined voting power, they may continue to be able to strongly influence or effectively control its decisions. The interests of the Significant Stockholder Group and their affiliates may not coincide with the interests of other holders of the Company Class A common stock.

In the ordinary course of their business activities, the Significant Stockholder Group and their affiliates may engage in activities where their interests conflict with our interests or those of our other stockholders. In addition, the Significant Stockholder Group may have an interest in pursuing acquisitions, divestitures, and other transactions that, in their judgment, could enhance their investment, even though such transactions might involve risks to you.

Our stock price has been, and is likely to continue to be, volatile. Fluctuations in revenue or results of operations could cause additional volatility in our stock price and thus our stockholders could incur substantial losses.

Our stock price has been volatile and could be subject to wide fluctuations in response to various factors, many of which are beyond our control. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. Any unanticipated shortfall in our revenue in any fiscal quarter could have an adverse effect on our results of operations in that quarter. The effect on our net income of such a shortfall could be exacerbated by the relatively fixed nature of most of our costs, which primarily include personnel costs as well as facilities costs. These fluctuations could cause the trading price of our stock to be negatively affected. Our quarterly operating results have varied substantially in the past and may vary substantially in the future.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation, as we are and as disclosed in Item 3, "Legal Proceedings". Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms.

Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our Class A common stock.

The Company bylaws designate the Court of Chancery of the State of Delaware, to the fullest extent permitted by law, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by the Company stockholders, which could limit the ability of the Company stockholders to obtain a favorable judicial forum for disputes with the Company or with directors, officers or employees of the Company and may discourage stockholders from bringing such claims.

Under the Company bylaws, unless the Company consents in writing to the selection of an alternative forum, the sole and exclusive forum will be the Court of Chancery of the State of Delaware for:

- any derivative action or proceeding brought on behalf of the Company;
- any action asserting a claim of breach of a fiduciary duty owed by, or any wrongdoing by, any director, officer or employee of the Company to the Company or the Company's stockholders;

- any action asserting a claim arising pursuant to any provision of the DGCL, the certificate of incorporation (including as it may be amended from time to time), or the bylaws;
- any action to interpret, apply, enforce or determine the validity of the certificate of incorporation or the bylaws; or
- any action asserting a claim governed by the internal affairs doctrine, in each case, except for, (1) any action as to which the Court of Chancery determines that there is an indispensable party not subject to the personal jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten (10) days following such determination) and (2) any action asserted under the Securities Exchange Act of 1934, as amended, or the rules and regulations promulgated thereunder, for which federal courts have exclusive jurisdiction.

These provisions of the Company's certificate of incorporation and bylaws could limit the ability of the Company stockholders to obtain a favorable judicial forum for certain disputes with the Company or with its directors, officers or other employees, which may discourage such lawsuits against the Company and its directors, officers, and employees. Alternatively, if a court were to find these provisions of the Company's certificate of incorporation or bylaws inapplicable to, or unenforceable in respect of, one or more of the types of actions or proceedings listed above including, without limitation, any actions asserted under the Securities Act of 1933, as amended, the Company may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect its business, financial condition and results of operations. In addition, there is uncertainty as to whether a court would enforce the Company's forum selection provision with respect to any actions asserted under the Securities Act of 1933, as amended, as investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Provisions in the Company's charter may inhibit a takeover of the Company, which could limit the price investors might be willing to pay in the future for the Company's Class A common stock and could entrench management.

The Company's certificate of incorporation contains provisions that may discourage unsolicited takeover proposals that shareholders may consider to be in their best interests. These provisions include the ability of the Board of Directors to designate the terms of and issue new series of preferred shares, which may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for the Company's securities.

General Risk Factors

We are currently and in the future may be, subject to securities class action litigation or other litigation that could cause us to incur significant legal expenses, divert management's attention, and result in harm to our business.

We are exposed to potential liabilities and reputational risk associated with securities class action litigation. We are party to a securities class action lawsuit as disclosed in Item 3, "Legal Proceedings". We may be subject to additional lawsuits, including class action or securities derivative lawsuits as well as incur additional legal fees and may face negative impacts to our stock price and reputation. In addition, we are obligated to indemnify and advance expenses to certain individuals involved in certain of these proceedings.

Any adverse judgment in or settlement of any pending or any future litigation could result in significant payments, fines and penalties that could have a material adverse effect on our business, results of operations, financial condition and reputation. Such payments, damages or settlement costs, if any, related to these matters could be in excess of our insurance coverage. The amount of time that is required to resolve these lawsuits is unpredictable and any litigation or claims against us, even those without merit, may cause us to incur substantial costs, divert management's attention from the day-to-day operation of our business, and materially harm our reputation.

We face significant and continuing competition, which could adversely affect our business, results of operations, and financial condition.

We face significant and continuing competition in our business, which is characterized by rapid technological change and significant price competition. Market share can shift as a result of technological innovation and other business factors. Our customers consider many factors when selecting a product, including product reliability, clinical outcomes, economic outcomes, price, and services provided by the manufacturer. Our ability to compete depends in large part on our ability to provide compelling clinical and economic benefits to our customers and payers, develop and commercialize new products and technologies and anticipate technological advances. Product introductions or enhancements by competitors which may have advanced technology, better features, or lower pricing may make our products obsolete or less competitive. In addition, consolidation in the healthcare industry continues to lead the demand for price concessions or to the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, results of operations or financial condition. The presence of this competition in our market may lead to pricing pressure, which would make it more difficult to sell our products at a price that will make us profitable

or prevent us from selling our products at all. As a result, we will be required to devote continued efforts and financial resources to bring our products under development to market, deliver cost-effective clinical outcomes, expand our geographic reach, enhance our existing products, and develop new products for the advanced wound care and soft tissue repair markets. Even if we develop cost effective and/or new products, they may not be covered or reimbursed due to cost-containment and other financial pressures from payers.

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.

Continued expansion of our business will be expensive and we may seek funds from stock offerings, borrowings under our existing or future credit facilities or other sources. Our capital requirements will depend on many factors, including:

- the revenues generated by sales of our products;
- the costs associated with expanding our sales and marketing efforts;
- the expenses we incur in manufacturing and selling our products;
- the costs of developing and commercializing new products or technologies;
- the cost of obtaining and maintaining regulatory approval or clearance of certain products and products in development;
- the number and timing of acquisitions and other strategic transactions such as our acquisitions of NuTech Medical and CPN Biosciences, and integration costs associated with such acquisitions;
- the costs associated with capital expenditures; and
- unanticipated general, legal, and administrative expenses.

Our operating plan may change as a result of many factors currently unknown to us and we may need additional funds sooner than planned. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. Furthermore, if we issue equity or convertible debt securities to raise capital, you may experience dilution, and the new equity or convertible debt securities may have rights, preferences, and privileges that are senior to or otherwise adversely affect your rights as a stockholder. In addition, if we raise capital through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our products, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise capital on acceptable terms, we may not be able to develop our product candidates, enhance our existing products, execute our business plan, take advantage of future opportunities, or respond to competitive pressure, changes in our supplier relationships, or unanticipated customer requirements. Any of these events could adversely affect our ability to achieve our development and commercialization goals, which could have a material adverse effect on our business, results of operations, and financial condition.

Our future success depends on our ability to retain key employees, consultants and advisors, and to attract, retain and motivate qualified personnel.

We are highly dependent on our executive officers, the loss of whose services may adversely impact the achievement of our objectives. In particular, we depend on Gary Gillheeney, our President and Chief Executive Officer. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives and scientific 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 medical device companies for individuals with similar skill sets. The inability to recruit or loss of the services of any executive, key employee, consultant or advisor may impede the progress of our research, development, and sales growth objectives.

Our ability to recruit, retain and motivate our employees and consultants will depend in part on our ability to offer attractive compensation. We may also need to increase the level of cash compensation that we pay to them, which may reduce funds available for research and development and support of our sales growth objectives. There can be no assurance that we will have sufficient cash available to offer our employees and consultants attractive compensation.

Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, prospects, financial condition or results of operations. We do not maintain "key person" insurance policies on the lives of these individuals or any of our other employees.

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 and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we can offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize product candidates will be limited.

Uncertainty and adverse changes in the general economic conditions, including recent turmoil in the global banking system, may negatively affect our business.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. If general economic conditions in the United States decline, or if consumers fear that economic conditions will decline, sales of our products may decline. Adverse changes may occur as a result of adverse economic conditions, fluctuating oil prices, supply chain problems, inflation, political instability, declining consumer confidence, a continuation or worsening of the COVID-19 pandemic or another pandemic, unemployment, fluctuations in stock markets, contraction of credit availability, or other factors affecting economic conditions generally. These changes may negatively affect the sales of our existing or development of future products, increase the cost, and decrease the availability of financing, or increase costs associated with producing and distributing our products and potential product candidates.

Moreover, there has been recent turmoil in the global banking system. On March 10, 2023, Silicon Valley Bank ("SVB"), was closed, followed on March 11, 2023 and May 1, 2023, by Signature Bank and First Republic Bank, respectively, and the FDIC was appointed as receiver for those banks. SVB is one of our lenders at which we maintained deposit and money market accounts prior to its closure and have since transferred all of our deposits previously held with the bank to other banking institutions, with the exception of $2.3 million which we maintain in one operating account at SVB. There have been reports of instability at other banks across the globe including Credit Suisse, which was acquired by UBS. Despite the steps taken to date by U.S. agencies to protect depositors and our current belief that we do not have exposure to loss as a result of SVB's receivership, the follow-on effects of the events surrounding the SVB, Signature Bank and First Republic Bank failures and pressure on other banks are unknown and could include failures of other financial institutions or significant disruptions to our operations, financial position, and reputation. A severe or prolonged economic downturn, such as the global financial crisis of 2007-2008, could result in a variety of risks to our business, including a decrease in the demand for our products and in our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our products. We cannot anticipate all the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

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

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

In addition, the preparation of financial statements in conformity with GAAP requires management to make assumptions, estimates and judgments that affect the amounts reported in the 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 revenues 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 failure to comply with regulatory obligations could result in negative effects on our business.

The failure by us or one of our suppliers to comply with applicable regulatory requirements could result in, among other things, the FDA or other governmental authorities:

- imposing fines and penalties on us;
- preventing us from manufacturing or selling our products;

- delaying or denying pending applications for approval or clearance of our products or of new uses or modifications to our existing products, or withdrawing or suspending current approvals or clearances;
- ordering or requesting a recall of our products;
- issuing warning letters or untitled letters;
- imposing operating restrictions, including a partial or total shutdown of production or investigation of any or all of our products;
- refusing to permit to import or export of our products;
- detaining or seizing our products;
- obtaining injunctions preventing us from manufacturing or distributing any or all of our products;
- commencing criminal prosecutions or seeking civil penalties; and
- requiring changes in our advertising and promotion practices.

Failure to comply with applicable regulatory requirements could also result in civil actions against us by private parties (e.g., under the federal Lanham Act and/or state unfair competition laws), and other unanticipated negative consequences. If any of these actions were to occur it could harm our reputation and cause our product sales to suffer and may prevent us from generating revenue.

Our officers, employees, independent contractors, principal investigators, consultants and commercial partners 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, or CROs), principal investigators, consultants and commercial partners may engage in fraudulent conduct or other illegal activity and/or may fail to disclose unauthorized activities to us. Misconduct by these parties could include, but is not limited to, intentional, reckless and/or negligent failures to comply with:

- the laws and regulations of the FDA and its foreign counterparts requiring the reporting of true, complete and accurate information to such regulatory bodies, including but not limited to safety problems associated with the use of our products;
- laws and regulations of the FDA and its foreign counterparts concerning the conduct of clinical trials and the protection of human research subjects;
- other laws and regulations of the FDA and its foreign counterparts relating to the manufacture, processing, packing, holding, investigating or distributing in commerce of medical devices, biological products and/or HCT/Ps; or
- manufacturing standards we have established.

In particular, companies involved in the manufacture of medical products are subject to laws and regulations intended to ensure that medical products that will be used in patients are safe and effective, and specifically that they are not adulterated or contaminated, that they are properly labeled, and have the identity, strength, quality and purity that which they are represented to possess. Further, companies involved in the research and development of medical products are subject to extensive laws and regulations intended to protect research subjects and ensure the integrity of data generated from clinical trials 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. Although we have a comprehensive compliance program designed to ensure that our employees', CRO partners', principal investigators', consultants', and commercial partners' activities and interactions with healthcare professionals and patients are appropriate, ethical, and consistent with all applicable laws, regulations, guidelines, policies and standards, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in preventing such conduct, mitigating risks, or reducing the chance of governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant fines, and other sanctions that may materially impair our ability to run a profitable business.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, results of operations, and financial condition.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, manufacture and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Unanticipated changes in effective tax rates or adverse outcomes resulting from examination of the Company's income or other tax returns could adversely affect the Company's financial condition and results of operations.

The Company is subject to income tax in the United States and Switzerland, and the Company's domestic tax liabilities will be subject to the allocation of expenses in differing jurisdictions. The Company's future effective tax rates could be subject to volatility or adversely affected by a number of factors, including:

- changes in the valuation of the Company's deferred tax assets and liabilities;
- expected timing and amount of the release of any tax valuation allowances;
- tax effects of stock-based compensation;
- costs related to intercompany restructurings;
- changes in tax laws, regulations or interpretations thereof; and
- lower than anticipated future earnings in jurisdictions where the Company has lower statutory tax rates and higher than anticipated future earnings in jurisdictions where the Company has higher statutory tax rates.

In addition, the Company may be subject to audits of the Company's income, sales and other taxes by U.S. federal, state, local and non-U.S. taxing authorities. Outcomes from these audits could have an adverse effect on the Company's financial condition and results of operations.

A market for the Company's securities may not continue, which would adversely affect the liquidity and price of the Company's securities.

The price of the Company's securities may fluctuate significantly due to general market and economic conditions. An active trading market for the Company's securities may never develop or, if developed, it may not be sustained. In addition, the price of the Company's securities can vary due to general economic conditions and forecasts, the Company's general business condition and the release of the Company's financial reports. Additionally, if the Company's securities are not listed on, or become delisted from, Nasdaq for any reason, and are quoted on the OTC Bulletin Board, an inter-dealer automated quotation system for equity securities that is not a national securities exchange, the liquidity and price of the Company's securities may be more limited than if the Company was quoted or listed on Nasdaq or another national securities exchange. You may be unable to sell your securities unless a market can be established or sustained.

The Company's quarterly operating results may fluctuate significantly and could fall below the expectations of securities analysts and investors due to seasonality and other factors, some of which are beyond the Company's control, resulting in a decline in the Company's stock price.

The Company's quarterly operating results may fluctuate significantly because of several factors, including:

- labor availability and costs for hourly and management personnel;
- profitability of the Company's products, especially in new markets and due to seasonal fluctuations;
- changes in interest or exchange rates;

- impairment of long-lived assets;
- macroeconomic conditions, both nationally and locally;
- negative publicity relating to our products;
- changes in consumer preferences and competitive conditions; and
- expansion to new markets.

If securities or industry analysts do not publish or cease publishing research or reports about the Company, its business, or its market, or if they change their recommendations regarding the Company Class A common stock adversely, then the price and trading volume of the Company Class A common stock could decline.

The trading market for the Company Class A common stock will be influenced by the research and reports that industry or securities analysts may publish about us, the Company's business, the Company's market, or the Company's competitors. Securities and industry analysts may stop publishing research on the Company. If any analyst who covers the Company were to cease coverage of the Company or fail to regularly publish reports on it, we could lose visibility in the financial markets, which could cause the Company's stock price or trading volume to decline. If any of the analysts who cover the Company change their recommendation regarding the Company's stock adversely, or provide more favorable relative recommendations about the Company's competitors, the price of the Company Class A common stock would likely decline.

Changes in laws, regulations or rules, or a failure to comply with any laws, regulations or rules, may adversely affect the Company's business, investments and results of operations.

The Company is subject to laws, regulations and rules enacted by national, regional and local governments and Nasdaq. In particular, the Company is required to comply with certain SEC, Nasdaq and other legal or regulatory requirements. Compliance with, and monitoring of, applicable laws, regulations and rules is difficult, time-consuming and costly. Those laws, regulations or rules and their interpretation and application may also change from time to time and those changes could have a material adverse effect on the Company's business, investments and results of operations. In addition, a failure to comply with applicable laws, regulations or rules, as interpreted and applied, could have a material adverse effect on the Company's business and results of operations.

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our securities.

If we fail to satisfy the continued listing requirements of Nasdaq such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our securities. Such a delisting would likely have a negative effect on the price of the securities and would impair your ability to sell or purchase the securities when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our securities to become listed again, stabilize the market price or improve the liquidity of our securities, prevent our securities from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements. Additionally, if our securities are not listed on, or become delisted from, Nasdaq for any reason, trading our common stock could be conducted only in the over-the-counter (OTC) market or on an electronic bulletin board established for unlisted securities such as the OTC Bulletin Board, an inter-dealer automated quotation system for equity securities that is not a national securities exchange, the liquidity and price of our securities may be more limited than if we were quoted or listed on Nasdaq or another national securities exchange. You may be unable to sell your securities unless a market can be established or sustained.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

We recognize the importance of developing, implementing, and maintaining measures to safeguard our information systems and protect the confidentiality, integrity, and availability of our data and to address potential cybersecurity incidents that may materially affect our business.

Our information security team manages and enhances our cybersecurity infrastructure with the ultimate goal of preventing cybersecurity incidents to the extent feasible, while simultaneously increasing our system resilience in an effort to minimize the business impact should an incident occur. We utilize cybersecurity tools, including the Collective Controls Catalog, in assessing the threat landscape and continuously monitoring our environment.

We face a number of cybersecurity risks in connection with our business. We have, from time to time, experienced threats to our data and systems, including malware and computer virus attacks. However, such risks and threats have not materially affected our business strategy, results of operations, or financial condition to date.

Third-party service providers and consultants

Cybersecurity partners are a key part of our cybersecurity infrastructure. We partner with cybersecurity companies and leverage their technology and expertise to better protect the Company. From time to time, we engage certain vendors to monitor our environment, which includes an outsourced security operations center. We may also from time to time engage partners for periodic penetration testing and vulnerability assessments. We intend to continue to work to formalize our cybersecurity program, including developing processes for third-party service provider cyber-risk oversight and management.

Governance

Our cybersecurity organization, led by our Assistant Vice President of IT and our Director of Information Security, is responsible for our overall information security strategy, policy, security engineering, operations and cyber threat detection and response. Within our team, our current Director of Information Security has professional cybersecurity certifications. The Company's Board of Directors administers risk management oversight through the Audit Committee of the Board. Our Audit Committee receives quarterly updates about the effectiveness of the Company's cybersecurity and information security programs, vulnerability and threat detection, progress relative to the Company's cybersecurity roadmap, and the status of projects to strengthen our information security systems. The Audit Committee discusses with Company management and the Board the Company's processes with respect to risk assessment and risk management.

ITEM 2. PROPERTIES

Our corporate headquarters is located on our four-building campus in Canton, Massachusetts, comprising approximately 300,000 square feet of leased and purchased space devoted to manufacturing, shipping, operations, and research and development. Three of the buildings are leased. The leases were initially set to expire on December 31, 2022, and were subsequently extended to December 31, 2027 when we exercised an option to renew these leases for an additional five-year term in December 2021. We lease the buildings in Canton from entities that are controlled by Alan A. Ades, Albert Erani, Dennis Erani and Glenn H. Nussdorf, who are also our stockholders. In addition, Messrs. Ades and Nussdorf are members of our Board of Directors.

In Norwood, Massachusetts, we have a leased facility of approximately 43,850 square feet for office, laboratory, and manufacturing use. The lease commenced on March 13, 2019. The rent commencement date was February 1, 2020. The initial lease term is ten years from the rent commencement date and was extended for additional five years in December 2021. We have an option to extend the term for another ten years if exercised within 16-24 months from the end of the lease term.

We lease smaller facilities in Alabama, California, Florida, and Massachusetts, for manufacturing, warehouse, office, and laboratory space, under agreements with varying expiration dates through 2031.

ITEM 3. LEGAL PROCEEDINGS

On December 10, 2021, a class action complaint captioned Somogyi v. Organogenesis Holdings Inc., et al. was filed on behalf of a putative class of all purchasers of our securities against us and our Chief Executive Officer and Chief Financial Officer in the

United States District Court for the Eastern District of New York. The court appointed Donald Martin as lead plaintiff. Mr. Martin filed an amended complaint on October 24, 2022 that brings claims on behalf of a purported class of all purchasers of our securities from August 10, 2020 through August 9, 2022 and alleges violations of federal securities law in connection with alleged false and misleading statements with respect to, among other matters, revenue, sales growth and ability to compete in connection with our Affinity and PuraPly XT products. The amended complaint alleges violations of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder, and seeks unquantified damages as well as attorneys' fees, expert fees and other costs. The action is in the early stages of litigation. We believe the claims are without merit and intend to vigorously contest them. On March 13, 2023, we filed our motion to dismiss the litigation for failure to state a claim upon which relief can be granted. Briefing was completed on May 30, 2023 and on February 20, 2024, the Court heard oral arguments on the motion to dismiss. The timing for a ruling on the motion to dismiss is currently uncertain.

We are not a party to any other material legal proceedings. From time to time, we may become involved in litigation or other legal proceedings relating to claims arising from the ordinary course of business. These matters may include intellectual property, employment and other general claims. With respect to our outstanding legal matters, based on our current knowledge, we believe that the amount or range of reasonably possible loss will not, either individually or in the aggregate, have a material adverse effect on our business, consolidated financial position, results of operations, or cash flows. However, the outcome of such legal matters is inherently unpredictable and subject to significant uncertainties.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our Class A common stock is listed on the Nasdaq Capital Market under the symbol "ORGO". As of February 26, 2024, a total of 131,963,176 shares of our Class A common stock were outstanding and we had 607 holders of record of our Class A common stock. This number does not include shareholders for whom shares are held in "nominee" or "street" name.

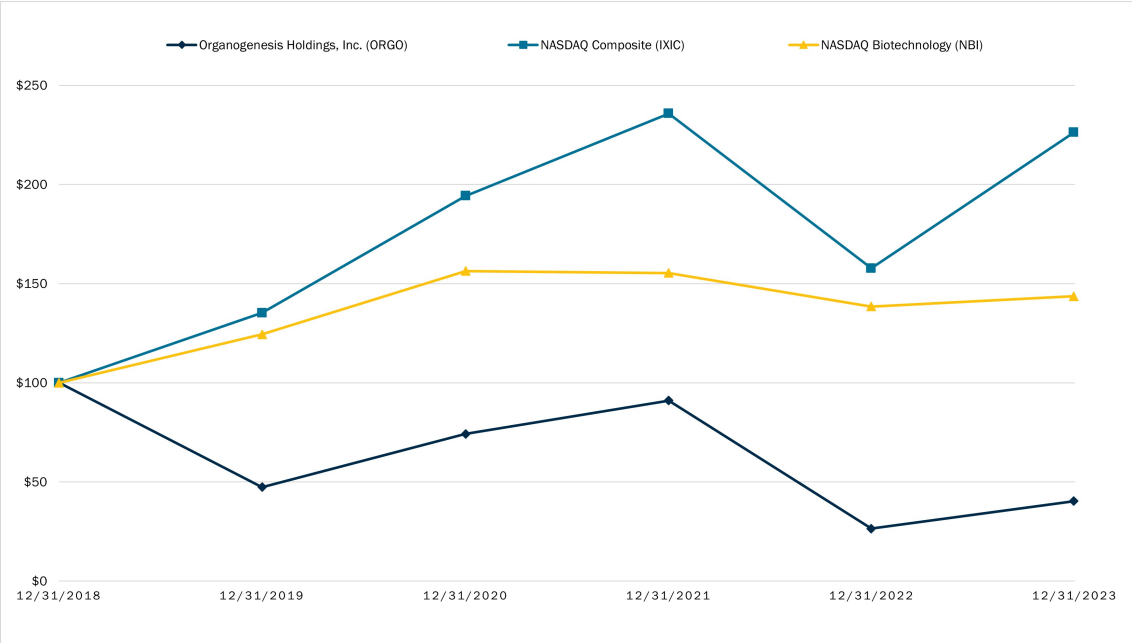
Dividend policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, to finance the growth and development of our business. We do not expect to pay any cash dividends on our Class A common stock in the foreseeable future. In addition, the terms of our 2021 Credit Agreement restrict our ability to pay cash dividends on our capital stock without the bank's consent.

Stock Performance Graph[(1)]

The following graph shows a comparison from December 31, 2018 through December 29, 2023 of cumulative total return on assumed investments of $100.00 in cash in each of our Class A common stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Index. Such returns are based on historical results and are not intended to suggest future performance. Data for the NASDAQ Composite Index and the NASDAQ Biotechnology Index assume reinvestment of dividends.

COMPARISON OF FIVE YEARS CUMULATIVE TOTAL RETURN
Among Organogenesis Holdings Inc., the NASDAQ Composite Index,
and the NASDAQ Biotechnology Index



(1) This performance graph shall not be deemed to be "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that

Section, and shall not be deemed incorporated by reference into any filing of Organogenesis Holdings Inc. under the Securities Act of 1933, as amended.

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors" section of this Annual Report on Form 10-K.

Unless the context otherwise requires, for purposes of this section, the terms we," "us," "our," "the Company," "Organogenesis" and "ORGO" will refer to Organogenesis Holdings Inc. and its subsidiaries as they currently exist.

Overview

Organogenesis is a leading regenerative medicine company focused on the development, manufacture, and commercialization of solutions for the Advanced Wound Care and Surgical & Sports Medicine markets. Our products have been shown through clinical and scientific studies to support and in some cases accelerate tissue healing and improve patient outcomes. We are advancing the standard of care in each phase of the healing process through multiple breakthroughs in tissue engineering and cell therapy. Our solutions address large and growing markets driven by aging demographics and increases in comorbidities such as diabetes, obesity, cardiovascular and peripheral vascular disease. We offer our differentiated products and in-house customer support to a wide range of health care customers including hospitals, wound care centers, government facilities, ASCs and physician offices. Our mission is to provide integrated healing solutions that substantially improve medical outcomes and the lives of patients while lowering the overall cost of care.

We offer a comprehensive portfolio of products in the markets we serve that address patient needs across the continuum of care. We have and intend to continue to generate data from clinical trials, real-world outcomes and health economics research that validate the clinical efficacy and value proposition offered by our products. Several of our existing and pipeline products in our portfolio have PMA, or 510(k) clearance from the FDA. Given the extensive time and cost required to conduct clinical trials and receive FDA approvals, we believe that our data and regulatory approvals provide us with a strong competitive advantage. Our product development expertise and multiple technology platforms provide a robust product pipeline, which we believe will drive future growth.

In the Advanced Wound Care market, we focus on the development and commercialization of advanced wound care products for the treatment of chronic and acute wounds in various treatment settings. We have a comprehensive portfolio of regenerative medicine products capable of supporting patients from early in the wound healing process through wound closure regardless of wound type. Our Advanced Wound Care products include Apligraf for the treatment of VLUs and DFUs; Dermagraft for the treatment of DFUs (manufacturing and distribution currently suspended pending transition to a new manufacturing facility or engagement of a third-party manufacturer); PuraPly AM and PuraPly XT as antimicrobial barriers and native, cross-linked ECM scaffold for a broad variety of wound types; and Affinity, Novachor and NuShield placental allografts to address a variety of wound sizes and types as a protective barrier and ECM scaffold. We have a highly trained and specialized direct wound care sales force paired with comprehensive customer support services.

In the Surgical & Sports Medicine market, we are leveraging our broad regenerative medicine capabilities to address chronic and acute surgical wounds and tendon and ligament injuries. Our Sports Medicine products include NuShield for surgical applications in targeted soft tissue repairs; and Affinity, Novachor, PuraPly MZ, PuraPly AM, and PuraPly SX for management of open wounds in the surgical setting. We currently sell these products through independent agencies and our direct sales force.

We generated net revenue of $433.1 million, $450.9 million, and $467.4 million for the years ended December 31, 2023, 2022, and 2021, respectively. We reported net income of $4.9 million, $15.5 million, and $94.2 million (which includes a $48.3 million benefit from release of a tax valuation allowance) for the years ended December 31, 2023, 2022, and 2021, respectively. While we reported net income for the most recent four years, we have incurred significant losses since inception and we may incur operating losses in the future as we expend resources as part of our efforts to grow our organization to support the planned expansion of our business. As of December 31, 2023, we had an accumulated deficit of $41.0 million. Our primary sources of capital to date have been from sales of our products, borrowings from related parties and institutional lenders and proceeds from the sale of our Class A common stock. We operate as one segment of regenerative medicine.

CPN Acquisition

On September 17, 2020, we acquired certain assets and assumed certain liabilities of CPN Biosciences, LLC (CPN) pursuant to an asset purchase agreement dated July 24, 2020, which was accounted for using the acquisition method of accounting in accordance with applicable accounting standards. The aggregated consideration amounted to $19.0 million as of the acquisition date which consisted of $6.4 million in cash, 2,151,438 shares of our common stock with a fair value of $8.8 million, and a contingent consideration (the Earnout) with a fair value at such time of $3.8 million. At the closing, we paid $5.8 million in cash and issued 1,947,953 shares of our Class A common stock. The remaining consideration of $1.4 million was held back and was released in April 2022 by the Company paying $0.6 million in cash and issuing 203,485 shares of the Company's Class A common stock to the former equity holders of CPN. As of the conclusion of the Earnout period on June 30, 2022, the Company calculated the Earnout liability to be $0. The results of operations of CPN have been included in our consolidated financial statements beginning on the acquisition date.

Dermagraft

As previously disclosed, manufacturing of Dermagraft was suspended in the fourth quarter of 2021 and sales of Dermagraft were suspended in the second quarter of 2022. We currently plan to transition our Dermagraft manufacturing to a new manufacturing facility or engage a third-party manufacturer, which we expect will result in substantial long-term cost savings. In the period when Dermagraft is not available, we expect that customers will be willing to substitute Apligraf for Dermagraft and that the suspension of Dermagraft sales will not have a material impact on our net revenue. However, if we do not realize the expected substantial long-term cost savings or if customers are unwilling to substitute Apligraf for Dermagraft during the period in which Dermagraft is unavailable, it could have an adverse effect on our net revenue and results of operations.

Local Coverage Determinations

In August 2023, three MACs issued LCDs eliminating coverage for DFUs and VLUs for over 130 products, including five of our commercially marketed products. The LCDs were scheduled to take effect on September 17, 2023, and subsequently delayed to October 1, 2023. Given the potential adverse impact these LCDs could have on patients and on our business, we worked with our advisors to convince the MACs to withdraw the LCDs and incurred legal expenses and compensation expenses related to retention for impacted sales employees of $1.2 million and $0.7 million, respectively, for the year ended December 31, 2023. On September 28, 2023, the three MACs withdrew the LCDs. Notwithstanding the ultimate withdrawal of the LCDs, we believe that some of our customers elected to purchase covered products from our competitors, reducing our revenue for the third and fourth quarters of fiscal 2023.

License And Manufacturing Agreement

In November 2023, we entered into a trademark license and manufacturing agreement with Vivex to sell its Dual and Matrix products, with the option to license the VIA products. We paid an upfront licensing fee to Vivex to sell Dual and Matrix, and also agreed to pay a fixed milestone payment for Dual in the event that its ASP is published by certain government agencies for a specified period of time. In addition, the Company is required to pay a low double-digit royalty and a high single-digit royalty on the Net Sales of Dual and Matrix, respectively, during the royalty term, as defined in the agreement with Vivex. The royalty term is commensurate with the initial term of the contract and will continue for each subsequent renewal period. The initial term of the agreement expires on December 31, 2026 and can be renewed for up to five additional one-year terms. We paid $5.0 million in upfront licensing fees in the fourth quarter of 2023, and accrued an additional $2.5 million for a milestone payment that we have determined we are probable of owing to Vivex.

Management's Use of Non-GAAP Measures

Our management uses financial measures that are not in accordance with GAAP (Non-GAAP), in addition to financial measures in accordance with GAAP, to evaluate our operating results. These Non-GAAP financial measures should be considered supplemental to, and not a substitute for, our reported financial results prepared in accordance with GAAP. Our management uses Adjusted EBITDA to evaluate our operating performance and trends and make planning decisions. Our management believes Adjusted EBITDA helps identify underlying trends in our business that could otherwise be masked by the effect of the items that we exclude. Accordingly, we believe that Adjusted EBITDA provides useful information to investors and others in understanding and evaluating our operating results, enhancing the overall understanding of our past performance and future prospects, and allowing for greater transparency with respect to key financial metrics used by our management in its financial and operational decision-making.

We define EBITDA as net income (loss) before depreciation and amortization, interest expense and income taxes. We define Adjusted EBITDA as EBITDA, further adjusted for the impact of certain items that we do not consider indicative of our core operating performance. These items include non-cash equity compensation, restructuring charges, recovery of certain notes receivable from related parties, write-off of the capitalized costs related to certain unfinished construction work and other long-term assets, the change in the fair value of the earnout liability in connection with the CPN acquisition, fees paid in connection with settlement of previously disputed GPO fees, loss on the extinguishment of debt, and the cancellation fee for terminating certain agreements or pausing a certain construction project. We have presented Adjusted EBITDA in this Annual Report on Form 10-K because it is a key measure used by our management and Board of Directors to understand and evaluate our operating performance, generate future operating plans and make strategic decisions regarding the allocation of capital. In particular, we believe that the exclusion of certain items in calculating Adjusted EBITDA can produce a useful measure for period-to-period comparisons of our business.

Our Adjusted EBITDA is not prepared in accordance with GAAP, and should not be considered in isolation of, or as an alternative to, measures prepared in accordance with GAAP. There are a number of limitations related to the use of Adjusted EBITDA rather than net income (loss), which is the most directly comparable financial measure calculated and presented in accordance with GAAP. Some of these limitations are:

- Although depreciation and amortization are non-cash charges, the assets that we currently depreciate and amortize will likely have to be replaced in the future, and Adjusted EBITDA does not reflect the cash required to fund such replacements;
- Adjusted EBITDA does not reflect interest expense or the cash requirements necessary to service payments on our debt;
- Adjusted EBITDA excludes stock-based compensation expense which has been, and will continue to be for the foreseeable future, a significant recurring non-cash expense for our business and an important part of our compensation strategy;
- Adjusted EBITDA does not reflect the effect of earnings or charges resulting from matters that our management does not consider to be indicative of our ongoing operations. However, some of these charges and gains (such as restructuring charge, mark-to-market adjustments, etc.) have recurred and may recur; and
- Other companies, including companies in our industry, may calculate Adjusted EBITDA differently, which reduces its usefulness as a comparative measure.

Because of these limitations, we consider, and you should consider, Adjusted EBITDA together with other operating and financial performance measures presented in accordance with GAAP. A reconciliation of Adjusted EBITDA from net income (loss), the most directly comparable financial measure calculated in accordance with GAAP, has been included herein.

Components of Our Consolidated Results of Operations

In assessing the performance of our business, we consider a variety of performance and financial measures. We believe the items discussed below provide insight into the factors that affect these key measures.

Revenue

We derive our net revenue from our portfolio of Advanced Wound Care and Surgical & Sports Medicine products. We primarily sell our Advanced Wound Care products through direct sales representatives who manage and maintain the sales relationships with hospitals, wound care centers, government facilities, ASCs, and physician offices. We primarily sell our Surgical & Sports Medicine products through third-party agencies. As of December 31, 2023, we had approximately 260 direct sales representatives and approximately 160 independent agencies.

We recognize revenue from sales of our Advanced Wound Care and Surgical & Sports Medicine products when the customer obtains control of our product, which occurs at a point in time and may be upon procedure date, shipment, or delivery, based on the contractual terms of a contract. We record revenue net of a reserve for returns, discounts and GPO rebates, which represent a direct reduction to the revenue we recognize.

Several factors affect our reported revenue in any period, including product, payer and geographic sales mix, operational effectiveness, pricing realization, marketing and promotional efforts, the timing of orders and shipments, regulatory actions including healthcare reimbursement scenarios, competition and business acquisitions.

Cost of goods sold and gross profit

Cost of goods sold includes personnel costs, product testing costs, quality assurance costs, raw materials and product costs, manufacturing costs, and the costs associated with our manufacturing and warehouse facilities. The changes in our cost of goods sold correspond with the changes in sales units and are also affected by product mix.

Gross profit is calculated as net revenue less cost of goods sold and generally increases as revenue increases. Our gross profit is affected by product and geographic sales mix, realized pricing of our products, the efficiency of our manufacturing operations and the costs of materials used and fees charged by third-party manufacturers to produce our products. Regulatory actions, including healthcare reimbursement scenarios, which may require costly expenditures or result in pricing pressures, may decrease our gross profit.

Selling, general and administrative expenses

Selling, general and administrative expenses generally include personnel costs for sales, marketing, sales support, customer support, and general and administrative personnel, sales commissions, incentive compensation, insurance, professional fees, depreciation, amortization, bad debt expense, royalties, information systems costs, gain or loss on disposal of long-lived assets, and costs associated with our administrative facilities. We generally expect our selling, general and administrative expenses to continue to increase due to increased investments in market development and the geographic expansion of our sales forces as we drive for continued revenue growth.

Research and development expenses

Research and development expenses include expenses for clinical trials, personnel costs for our research and development personnel, expenses related to improvements in our manufacturing processes, enhancements to our currently available products, and additional investments in our product and platform development pipeline. We expense research and development costs as incurred. We generally expect that research and development expenses will increase as we continue to conduct clinical trials on new and existing products, move products through the regulatory pathway (e.g., seek BLA approval), add personnel to support product enhancements as well as to bring new products to market, and enhance our manufacturing process and procedures.

Other expense, net

Interest expense, net—Interest expense, net consists of interest on our outstanding indebtedness, including amortization of debt discount and debt issuance costs, net of interest income recognized.

Loss on the extinguishment of debt— In August 2021, upon entering into the 2021 Credit Agreement, we paid an aggregate amount of $70.6 million associated with the termination of the 2019 Credit Agreement, including unpaid principal, accrued interest, the Final Payment and a prepayment fee. We recognized $1.9 million as loss on the extinguishment of the loan for the year ended December 31, 2021.

Income taxes

We account for income taxes using an asset and liability approach. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Valuation allowances are provided when necessary to reduce net deferred tax assets to an amount that is more likely than not to be realized.

In determining whether a valuation allowance for deferred tax assets is necessary, we analyze both positive and negative evidence related to the realization of deferred tax assets including projected future taxable income, recent financial results and estimates of future reversals of deferred tax assets and liabilities. In addition, we consider whether it is more likely than not that the

tax position will be sustained on examination by taxing authorities based on the technical merits of the position. In consideration of the factors discussed above, in the fourth quarter of 2021, we determined it was more likely than not that our deferred tax assets would be realized in the future and released the valuation allowance on our net U.S. deferred tax assets as of December 31, 2021, resulting in a benefit of $48.3 million in income taxes. We believe that our net U.S. deferred tax assets did not require a valuation allowance as of December 31, 2023.

Our U.S. provision for income taxes relates to current tax expense associated with taxable income that could not be offset by net operating losses or research and development credits. The utilization of our remaining federal net operating losses is subject to an 80% taxable income limitation and for certain states we have no net operating losses remaining to offset state taxable income or the utilization of the remaining state net operating losses are subject to a limitation. We have also recorded a foreign provision for income taxes related to our wholly-owned subsidiary in Switzerland.

We account for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Results of Operations

The following table sets forth, for the periods indicated, our results of operations:

	Year Ended December 31,		
	2023	**2022**	**2021**
Net revenue	$ 433,140	$ 450,893	$ 467,359
Cost of goods sold	106,481	105,019	114,199
Gross profit	326,659	345,874	353,160
Operating expenses:			
Selling, general and administrative	269,754	283,808	250,200
Research and development	44,380	39,762	30,742
Total operating expenses	314,134	323,570	280,942
Income from operations	12,525	22,304	72,218
Other expense, net:			
Interest expense, net	(2,190)	(2,009)	(7,236)
Loss on the extinguishment of debt	—	—	(1,883)
Other income (loss), net	57	(13)	(13)
Total other expense, net	(2,133)	(2,022)	(9,132)
Net income before income taxes	10,392	20,282	63,086
Income tax (expense) benefit	(5,447)	(4,750)	31,116
Net income and comprehensive income	$ 4,945	$ 15,532	$ 94,202

EBITDA and Adjusted EBITDA

The following table presents a reconciliation of GAAP net income to non-GAAP EBITDA and non-GAAP Adjusted EBITDA, for each of the periods presented:

	Year Ended December 31,		
	2023	2022	2021
	(in thousands)		
Net income	$ 4,945	$ 15,532	$ 94,202
Interest expense, net	2,190	2,009	7,236
Income tax expense (benefit)	5,447	4,750	(31,116)
Depreciation	10,448	5,845	5,781
Amortization	4,918	4,883	4,949
EBITDA	27,948	33,019	81,052
Stock-based compensation expense	8,996	6,552	3,864
Restructuring charge (1)	3,796	2,268	4,704
Recovery of certain notes receivable from related parties (2)	—	—	(179)
Write-off of certain assets (3)	—	4,200	1,104
Change in fair value of earnout (4)	—	—	(3,985)
Settlement fee (5)	—	2,600	700
Loss on extinguishment of debt (6)	—	—	1,883
Facility construction project pause (7)	—	632	—
Legal and consulting fees (8)	1,182	—	—
Sales retention (9)	694	—	—
Adjusted EBITDA	$ 42,616	$ 49,271	$ 89,143

(1) Amounts reflect employee retention and benefits as well as other exit costs associated with the Company's restructuring activities. See Note 11, *Restructuring*, to our audited consolidated financial statements included in this Annual Report on Form 10-K.

(2) Amounts reflect the collection of certain notes receivable from related parties previously reserved. See Note 19, *Related Party Transactions*, to our audited consolidated financial statements included in this Annual Report on Form 10-K.

(3) Amount in 2021 reflects the write-off of certain design and consulting fees previously capitalized related to the construction in progress at one of the Company's Canton, Massachusetts facilities. Amount in 2022 reflects the disposal of certain equipment related to the same facility. See Note 8, *Property and Equipment, Net*, to our audited consolidated financial statements included in this Annual Report on Form 10-K.

(4) Amounts reflect the change in the fair value of the earnout liability in connection with the CPN acquisition. See Note 3, *Acquisition* to our audited consolidated financial statements included in this Annual Report on Form 10-K.

(5) Amounts reflect the fee the Company paid to a GPO to settle previously disputed GPO fees. See Note 2, *Significant Accounting Policies* to our audited consolidated financial statements included in this Annual Report on Form 10-K.

(6) Amount reflects the loss recognized on the extinguishment of the 2019 Credit Agreement upon repayment in 2021. See Note 12, *Long-Term Debt Obligations*, to our audited consolidated financial statements included in this Annual Report on Form 10-K.

(7) Amount reflects the cancellation fees incurred in connection with the Company's decision to pause one of its manufacturing facility construction projects.

(8) Amount reflects the legal and consulting fees incurred related to the recently published and withdrawn LCDs.

(9) Amount reflects the compensation expenses related to retention for those sales employees impacted by the recently published and withdrawn LCDs.

Comparison of the Years Ended December 31, 2023, 2022, and 2021

Revenue

	Years Ended December 31,			Change			
	2023	2022	2021	2023 to 2022		2022 to 2021	
	(in thousands, except for percentages)						
Advanced Wound Care	$ 405,514	$ 422,231	$ 430,237	$ (16,717)	(4%)	$ (8,006)	(2%)
Surgical & Sports Medicine	27,626	28,662	37,122	(1,036)	(4%)	(8,460)	(23%)
Net revenue	$ 433,140	$ 450,893	$ 467,359	$ (17,753)	(4%)	$ (16,466)	(4%)

For the year ended December 31, 2023, net revenue from our Advanced Wound Care products decreased by $16.7 million, or 4%, as compared to the year ended December 31, 2022. The decrease in Advanced Wound Care net revenue was primarily attributable to a decrease in sales of certain of our products due to changes in customer buying patterns as well as the impact of the recently withdrawn LCDs on sales of certain of our products, partially offset by an increase in sales of certain of our products to our existing and new customers.

For the year ended December 31, 2023, net revenue from our Surgical & Sports Medicine products decreased by $1.0 million, or 4%, as compared to the year ended December 31, 2022. The decrease in Surgical & Sports Medicine net revenue was primarily due to a shift in distributor focus.

For the year ended December 31, 2022, net revenue from our Advanced Wound Care products decreased by $8.0 million, or 2%, as compared to the year ended December 31, 2021. The decrease in Advanced Wound Care net revenue was primarily attributable to a decrease in sales of certain of our non-PuraPly products and the settlement fee with a GPO recorded as a direct reduction of revenue in the year ended December 31, 2022.

For the year ended December 31, 2022, net revenue from our Surgical & Sports Medicine products decreased by $8.5 million, or 23%, as compared to the year ended December 31, 2021. The decrease in Surgical & Sports Medicine net revenue was primarily due to the continued impact of the suspension of marketing of our ReNu and NuCel products in connection with the expiration of the FDA's enforcement grace period on May 31, 2021.

Cost of Goods Sold and Gross Profit

	Years Ended December 31,			Change			
	2023	2022	2021	2023 to 2022		2022 to 2021	
	(in thousands, except for percentages)						
Cost of goods sold	$ 106,481	$ 105,019	$ 114,199	$ 1,462	1%	$ (9,180)	(8%)
Gross profit	$ 326,659	$ 345,874	$ 353,160	$ (19,215)	(6%)	$ (7,286)	(2%)

For the year ended December 31, 2023, cost of goods sold increased by $1.5 million, or 1%, as compared to the year ended December 31, 2022. The increase in cost of goods sold was primarily due to product mix.

For the year ended December 31, 2023, gross profit decreased by $19.2 million, or 6%, as compared to the year ended December 31, 2022. The decrease in gross profit resulted primarily from a decrease in the pricing for certain of our products, as well as a shift in product mix.

For the year ended December 31, 2022, cost of goods sold decreased by $9.2 million, or 8%, as compared to the year ended December 31, 2021. The decrease in cost of goods sold was primarily due to decreased sales volume in our Advanced Wound Care and Surgical & Sports Medicine products.

For the year ended December 31, 2022, gross profit decreased by $7.3 million, or 2%, as compared to the year ended December 31, 2021. The decrease in gross profit resulted primarily from decreased sales volume and increased manufacturing-related costs, partially offset by a shift in product mix to our higher gross margin products.

Selling, General and Administrative Expenses

	Years Ended December 31,			Change			
	2023	2022	2021	2023 to 2022		2022 to 2021	
	(in thousands, except for percentages)						
Selling, general and administrative	$ 269,754	$ 283,808	$ 250,200	$ (14,054)	(5%)	$ 33,608	13%

For the year ended December 31, 2023, selling, general and administrative expenses decreased by $14.1 million, or 5%, as compared to the year ended December 31, 2022. The decrease in selling, general and administrative expenses was primarily due to a $6.1 million decrease in compensation and restructuring, largely related to decreased commissions paid to our sales force; a $4.4 million decrease primarily related to disposal of certain equipment related to the construction in progress in one of the Company's Canton, Massachusetts facilities; a $1.5 million decrease in royalty expenses, and a $3.3 million decrease in travel-related expenses. These expenses were partially offset by a $1.2 million increase in legal and consulting costs primarily related to efforts to convince three MACs to withdraw the final LCDs for skin substitutes for the treatment of DFUs and VSUs.

For the year ended December 31, 2022, selling, general and administrative expenses increased by $33.6 million, or 13%, as compared to the year ended December 31, 2021. The increase in selling, general and administrative expenses was primarily due to a $12.2 million increase related to additional headcount, primarily in our direct sales force, a $10.0 million increase related to increased travel and marketing programs amid the relaxed COVID-19 travel restrictions, a $5.6 million increase in legal, royalty and consulting costs associated with the ongoing operations of our business and the ERP system implementation, and a $4.2 million charge for disposal of certain equipment related to the construction in progress at one of the Company's Canton Massachusetts facilities and $0.6 million cancellation fees incurred in connection with the Company's decision to pause the construction project for the same facility. In addition, in the year ended December 31, 2021, the Company recorded a $4.0 million reduction to the selling, general and administrative expenses related to the CPN Earnout fair value adjustments. These increases were partially offset by a $1.7 million miscellaneous decrease and a $1.3 million decrease in restructuring costs due to the smaller scale of the restructuring activities associated with closing the Birmingham office in 2022 as compared to the restructuring activities associated with closing the La Jolla office in 2021.

Research and Development Expenses

	Years Ended December 31,			Change			
	2023	2022	2021	2023 to 2022		2022 to 2021	
	(in thousands, except for percentages)						
Research and development	$ 44,380	$ 39,762	$ 30,742	$ 4,618	12%	$ 9,020	29%

For the year ended December 31, 2023, research and development expenses increased by $4.6 million, or 12%, as compared to the year ended December 31, 2022. The increase in research and development expenses was primarily driven by an increase in compensation expenses of $2.2 million, due to increased headcount associated with our existing Advanced Wound Care and Surgical & Sports Medicine products, an increase of $2.4 million in other clinical research and consulting costs associated with our pipeline products not yet commercialized, and an increase in the clinical study and related costs necessary to seek regulatory approvals for certain of our product candidates.

For the year ended December 31, 2022, research and development expenses increased by $9.0 million, or 29%, as compared to the year ended December 31, 2021. The increase in research and development expenses was primarily due to increased headcount associated with our existing Advanced Wound Care and Surgical & Sports Medicine products, an increase in product costs associated with our pipeline products not yet commercialized and an increase in the clinical study and related costs necessary to seek regulatory approvals for certain of our products.

Other Expense, Net

	Years Ended December 31,			Change			
	2023	2022	2021	2023 to 2022		2022 to 2021	
	(in thousands, except for percentages)						
Interest expense, net	$ (2,190)	$ (2,009)	$ (7,236)	$ (181)	9%	$ 5,227	(72%)
Loss on the extinguishment of debt	—	—	(1,883)	—	**	1,883	(100%)
Other income (expense), net	57	(13)	(13)	70	(538%)	—	0%
Total other expense, net	$ (2,133)	$ (2,022)	$ (9,132)	$ (111)	5%	$ 7,110	(78%)

** not meaningful

For the year ended December 31, 2023, total other expense, net, increased by $0.1 million, or 5%, as compared to the year ended December 31, 2022. The increase resulted primarily from increases in interest rates in 2023.

For the year ended December 31, 2022, total other expense, net, decreased by $7.1 million, or 78%, as compared to the year ended December 31, 2021. The decrease in interest expense in 2022 resulted from the lower interest rate for the borrowings under the 2021 Credit Agreement. Loss on extinguishment of debt of $1.9 million in 2021 was related to loss recognized on the extinguishment of the 2019 Credit Agreement upon repayment in August 2021.

Income Tax (Expense) Benefit

	Years Ended December 31,			Change			
	2023	2022	2021	2023 to 2022		2022 to 2021	
	(in thousands, except for percentages)						
Income tax (expense) benefit	$ (5,447)	$ (4,750)	$ 31,116	$ (697)	15%	$ (35,866)	(115%)

For the year ended December 31, 2023, income tax expense of $5.4 million included $3.4 million of current income taxes and $2.0 million of deferred income taxes. The effective tax rate for 2023 was 52.4% and was computed based on the statutory rate of 21% adjusted primarily for state and local income taxes, nondeductible officer compensation and certain meals and other expenses that were fully deductible in prior years pursuant to temporary relief provisions enacted as part of the Taxpayer Certainty and Disaster Tax Relief Act for tax years 2021 and 2022, but that are now subject to a deduction limitation.

For the year ended December 31, 2022, income tax expense of $4.8 million included $2.8 million of current income taxes and $2.0 million of deferred income taxes. The effective tax rate for 2022 was 23.4% and was computed based on the statutory rate of 21% adjusted primarily for state and local income taxes, nondeductible officer compensation and an out-of-period adjustment for an error included in the beginning balance of the deferred tax asset. For the year ended December 31, 2021, income tax benefit was $31.1 million, which primarily resulted from the release of the valuation allowance previously recorded against the full amount of our net U.S. deferred tax assets as of December 31, 2021. See Note 15, *Income Taxes* to our audited consolidated financial statements included in this Annual Report on Form 10-K.

Liquidity and Capital Resources

Since our inception, we have funded our operations and capital expenditures through cash flows from product sales, loans from affiliates and entities controlled by certain of our affiliates, third-party debt and proceeds from the sale of our capital stock. As of December 31, 2023, we had an accumulated deficit of $41.0 million and working capital of $144.5 million which included $103.8 million in cash and cash equivalents. We also have $125.0 million available for future revolving borrowings under our Revolving Facility (see Note 12, *Long-Term Debt Obligations*, to our audited consolidated financial statements included in this Annual Report on Form 10-K). For the year ended December 31, 2023, we reported $433.1 million in net revenue, $4.9 million in net income and $30.9 million of cash inflows from operating activities. We expect that our cash on hand and other components of working capital as of December 31, 2023, availability under the 2021 Credit Agreement, plus net cash flows from product sales, will be sufficient to fund our operating expenses, capital expenditure requirements and debt service payments for at least 12 months beyond the filing date of this Annual Report on Form 10-K.

Our primary uses of cash are working capital requirements, capital expenditure and debt service payments. Additionally, from time to time, we may use capital for acquisitions and other investing and financing activities. Working capital is used principally for our personnel as well as manufacturing costs related to the production of our products. Our working capital requirements vary from period to period depending on manufacturing volumes, the timing of shipments and the payment cycles of our customers and payers.

Our capital expenditures consist primarily of building improvements, manufacturing equipment, and computer hardware and software.

To the extent additional funds are necessary to meet our long-term liquidity needs as we continue to execute on our business strategy, we anticipate that they will be obtained through additional equity or debt financings, other strategic transactions or a combination of these potential sources of funds. There can be no assurance that we will be able to obtain additional funds on terms acceptable to us, on a timely basis or at all.

The following table presents our cash and outstanding debt as of the dates indicated:

	December 31,	
	2023	2022
	(in thousands)	
Cash and cash equivalents	$ 103,840	$ 102,478
Line of credit	$ —	$ —
Term loan net of debt discount and issuance cost	66,231	70,769
Finance lease obligations	2,969	—
Total debt	$ 69,200	$ 70,769

Under the Revolving Facility, we have up to $125.0 million available for future revolving borrowings, subject to maintaining compliance with financial and non-financial covenants.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	Year Ended December 31,		
	2023	2022	2021
	(in thousands)		
Net cash provided by operating activities	$ 30,917	$ 24,859	$ 61,978
Net cash used in investing activities	(24,364)	(33,898)	(31,220)
Net cash used in financing activities	(5,505)	(2,199)	(1,036)
Net increase (decrease) in cash and restricted cash	$ 1,048	$ (11,238)	$ 29,722

Operating Activities

During the year ended December 31, 2023, net cash provided by operating activities was $30.9 million, resulting from our net income of $4.9 million, non-cash charges of $44.0 million, partially offset by net cash used in connection with changes in our operating assets and liabilities of $18.1 million. Net cash used in changes in our operating assets and liabilities included an increase in inventories and prepaid expenses of a total of $18.3 million, and a decrease in net operating lease liabilities of $8.4 million, partially offset by an increase in accounts payable, accrued expenses, and other current and noncurrent liabilities of $3.1 million, and a decrease in accounts receivable of $5.5 million.

During the year ended December 31, 2022, net cash provided by operating activities was $24.9 million, resulting from our net income of $15.5 million, non-cash charges of $43.4 million, partially offset by net cash used in connection with changes in our operating assets and liabilities of $34.1 million. Net cash used in changes in our operating assets and liabilities included an increase in accounts receivable of $8.8 million, an increase in inventory and prepaid expenses of $9.8 million, a decrease in operating lease liability of $7.0 million and a decrease of accrued expenses of $11.9 million, all of which were partially offset by an increase in accounts payable and other liabilities of $3.3 million.

During the year ended December 31, 2021, net cash provided by operating activities was $62.0 million, resulting from our net income of $94.2 million, non-cash charges of $4.8 million, partially offset by net cash used in connection with changes in our operating assets and liabilities of $37.0 million. The non-cash charges of $4.8 million consisted of $36.8 million standard non-cash items primarily related to depreciation and amortization, stock-based compensation expense, and inventory reserve, partially offset by the deferred tax benefit of $32.0 million primarily resulting from the release of the valuation allowance previously recorded against the full amount of our net U.S. deferred tax assets as of December 31, 2021. Net cash used in changes in our operating assets and liabilities included an increase in accounts receivable of $28.7 million, an increase in inventory of $9.3 million, and a decrease

in operating leases and other liabilities of $12.2 million, all of which were partially offset by an increase in accounts payable, accrued expenses and other current liabilities of $13.2 million.

Investing Activities

During the year ended December 31, 2023, we used $24.4 million of cash in investing activities solely consisting of capital expenditures.

During the year ended December 31, 2022, we used $33.9 million of cash in investing activities solely consisting of capital expenditures.

During the year ended December 31, 2021, we used $31.2 million of cash in investing activities solely consisting of capital expenditures.

Financing Activities

During the year ended December 31, 2023, net cash used in financing activities was $5.5 million. This consisted primarily of principal payments on the Term Loan of $4.7 million, and on finance lease obligations of $0.5 million, and payments of $0.3 million in connection with stock awards activities.

During the year ended December 31, 2022, net cash used in financing activities was $2.2 million. This consisted primarily of the payment of term loan and finance lease obligations of $3.0 million and the payment of $0.6 million related to the CPN deferred acquisition consideration, partially offset by the net receipts of $1.4 million in connection with stock awards activities.

During the year ended December 31, 2021, net cash used in financing activities was $1.0 million. This consisted primarily of the repayment of borrowings of $70.0 million under the 2019 Credit Agreement, the payment of $1.6 million to extinguish this debt facility, the payment of finance lease obligations of $2.6 million, and the payment of $2.2 million related to other financing activities. The net cash used in financing activities was principally offset by $73.2 million in net proceeds from the 2021 Credit Agreement and $2.2 million in proceeds from the exercise of common stock options.

Indebtedness

2021 Credit Agreement

In August 2021, we and our subsidiaries entered into a credit agreement with SVB and several other lenders, which we refer to as the 2021 Credit Agreement. The 2021 Credit Agreement, as amended, provides for a term loan facility not to exceed $75.0 million (the Term Loan Facility) and a revolving credit facility not to exceed $125.0 million (the Revolving Facility).

Advances made under the 2021 Credit Agreement may be either SOFR Loans or ABR Loans, at our option. For SOFR Loans, the interest rate is a per annum interest rate equal to the Adjusted Term SOFR plus an Applicable Margin between 2.00% to 3.25% based on the Total Net Leverage Ratio. For ABR Loans, the interest rate is equal to (1) the highest of (a) the Wall Street Journal Prime Rate, (b) the Federal Funds Rate plus 0.50% and (c) the Adjusted Term SOFR rate plus 1.0%, *plus* (2) an Applicable Margin between 1.00% to 2.25% based on the Total Net Leverage Ratio. On December 31, 2023, the applicable interest rate for outstanding borrowings is 7.44%.

The 2021 Credit Agreement requires us to make consecutive quarterly installment payments equal to the following: (a) from September 30, 2021 through and including June 30, 2022, $0.5 million; (b) from September 30, 2022 through and including June 30, 2023, $0.9 million; (c) from September 30, 2023 through and including June 30, 2025, $1.4 million and (d) from September 30, 2025 and the last day of each quarter thereafter until August 6, 2026 (the "Term Loan Maturity Date"), $1.9 million. The remaining principal balance of $50.6 million is also due on the Term Loan Maturity Date. We may prepay the Term Loan Facility. Once repaid, amounts borrowed under the Term Loan Facility may not be re-borrowed.

We must pay in arrears, on the first day of each quarter prior to August 6, 2026 (the "Revolving Termination Date") and on the Revolving Termination Date, a fee for our non-use of available funds (the Commitment Fee). The Commitment Fee rate is between 0.25% to 0.45% based on the Total Net Leverage Ratio. We may elect to reduce or terminate the Revolving Facility in its entirety at any time by repaying all outstanding principal and unpaid accrued interest.

Under the 2021 Credit Agreement, we are required to comply with certain financial covenants including the Consolidated Fixed Charge Coverage Ratio and Consolidated Total Net Leverage Ratio, tested quarterly. In addition, we are also required to make representations and warranties and comply with certain non-financial covenants that are customary in loan agreements of this type, including restrictions on the payment of dividends, repurchase of stock, incurrence of indebtedness, dispositions and acquisitions.

As of December 31, 2023, we were in compliance with the covenants under the 2021 Credit Agreement. We had outstanding borrowings of $66.6 million under our Term Loan Facility and no borrowings outstanding under our Revolving Facility with $125 million available for future revolving borrowings, respectively.

2019 Credit Agreement

In March 2019, we, our subsidiaries and SVB, and several other lenders thereto entered into a credit agreement, as amended (the 2019 Credit Agreement), providing for a term loan facility of $40.0 million and a revolving credit facility of up to $60.0 million. Both facilities were set to mature in 2024. In August 2021, upon entering into the 2021 Credit Agreement, we settled the 2019 Credit Agreement. For a further description of the 2019 Credit Agreement, see Note 12, *Long-Term Debt Obligations*, included in this Annual Report on Form 10-K.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements have been prepared in accordance with GAAP. The preparation of our consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, and the disclosure at the date of the consolidated financial statements, as well as revenue and expenses recorded during the reporting periods. Management bases its estimates, assumptions and judgments on historical experience and on various other factors that it believes to be reasonable under the circumstances. Different assumptions and judgments would change the estimates used in the preparation of our consolidated financial statements, which, in turn, could materially change our results from those reported. Management evaluates its estimates, assumptions and judgments on an ongoing basis. Historically, our critical accounting estimates have not differed materially from actual results. However, if our assumptions change, we may need to revise our estimates or take other corrective actions, either of which may also have a material adverse effect on our consolidated statements of operations, liquidity and financial condition.

We believe the following critical accounting policies involve significant areas where management applies judgments and estimates in the preparation of our consolidated financial statements.

Revenue Recognition

We generate revenue through the sale of Advanced Wound Care and Surgical & Sports Medicine products. There is a single performance obligation in all of our contracts, which is our promise to transfer our product to customers based on specific payment and shipping terms in the arrangement. The entire transaction price is allocated to this single performance obligation. Product revenue is recognized when a customer obtains control of our product which occurs at a point in time and may be upon shipment, procedure date, or delivery, based on the terms of the contract. Revenue is recorded net of a reserve for returns, discounts and GPO rebates, which represent a direct reduction to the revenue we recognize. These reductions are accrued at the time revenue is recognized, based upon historical experience and specific circumstances.

Accounts Receivable, Net

Accounts receivables are stated at invoice value less estimated allowances for credit losses. We continually monitor customer payments and maintain a reserve for estimated losses resulting from our customers' inability to make required payments. We consider factors such as historical experience, credit quality, age of the accounts receivable balances, geography-related risks and economic conditions that may affect a customer's ability to pay. In cases where there are circumstances that may impair a specific customer's ability to meet its financial obligations, a specific allowance is recorded against amounts due, and thereby reduces the net recognized receivable to the amount reasonably believed to be collectible. Accounts receivables are written off when deemed uncollectible. Recoveries of accounts receivables previously written off are recorded when received.

Inventory

Inventory is stated at the lower of cost (determined under the first-in first-out method) or net realizable value. Inventory includes raw materials, work in process and finished goods. It also includes cell banks and the cost of tests mandated by regulatory agencies, of the materials to qualify them for production.

We regularly review inventory quantities on hand and record a provision to write down excess and obsolete inventory to its estimated net realizable value based upon management's assumptions of future material usage, yields and obsolescence, which are a result of future demand and market conditions and the effective life of certain inventory items. Our excess and obsolete inventory review process includes analysis of sales forecasts and historical sales as compared to inventory on hand and working with operations to maximize recovery of excess inventory. The estimate of excess quantities is subjective and primarily dependent on our estimate of future demand for a particular product. If the estimate of future demand is inaccurate based on actual sales, we may increase the write-down for excess inventory for that component.

Income Taxes

We account for income taxes using an asset and liability approach. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Valuation allowances are provided when necessary to reduce net deferred tax assets to an amount that is more likely than not to be realized.

In determining whether a valuation allowance for deferred tax assets is necessary, we analyze both positive and negative evidence related to the realization of deferred tax assets including projected future taxable income, recent financial results and estimates of future reversals of deferred tax assets and liabilities. In addition, we consider whether it is more likely than not that the tax position will be sustained on examination by taxing authorities based on the technical merits of the position. In consideration of the factors discussed above, in the fourth quarter of 2021, we determined it was more likely than not that our deferred tax assets would be realized in the future and released the valuation allowance on our net U.S. deferred tax assets as of December 31, 2021, resulting in a benefit of $48.3 million in income taxes. We maintained the same position that our net U.S. deferred tax assets did not require a valuation allowance as of December 31, 2023.

We account for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Impairment of Long-Lived Assets

We review long-lived assets, excluding goodwill, for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. Factors that we consider in deciding when to perform an impairment review include, but are not limited to, significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. When such an event occurs, we determine whether there has been impairment by comparing the anticipated undiscounted future net cash flows to the related asset group's carrying value. If an asset is determined to be impaired, the asset is written down to fair value, which is determined based on discounted cash flows or appraised value, depending on the nature of the asset. Significant judgments and estimates used by management when evaluating long-lived assets for impairment include: an assessment as to whether an adverse event or circumstance has triggered the need for an impairment review; determination of asset groups, the primary asset within each group, and the primary asset's average estimated useful life; undiscounted future cash flows generated by the assets; and determination of fair value when an impairment is deemed to exist, which may require assumptions related to future general economic conditions, future expected production volumes, product pricing and cost estimates, working capital and capital investment requirements, discount rates and estimated liquidation values.

Off-Balance Sheet Arrangements

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

Recently Issued Accounting Pronouncements

For a description of recently issued accounting pronouncements, including the expected dates of adoption and the estimated effects, if any, on our consolidated financial statements, see Note 2, *Significant Accounting Policies* to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to various market risks, including fluctuations in interest rates and variability in currency exchange rates. We have established policies, procedures and internal processes governing our management of market risk.

Interest Rate Risk

As of December 31, 2023, we had $66.6 million in borrowings outstanding under our Term Loan Facility and no borrowings outstanding under our Revolving Facility, respectively. Borrowings under our 2021 Credit Agreement bear interest at variable rates. Based on the principal amount outstanding as of December 31, 2023, an immediate 10% change in the interest rate would not have a material impact on our financial position, results of operations or cash flows.

Foreign Currency and Market Risk

The majority of our employees and our major operations are currently located in the United States. The functional currency of our foreign subsidiary in Switzerland is the U.S. dollar. We have, in the normal course of business, engaged in contracts with contractors or other vendors in a currency other than the U.S. dollar. To date, we have had minimal exposure to fluctuations in foreign currency exchange rates as the time period from the date that transactions are initiated and the date of payment or receipt of payment is generally of short duration. Accordingly, we believe we do not have a material exposure to foreign currency risk.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements, together with the report of our independent registered public accounting firm, appear on pages F-1 through F-28 of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

The Company's management, with the participation of its principal executive officer and principal financial officer, evaluated the effectiveness of its disclosure controls and procedures as of December 31, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our management, including our principal executive officer and principal financial officer, concluded that, as of December 31, 2023, our disclosure controls and procedures were ineffective because we did not design and maintain effective controls over information technology general controls and proper segregation of duties to support the proper initiation and recording of transactions and the resulting impact on business process controls and applications that rely on such data.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the Company's principal executive officer and principal financial officer and effected by the Company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

Management conducted the assessment of the effectiveness of the Company's internal control over financial reporting based on criteria in the SEC guidance on conducting such assessments as of the end of the period covered by this report. Management

conducted the assessment based on certain criteria established in Internal Control— Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. As a result of this assessment, management concluded that, as of December 31, 2023, our internal control over financial reporting was ineffective due to the material weakness described below. As a result, the disclosure controls and procedures were ineffective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to our management, including the chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding disclosure.

We did not design and maintain effective controls over information technology general controls and proper segregation of duties to support the proper initiation and recording of transactions and the resulting impact on business process controls and applications that rely on such data.

Although management has made certain progress in remediating this material weakness, management concluded that the material weakness described above continued to exist as of December 31, 2023. Management has taken actions to remediate the deficiencies in its internal controls over financial reporting and implemented additional processes and controls designed to address the underlying causes of the above-mentioned material weakness. Management is committed to finalizing the remediation of the material weakness. Management's internal control remediation efforts include the following:

- In 2022, we finalized the plan to implement a new company-wide enterprise resource planning (ERP) system to provide additional systematic controls and segregation of duties for our accounting processes. Due, in part, to turnover in key positions and changes in design, our ERP system go-live date has been delayed. We anticipate the ERP system going live in 2024.
- In 2022, we determined that our forward facing customer sales systems were not catering to our customer needs. We plan to implement a new sales force software system in 2024.
- An outside firm will continue to assist management with performing control operating effectiveness testing throughout the year.
- We regularly reported the results of control testing to the key stakeholders across our organization, including our audit committee, on testing progress and defined corrective actions, and we monitored and reported on the results of control remediation. We have strengthened our internal policies, processes, and reviews through these actions.
- We have continued working on documenting and remediating weaknesses and structuring the Company's processes to meet SOX 404(b) requirements.

As management continues to evaluate and work to improve our internal control over financial reporting, management may determine it is necessary to take additional measures to address the material weakness. However, we believe the above actions will be effective in remediating the remaining material weakness and we will continue to devote significant time and attention to these remediation efforts. Until the controls have been operating for a sufficient period of time and management has concluded, through testing, that these controls are executed consistently and operating effectively, the material weakness described above will continue to exist.

Remediation of Previously Identified Material Weakness

As previously disclosed in Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2022, management concluded that there was a material weakness in our internal control over financial reporting specifically related to our identification and assessment of significant non-routine transactions. In response to the material weakness identified, management developed and implemented a remediation plan to address the underlying causes of the material weakness, which was subject to senior management review and oversight of the audit committee of the Board (the Audit Committee). In addition to the efforts described above, which are in process to remediate the remaining material weakness, the measures taken to remediate the material weakness associated with significant non-routine transactions are described in further detail in the "Changes in Internal Control Over Financial Reporting" section immediately below.

Changes in Internal Control Over Financial Reporting

During the quarter ended December 31, 2023, we concluded the design and implementation of new internal controls, which include review by the accounting function for accounting impacts of all contracts approved by legal, and strengthened existing process level internal controls, in response to the material weakness identified in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 related to the ineffective design and operation of certain internal controls over the identification and assessment of significant non-routine transactions, as described below:

• We have and will continue to train and cross train our employees on their internal control responsibilities and how to best support other control owners if personnel turnover issues within their departments occur. We have also supplemented our internal resources with third-party resources, where necessary.

• We implemented two new controls to ensure that significant transactions are identified and effectively communicated so that they are properly and timely reported. These controls require more frequent and formal cross-functional communication to ensure that the appropriate personnel within the finance and accounting function are made aware of all significant transactions that may have a material accounting impact to the consolidated financial statements.

Based on these activities, management has concluded that these remediation activities have addressed the material weakness related to the identification and assessment of significant non-routine transactions and believes that the design and operation of these controls address the related risks of material misstatement to such transactions and related consolidated financial statement line items and disclosures.

As the implementation of the new ERP system continues and our remediation efforts for the remaining material weakness continue, we will continue to change our processes and procedures, which in turn, could result in changes to our internal control over financial reporting. As such changes occur, we will evaluate quarterly whether such changes materially affect our internal control over financial reporting.

Attestation Report of the Registered Public Accounting Firm

The effectiveness of the Company's internal control over financial reporting as of December 31, 2023, has been audited by RSM US LLP, an independent registered public accounting firm, as stated in their attestation report, which appears in Item 8 above.

ITEM 9B. OTHER INFORMATION

During the three months ended December 31, 2023, no director or officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-rule 10b5-1 trading arrangement," as each term is defined in item 408(a) of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2024 Annual Meeting of Stockholders which will be filed with the Securities and Exchange Commission no later than 120 days after the end of our fiscal year (the Proxy Statement).

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to our Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as a part of this Report:

(1) Financial Statements —See Index to Consolidated Financial Statements and Item 8 of this Annual Report on Form 10-K.

(2) Financial Statement Schedules —Schedules are omitted because they are not applicable, or are not required, or because the information is included in the Consolidated Financial Statements and notes thereto.

(3) Index to Exhibits.

Exhibit Index

Exhibit No.	Exhibit
3.1	Certificate of Incorporation of Organogenesis Holdings Inc. (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-3/A (File No. 333-233621) filed with the SEC on September 16, 2019)
3.2	Certificate of Amendment of Certificate of Incorporation of Organogenesis Holdings Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on June 27, 2022)
3.3	Bylaws of Organogenesis Holdings Inc. (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-3/A (File No. 333-233621) filed with the SEC on September 16, 2019)
4.1	Description of Securities registered pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K (File No. 001-37906) filed with the SEC on March 9, 2020)
10.1	Amended and Restated Registration Rights Agreement dated as of December 10, 2018 among Organogenesis Holdings Inc., Avista Acquisition Corp., Avista Capital Partners Fund IV L.P., Avista Capital Partners Fund IV (Offshore), L.P., and certain holders of Organogenesis Common Stock (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.2	Lease dated as of January 1, 2013 by and between Organogenesis Inc. and 65 Dan Road SPE, LLC (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.3	Lease dated as of January 1, 2013 by and between Organogenesis Inc. and 85 Dan Road Associates, LLC (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.4	Lease dated as of January 1, 2013 by and between Organogenesis Inc. and Dan Road Equity I, LLC (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.5‡	Amended and Restated Key Employee Agreement dated as of February 1, 2007 by and between Organogenesis Inc. and Gary Gillheeney (incorporated by reference to Exhibit 10.13 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.6‡	Employee Letter Agreement dated as of February 14, 2017 by and between Organogenesis Inc. and Patrick Bilbo (incorporated by reference to Exhibit 10.14 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.7‡	Employee Letter Agreement dated as of February 14, 2017 by and between Organogenesis Inc. and Antonio Montecalvo (incorporated by reference to Exhibit 10.16 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.8‡	Employee Letter Agreement dated as of January 19, 2018 by and between Organogenesis Inc. and Lori Freedman (incorporated by reference to Exhibit 10.18 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)

Exhibit No.	Exhibit
10.9‡	Employee Letter Agreement dated as of May 9, 2017 by and between Organogenesis Inc. and Brian Grow (incorporated by reference to Exhibit 10.19 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.10‡	2003 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.27 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.11‡	Form of Incentive Stock Option Agreement under the 2003 Stock Incentive Plan (incorporated by reference to Exhibit 10.28 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.12‡	Form of Non-Statutory Stock Option Agreement under the 2003 Stock Incentive Plan (incorporated by reference to Exhibit 10.29 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.13‡	2018 Equity Incentive Plan (as amended) (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-37906) filed with the SEC on August 9, 2022)
10.14‡	Form of Incentive Stock Option Agreement under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.31 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.15‡	Form of Non-Statutory Stock Option Agreement under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.32 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.16‡	Form of Restricted Stock Unit Agreement under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q (File No. 001-37906) filed with the SEC on May 11, 2020)
10.17‡	Form of Indemnification Agreement for Directors and Officers (incorporated by reference to Exhibit 10.33 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.18†	Settlement and License Agreement effective as of October 25, 2017 by and among Organogenesis Inc., RESORBA Medical GmbH, and Advanced Medical Solutions Group plc (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement in Form S-4 (File No. 333-227090) filed with the SEC on October 9, 2018)
10.19	Amended and Restated Code of Ethics and Conduct of ORGO adopted on December 10, 2018 (incorporated by reference to Exhibit 10.35 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.20	Controlling Stockholders Agreement dated as of December 10, 2018 by and among ORGO and the Controlling Entities (incorporated by reference to Exhibit 10.36 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.21	Lease dated March 13, 2019 between Organogenesis Inc., as tenant, and Bobson Norwood Commercial, LLC, as landlord (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on March 19, 2019)
10.22‡	Summary of Amendment to Severance for Gary S. Gillheeney, Sr. (incorporated by reference to Exhibit 10.43 to the Company's Annual Report on Form 10-K/A (File No. 001-37906) filed with the SEC on April 29, 2020)
10.23‡	Offer Letter dated January 15, 2021 between the Company and David C. Francisco (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on February 16, 2021)
10.24‡	Change in Control Retention Agreement between Organogenesis Holdings Inc. and Gary S. Gillheeney, Sr. effective as of May 10, 2021 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q (File No. 001-37906) filed with the SEC on May 10, 2021)
10.25‡	Form of Change in Control Retention Agreement (Non-CEO Executive Officers) (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q (File No. 001-37906) filed with the SEC on May 10, 2021)
10.26‡	Form of Change in Control Retention Agreement (Independent Directors) (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q (File No. 001-37906) filed with the SEC on May 10, 2021)

Exhibit No.	Exhibit
10.27	Credit Agreement dated and effective as of August 6, 2021 among Organogenesis Holdings Inc., as borrower, Organogenesis Inc. and Prime Merger Sub, LLC, as guarantors, and Silicon Valley Bank, as Administrative Agent, Lead Arranger, Bookrunner, Issuing Lender and Swingline Lender, and Silicon Valley Bank and the several other lenders from time to time party thereto, collectively as Lenders (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on August 9, 2021)
10.28	First Amendment to Credit Agreement dated as of December 8, 2022 by and among Organogenesis Holdings Inc., as borrower, the several banks and other financial institutions or entities party hereto and Silicon Valley Bank, as the Administrative Agent, and as the Issuing Lender and the Swingline Lender (incorporated by reference to Exhibit 10.33 to the Company's Annual Report on Form 10-K (File No. 001-37906) filed with the SEC on March 1, 2023)
10.29	Second Amendment to Credit Agreement dated and effective as of April 17, 2023 by and among Organogenesis Holdings Inc., as borrower, the several banks and other financial institutions or entities party hereto and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (successor by purchase to the Federal Deposit Insurance Corporation as receiver for Silicon Valley Bridge Bank, N.A. (as successor to Silicon Valley Bank)), as the Administrative Agent (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-37906) filed with the SEC on May 10, 2023)
10.30	Purchase and Sale Agreement dated as of August 11, 2021 by and between Organogenesis Inc. and 275 Dan Road SPE, LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on August 16, 2021)
21.1*	Subsidiaries of Organogenesis Holdings Inc.
23.1*	Consent of RSM US LLP
31.1*	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934
32.1*	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1*	Organogenesis Holdings Inc. Compensation Recovery Policy as adopted on November 1, 2023
101*	The following materials from the Annual Report of Organogenesis Holdings Inc. on Form 10-K for the year ended December 31, 2023, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2023 and December 31, 2022 of Organogenesis Holdings Inc., (ii) Consolidated Statements of Operations and Comprehensive Income for the years ended December 31, 2023, 2022, and 2021 of Organogenesis Holdings Inc., (iii) Consolidated Statements of Stockholders' Equity for the years ended December 31, 2023, 2022, and 2021 of Organogenesis Holdings Inc., (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2023, 2022, and 2021 of Organogenesis Holdings Inc., and (v) Notes to Consolidated Financial Statements of Organogenesis Holdings Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
† Confidential treatment granted as to portions of this Exhibit. The confidential portions of this Exhibit have been omitted and are marked by asterisks.
‡ Management contract or compensatory plan or arrangement.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

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

ORGANOGENESIS HOLDINGS INC.

By: /s/ Gary S. Gillheeney, Sr.
Gary S. Gillheeney, Sr.
Chief Executive Officer, President, and Chair of the Board of Directors
Date: February 29, 2024

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

Signature	Title	Date
/s/ Gary S. Gillheeney, Sr. **Gary S. Gillheeney, Sr.**	Chief Executive Officer, President and Chair of the Board of Directors (Principal Executive Officer)	February 29, 2024
/s/ David Francisco **David Francisco**	Chief Financial Officer (Principal Financial and Accounting Officer)	February 29, 2024
/s/ Alan A. Ades **Alan A. Ades**	Director	February 29, 2024
/s/ Robert Ades **Robert Ades**	Director	February 29, 2024
/s/ Michael J. Driscoll **Michael J. Driscoll**	Director	February 29, 2024
/s/ Prathyusha Duraibabu **Prathyusha Duraibabu**	Director	February 29, 2024
/s/ David Erani **David Erani**	Director	February 29, 2024
/s/ Jon Giacomin **Jon Giacomin**	Director	February 29, 2024
/s/ Michele Korfin **Michele Korfin**	Director	February 29, 2024
/s/ Arthur S. Leibowitz **Arthur S. Leibowitz**	Director	February 29, 2024
/s/ Glenn H. Nussdorf **Glenn H. Nussdorf**	Director	February 29, 2024
/s/ Gilberto Quintero **Gilberto Quintero**	Director	February 29, 2024

ORGANOGENESIS HOLDINGS INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Organogenesis Holdings Inc.

Opinion on the Financial Statements
We have audited the accompanying consolidated balance sheets of Organogenesis Holdings Inc. and its subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2023, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023 based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. Our report dated February 29, 2024 expressed an opinion that the Company had not maintained effective internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013.

Basis for Opinion
These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters
The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Identification of significant non-routine transactions
Non-routine transactions represent activities that occur only periodically and are generally not part of the routine flow of transactions. From time to time, the Company enters into certain non-routine transactions that require management to apply judgement in determining the appropriate accounting treatment, including the identification of certain impairment triggers relating to recoverability of long-lived assets discussed in Note 8 to the financial statements which resulted in a recoverability test analysis and the License and Manufacturing Agreement discussed in Note 18 to the financial statements which resulted in the capitalization and deferral of an upfront licensing fee and expected milestone payment. Management must exercise significant judgment in the identification of significant non-routine transactions given that they are unique and not part of the routine flow of the Company’s transactions.

We identified management’s identification and assessment of significant non-routine transactions as a critical audit matter due to the subjectivity in determining the sufficiency of the results of the actions taken by management to identify all significant non-routine transactions.

Our audit procedures related to the Company’s identification of significant non-routine transactions included the following, among others:

- We obtained an understanding of the relevant controls related to management's timely identification and assessment of significant non-routine transactions and tested such controls for design and operating effectiveness.
- We read public filings from the Company with a focus on identifying significant non-routine transactions.
- We inspected the Company's minutes from meetings of the Board of Directors, including committees of the Board of Directors.
- We made inquiries of executive management, employees outside of the accounting function, and members of the Board of Directors.
- We obtained written letters from the Company's external counsel related to pending or threatened legal matters.

/s/ RSM US LLP

We have served as the Company's auditor since 2004.
Boston, Massachusetts
February 29, 2024

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Organogenesis Holdings Inc.

Opinion on the Internal Control Over Financial Reporting
We have audited Organogenesis Holdings Inc.'s (the Company) internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. In our opinion, because of the effect of the material weakness described below on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2023, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements of the Company and our report dated February 29, 2024 expressed an unqualified opinion.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. The Company did not design and maintain effective controls over information technology general controls and proper segregation of duties to support the proper initiation and recording of transactions and the resulting impact on business process controls and applications that rely on such data. This material weakness was considered in determining the nature, timing and extent of audit tests applied in our audit of the 2023 financial statements, and this report does not affect our report dated February 29, 2024 on those financial statements.

Basis for Opinion
The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting
A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ RSM US LLP

Boston, Massachusetts
February 29, 2024

ORGANOGENESIS HOLDINGS INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 103,840	$ 102,478
Restricted cash	498	812
Accounts receivable, net	81,999	89,450
Inventories	28,253	24,783
Prepaid expenses and other current assets	10,454	5,086
Total current assets	225,044	222,609
Property and equipment, net	116,228	102,463
Intangible assets, net	15,871	20,789
Goodwill	28,772	28,772
Operating lease right-of-use assets, net	40,118	43,192
Deferred tax asset, net	28,002	30,014
Other assets	5,990	1,520
Total assets	$ 460,025	$ 449,359
Liabilities and Stockholders' Equity		
Current liabilities:		
Current portion of term loan	$ 5,486	$ 4,538
Current portion of finance lease obligations	1,081	—
Current portion of operating lease obligations - related party	3,140	3,001
Current portion of operating lease obligations	10,004	8,707

Accounts payable	30,724	32,330
Accrued expenses and other current liabilities	30,074	26,447
Total current liabilities	80,509	75,023
Term loan, net of current portion	60,745	66,231
Finance lease obligations, net of current portion	1,888	—
Operating lease obligations, net of current portion - related party	17,227	20,367
Operating lease obligations, net of current portion	19,780	20,947
Other liabilities	1,213	1,122
Total liabilities	181,362	183,690
Commitments and contingencies (Note 18)		
Stockholders' equity:		
Preferred stock, $ 0.0001 par value; 1,000,000 shares authorized; none issued	—	—
Common stock, $ 0.0001 par value; 400,000,000 shares authorized; 132,044,944 and 131,647,677 shares issued; 131,316,396 and 130,919,129 shares outstanding at December 31, 2023 and 2022, respectively.	13	13
Additional paid-in capital	319,621	310,957
Accumulated deficit	(40,971)	(45,301)

Total stockholders' equity	278,663	265,669
Total liabilities and stockholders' equity	460,025	449,359
	$	$

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

ORGANOGENESIS HOLDINGS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME

(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2023	**2022**	**2021**
Net revenue	$ 433,140	$ 450,893	$ 467,359
Cost of goods sold	106,481	105,019	114,199
Gross profit	326,659	345,874	353,160
Operating expenses:			
Selling, general and administrative	269,754	283,808	250,200
Research and development	44,380	39,762	30,742
Total operating expenses	314,134	323,570	280,942
Income from operations	12,525	22,304	72,218
Other expense, net:			
Interest expense, net	(2,190)	(2,009)	(7,236)
Loss on the extinguishment of debt	—	—	(1,883)
Other income (loss), net	57	(13)	(13)
Total other expense, net	(2,133)	(2,022)	(9,132)
Net income before income taxes	10,392	20,282	63,086
Income tax (expense) benefit	(5,447)	(4,750)	31,116
Net income and comprehensive income	$ 4,945	$ 15,532	$ 94,202
Net income, per share:			
Basic	$ 0.04	$ 0.12	$ 0.73
Diluted	$ 0.04	$ 0.12	$ 0.70
Weighted-average common shares outstanding			

Basic			
	131,231,317	130,070,231	128,331,022
Diluted			
	132,746,727	132,383,152	133,662,659

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

ORGANOGENESIS HOLDINGS INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share amounts)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance as of December 31, 2020	127,731,833	$ 13	$ 296,830	$ (155,035)	$ 141,808
Exercise of stock options	760,458	—	2,198	—	2,198
Vesting of RSUs, net of shares surrendered to pay taxes	187,901	—	(737)	—	(737)
Stock-based compensation expense	—	—	3,864	—	3,864
Net income	—	—	—	94,202	94,202
Balance as of December 31, 2021	128,680,192	13	302,155	(60,833)	241,335
Exercise of stock options	1,864,961	—	2,070	—	2,070
Vesting of RSUs, net of shares surrendered to pay taxes	170,491	—	(648)	—	(648)
Issuance of common stock associated with CPN acquisition	203,485	—	828	—	828
Stock-based compensation expense	—	—	6,552	—	6,552
Net income	—	—	—	15,532	15,532
Balance as of December 31, 2022	130,919,129	13	310,957	(45,301)	265,669
Cumulative-effect adjustment from adoption of ASU 2016-13, net of tax (Note 2)	—	—	—	(615)	(615)
Vesting of RSUs, net of shares surrendered to pay taxes	397,267	—	(332)	—	(332)
Stock-based compensation expense	—	—	8,996	—	8,996
Net income	—	—	—	4,945	4,945
Balance as of December 31, 2023	131,316,396	$ 13	$ 319,621	$ (40,971)	$ 278,663

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

ORGANOGENESIS HOLDINGS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2023	**2022**	**2021**
Cash flows from operating activities:			
Net income	$ 4,945	$ 15,532	$ 94,202
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	10,448	5,845	5,781
Amortization of intangible assets	4,918	4,883	4,949
Amortization of operating lease right-of-use assets	8,083	7,303	5,946
Non-cash interest expense	427	434	346
Deferred interest expense	490	501	1,493
Deferred tax expense (benefit)	2,012	1,980	(31,976)
Loss on disposal of property and equipment	235	4,482	1,407
Loss on lease termination	559	—	—
Provision recorded for credit losses	1,297	1,781	2,999
Adjustment for excess and obsolete inventories	6,580	9,648	12,079
Stock-based compensation	8,996	6,552	3,864
Loss on extinguishment of debt	—	—	1,883
Change in fair value of earnout liability	—	—	(3,985)
Changes in operating assets and liabilities:			

Accounts receivable	5,539	(8,770)	(28,654)
Inventories	(8,179)	(9,410)	(9,302)
Prepaid expenses and other current and other assets	(10,115)	(378)	(34)
Operating leases	(8,439)	(7,006)	(6,156)
Accounts payable	(108)	3,260	3,847
Accrued expenses and other current liabilities	3,138	(11,850)	9,354
Other liabilities	91	72	(6,065)
Net cash provided by operating activities	30,917	24,859	61,978
Cash flows from investing activities:			
Purchases of property and equipment	(24,364)	(33,898)	(31,220)
Net cash used in investing activities	(24,364)	(33,898)	(31,220)
Cash flows from financing activities:			
Line of credit repayments under the 2019 Credit Agreement	—	—	(10,000)
Term loan repayments under the 2019 Credit Agreement	—	—	(60,000)
Proceeds from term loan under the 2021 Credit Agreement, net of debt discount and issuance cost	—	—	73,174
Term loan repayments under the 2021 Credit Agreement	(4,688)	(2,813)	(938)
Principal repayments of finance lease obligations	(485)	(200)	(2,630)
Proceeds from the exercise of stock options	—	2,070	2,198

Payments of withholding taxes in connection with RSUs vesting	(332)	(648)	(737)
Payments of deferred acquisition consideration	—	(608)	(483)
Payment to extinguish debt	—	—	(1,620)
Net cash used in financing activities	(5,505)	(2,199)	(1,036)
Change in cash, cash equivalents and restricted cash	1,048	(11,238)	29,722
Cash, cash equivalents, and restricted cash, beginning of year	103,290	114,528	84,806
Cash, cash equivalents, and restricted cash, end of year	$ 104,338	$ 103,290	$ 114,528
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 5,436	$ 2,649	$ 5,787
Cash paid for income taxes	$ 3,052	$ 1,201	$ 607
Supplemental disclosure of non-cash investing and financing activities:			
Cumulative effect adjustment for adoption of ASU No. 2016-13 (Note 2)	$ 615	$ —	$ —
Deferred acquisition consideration and earnout liability recorded for business acquisition	$ —	$ 828	$ —
Purchases of property and equipment in accounts payable and accrued expenses	$ 841	$ 1,928	$ 3,750
Right-of-use assets obtained through operating lease obligations	$ 5,869	$ 1,350	$ 53,793
Right-of-use assets obtained through finance lease obligations	$ 3,454	$ —	$ —

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

1. Nature of Business and Basis of Presentation

Organogenesis Holdings Inc. ("ORGO" or the "Company") is a leading regenerative medicine company focused on the development, manufacture, and commercialization of solutions for the Advanced Wound Care and Surgical & Sports Medicine markets. Several of the existing and pipeline products in the Company's portfolio have Premarket Application ("PMA") approval, or Premarket Notification 510(k) clearance from the United States Food and Drug Administration ("FDA"). The Company's customers include hospitals, wound care centers, government facilities, ambulatory surgery centers ("ASCs") and physician offices. The Company has

one

operating and reportable segment.

2. Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported results of operations during the reporting periods. In preparing the consolidated financial statements, the estimates and assumptions that management considers to be significant and that present the greatest amount of uncertainty include revenue recognition; sales returns and credit losses; inventory reserve; recognition and measurement of current and deferred income tax assets and liabilities; the assessment of recoverability of long-lived assets, and the valuation and recognition of stock-based compensation. Actual results and outcomes may differ significantly from those estimates and assumptions.

Principles of Consolidation

The consolidated financial statements include the accounts and results of operations of Organogenesis Holdings Inc., and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Foreign Currency

The Company's functional currency, including the Company's Swiss subsidiary, Organogenesis GmbH, is the U.S. dollar. Foreign currency gains and losses resulting from re-measurement of assets and liabilities held in foreign currencies and transactions settled in a currency other than the functional currency are included separately as non-operating income or expense in the consolidated statements of operations and comprehensive income as a component of other expense, net. The foreign currency amounts recorded for all periods presented were insignificant.

Segment Reporting

Operating segments are defined as components of an enterprise about which discrete financial information is available that is evaluated regularly by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance for the organization. The Company's chief operating decision maker is the Chief Executive Officer. The Company's chief operating decision maker reviews consolidated operating results to make decisions about allocating resources and assessing performance for the entire Company. Accordingly, the Company has determined that it has a single operating segment—regenerative medicine.

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. The Company's portfolio includes regenerative medicine products in various stages, ranging from preclinical to late stage development, and commercialized advanced wound care and surgical and sports medicine products which support healing across a wide variety of wound types at many different types of facilities.

Cash and Cash Equivalents

The Company primarily maintains its cash in bank deposit accounts in the United States which, at times, may exceed the federally insured limits. The Company has not experienced losses in such accounts and believes it is not exposed to significant credit risk on cash. The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

Restricted Cash

The Company had restricted cash of $

498
and $

812
as of December 31, 2023 and 2022, respectively. Restricted cash represents employee deposits in connection with the Company's health benefit plan.

Accounts Receivable, Net

Accounts receivable are stated at invoice value less estimated allowances for credit losses. The Company evaluates expected credit losses on accounts receivable considering historical experience, credit quality, age of the accounts receivable balances, geography-related risks and current and expected economic conditions that may affect a customer's ability to pay. The Company continually monitors customer payments and in cases where there are circumstances that may impair a specific customer's ability to meet its financial obligations, a specific allowance is recorded against amounts due, thereby reducing the net recognized receivable to the amount reasonably believed to be collectible. Accounts receivable are charged against the allowance when deemed uncollectible. Recoveries of accounts receivables previously written off are recorded when received.

Inventories

Inventories are stated at the lower of cost (determined using the first-in first-out method) or net realizable value. Work in process and finished goods include materials, labor and allocated overhead. Inventories also include cell banks and the cost of tests mandated by regulatory agencies of the materials to qualify them for production.

The Company regularly reviews inventory quantities on hand and records a provision to write down excess and obsolete inventory to its estimated net realizable value based upon management's assumptions of future material usage, yields and obsolescence, which are a result of future demand and market conditions and the effective life of certain inventory items.

The Company also tests other components of its inventory for future growth projections. The Company determines the average yield of the component and compares it to projected revenue to ensure it is properly reserved.

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation. As of December 31, 2023 and 2022, the Company's property and equipment consisted of leasehold improvements, building, furniture and computers, and equipment. Depreciation expense is recognized using the straight-line method over the useful lives of the assets, which are as follows:

Leasehold improvements	Lesser of the life of the lease or the economic life of the asset
Building	30 years
Furniture and computers	3 - 5 years
Equipment	5 - 10 years

Construction in progress costs are capitalized when incurred until the assets are placed in service, at which time the costs will be transferred to the related property and equipment, and depreciated over their respective useful lives. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in the consolidated statements of operations and comprehensive income. Expenditures for repairs and maintenance are charged to expense as incurred. Expenditures for major improvements that extend the useful lives of the related asset are capitalized and depreciated over their remaining estimated useful lives.

Goodwill

Goodwill represents the excess of the purchase price of an acquired business over the fair value of the identifiable assets acquired and liabilities assumed. Goodwill is not amortized, but is tested for impairment at least annually (as of December 31), or more frequently if events or circumstances indicate the carrying value may no longer be recoverable and that an impairment loss may have occurred. Circumstances that could trigger an impairment test include, but are not limited to, a significant adverse change in the business climate or legal factors, an adverse action or assessment by a regulator, or unanticipated competition. The Company operates as one segment, which is considered to be the sole reporting unit, and therefore goodwill is tested for impairment at the consolidated level.

In accordance with ASC Topic 350, *Intangibles - Goodwill and Other*, the Company may first assess qualitative factors to determine whether it is necessary to perform the quantitative goodwill impairment test. If after assessing the totality of events or circumstances, the Company determines that it is more likely than not (i.e. greater than 50% likelihood) that the fair value of the reporting unit is less than its carrying amount, then the quantitative test is required. Otherwise, no further testing is required.

Alternatively, the Company can bypass the qualitative assessment and proceed directly to the quantitative test. The quantitative goodwill impairment test requires the Company to estimate and compare the fair value of the reporting unit with its carrying value. If the fair value of the reporting unit exceeds the carrying value of the net assets, goodwill is not impaired. If the fair value of the reporting unit is less than the carrying value, the difference is recorded as an impairment loss up to the amount of goodwill. At December 31, 2023, we elected to perform a quantitative analysis directly. We used the Company's market capitalization to approximate the fair value of the reporting unit. The fair value exceeded the carrying value and

no
impairment was recorded.

Intangible Assets Subject to Amortization

Intangible assets include intellectual property either owned by the Company or to which the Company has a license. Intangible assets acquired in a business combination are recognized at fair value using generally accepted valuation methods deemed appropriate for the type of intangible asset acquired. Intangible assets are reported net of accumulated amortization, separately from goodwill. Intangible assets with finite lives are amortized over their estimated useful lives. Intangible assets include developed technology and patents, trade names, trademarks, customer relationships and non-compete agreements obtained through business acquisitions. Amortization of intangible assets with finite lives is calculated on the straight-line or accelerated metho d based on the following estimated useful lives:

Trade names and trademarks	1 - 12 years
Developed technology	6 - 12 years
Customer relationships	10 years
Non-compete agreements	5 years

Impairment of Long-Lived Assets

Long-lived assets include property and equipment, definite-lived intangible assets, and right-of-use assets associated with our lease agreements. The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. Factors that the Company considers in deciding when to perform an impairment review include, but are not limited to, significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. When such an event occurs, the Company determines whether there has been impairment by comparing the anticipated undiscounted future net cash flows to the related asset group's carrying value. If an asset is determined to be impaired, the asset is written down to fair value, which is determined based on discounted cash flows or appraised value, depending on the nature of the asset. The Company did

no

t record any impairment of long-lived assets during the years ended December 31, 2023, 2022, or 2021.

Revenue Recognition

Product Revenue

The Company generates revenue through the sale of Advanced Wound Care and Surgical & Sports Medicine products. There is a single performance obligation in all of the Company's contracts, which is the Company's promise to transfer the Company's product to customers based on specific payment and shipping terms in the arrangement. The entire transaction price is allocated to this single performance obligation. Product revenue is recognized when a customer obtains control of the Company's product which occurs at a point in time and may be upon shipment, procedure date, or delivery, based on the terms of the contract.

Reserves for Variable Consideration

Revenues from product sales are recorded net of reserves for variable consideration which includes but is not limited to product return, discounts, rebates and GPO fees that are offered within contracts between the Company and its customers relating to the Company's sales of its products. These reserves are based on the amounts earned or to be claimed by its customers on the related sales and are recorded as a reduction of accounts receivable or an establishment of a liability. Where appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted for relevant factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract and is included in the net sales price to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately paid may differ from the Company's estimates. If actual results vary from the Company's estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known.

Product Returns

Consistent with industry practice, the Company generally offers customers a limited right of return for product purchased. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period in which the related product revenue is recognized. The Company currently estimates product return reserves using its historical return rates as well as factors that it becomes aware of that it believes could significantly impact its expected returns, including product recalls, pricing changes, or changes in reimbursement rates. The Company does not record an asset for the returned product as the product is discarded upon receipt.

Rebates and Allowances

The Company provides certain customers with rebates and allowances that are explicitly stated in the Company's contracts, resulting in a reduction of revenue and the establishment of a liability that is included in accrued expenses in the accompanying consolidated balance sheets in the period the related product revenue is recognized.

GPO Fees

The Company pays fees to GPOs for administrative services that the GPOs perform in connection with the purchases of the product by the GPO members. These fees are based on a contractually-determined percentage of the Company's applicable sales. The Company classifies these GPO fees as a reduction of revenue based on the substance of the relationship of all parties involved in the transaction. For the years ended December 31, 2023, 2022, and 2021, the Company recorded GPO fees of $

5,623

, $

6,654

and $

3,663

, respectively, as a direct reduction of revenue.

Other Revenue Policies

Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue.

Applying the practical expedient in paragraph ASC 606-10-32-18, the Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised products to the customer will be one year or less, which is the case with substantially all customers.

Applying the practical expedient in ASC 340-40-25-4, the Company recognizes the incremental costs of obtaining contracts as an expense when incurred if the amortization period of the assets that the Company otherwise would have recognized is one year or less. These costs are included in selling, general, and administrative expenses.

Applying the practical expedient in ASC 606-10-25-18B, the Company accounts for shipping and handling activities related to contracts with customers as costs to fulfill the promise to transfer the associated products. The Company records the related costs as part of the cost of goods sold.

Disaggregation of Revenue

The following table sets forth revenue by product category:

	Year Ended December 31,		
	2023	**2022**	**2021**
Advanced Wound Care	$ 405,514	$ 422,231	$ 430,237
Surgical and Sports Medicine	27,626	28,662	37,122
Total revenue	$ 433,140	$ 450,893	$ 467,359

For all periods presented, net revenue generated outside the United States represented less than 1% of total net revenue.

License and manufacturing agreement

The Company licenses the rights to sell certain of its products, which are manufactured by third parties, including the trademarks and other license rights associated with such products. Payments to the third parties under these arrangements typically include one or more of the following: non-refundable, upfront license fees; manufacturing supply services and associated purchase commitments at specified prices; milestone payments; and royalties on future product sales. The Company allocates payments in these arrangements based on the relative fair value of the goods and services received, and recognizes the expenses associated with each good or service as it receives the associated benefit.

Stock-Based Compensation

The Company measures stock-based awards granted to employees, non-employees, and directors based on the fair value of the awards on the date of grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues stock options, restricted stock units and restricted stock awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company has not issued any stock-based awards with performance-based vesting conditions.

Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company recognizes stock-based compensation expense within selling, general and administrative expenses in the consolidated statements of operations and comprehensive income for all share-based payments based upon the estimated grant-date fair value for the awards expected to ultimately vest.

The fair value of each restricted stock unit grant is based on the fair market value of the Company's Class A common stock on the date of grant. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company has been a public company for a short period of time, has limited public float and lacks company-specific historical and implied volatility information for its Class A common stock. Therefore, it estimates its expected stock price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on its Class A common stock and does not expect to pay any cash dividends in the foreseeable future.

Advertising

Advertising costs are expensed as incurred and are included in selling, general and administrative expenses in the consolidated statements of operations and comprehensive income. Advertising costs were approximately $

5,225

, $

4,812

, and $

5,522

, for the years ended December 31, 2023, 2022, and 2021, respectively.

Research and Development Costs

Research and development expenses include personnel costs for the Company's research and development personnel, expenses related to improvements in manufacturing processes, enhancements to the Company's currently available products, and additional investments in the product and platform development pipeline. Research and development expenses also include expenses for clinical trials. The Company expenses research and development costs as incurred.

Valuation of Contingent Purchase Earnout

In connection with the acquisition of CPN, the Company recognized a non-current liability for the fair value of the contingent consideration (the "Earnout") at the time of the acquisition in 2020. The Earnout liability was classified as a Level 3 measurement for which fair value was derived from inputs that were unobservable and significant to the overall fair value measurement. The fair value of such Earnout liability was estimated using a Monte Carlo simulation model that utilized key assumptions including forecasted revenues and volatilities of the underlying financial metrics during the Earnout period. The Company assessed the fair value of the Earnout liability at each reporting period. Any subsequent changes in the estimated fair value of the liability were reflected in selling, general and administrative expenses until the Earnout period ended and the liability was settled, during the year ended December 31, 2022.

Income Taxes

The Company accounts for income taxes using the asset and liability method which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statement and the tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company quarterly assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. In determining whether a valuation allowance for deferred tax assets is necessary, the Company analyzes both positive and negative evidence related to the realization of deferred tax assets, including projected future taxable income, recent financial results and estimates of future reversals of deferred tax assets and liabilities. In addition, the Company considers whether it is more likely than not that the tax position will be sustained on

examination by taxing authorities based on the technical merits of the position. In consideration of the factors discussed above, in the fourth quarter of 2021, the Company determined it was more likely than not that its deferred tax assets would be realized in the future and released the valuation allowance on the net U.S. deferred tax assets as of December 31, 2021, resulting in a benefit of $

48.3

million in income taxes. See Note 15, *Income Taxes*.

The Company accounts for uncertain income tax positions recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Fair Value of Financial Instruments

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying values of accounts receivable, inventories, prepaid expenses and other current assets, accounts payable and accrued expenses and other assets and liabilities approximate their fair values due to the short-term nature of these assets and liabilities. The carrying values of outstanding borrowings under the Company's debt arrangements (see Note 12, *Long-Term Debt Obligations*) approximate their fair values as determined based on a discounted cash flow model, which represents a Level 3 measurement.

Earnings per Share (EPS)

The Company determines earnings per share in accordance with the authoritative guidance in ASC Topic 260, *Earnings Per Share*. The Company has one class of common stock (Class A common stock) for purposes of the EPS calculation and therefore computes basic EPS by dividing net income by the weighted average number of common shares outstanding for the applicable period. Diluted EPS is computed in the same manner as basic EPS, except that the number of shares is computed by giving effect to all potential dilutive common shares. For purpose of this calculation, outstanding stock options, and unvested restricted stock are considered potential dilutive common shares.

Recently Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASC 326"). The FASB subsequently issued a few amendments to ASC 326. ASC 326 and all the related updates replace the incurred loss impairment methodology previously required under GAAP, with an expected loss methodology that requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates.

The Company adopted the standard as of January 1, 2023 using the modified retrospective method. Under this method, the Company applied the new credit loss measurement guidance to trade accounts receivable, the only financial asset of the Company that is impacted by ASC 326 and the related updates. The Company recorded a net reduction of $

615

to the opening balance of retained earnings as the cumulative effect of initially applying the standard. Results for reporting periods beginning after January 1, 2023 are presented in accordance with ASC 326. Prior period amounts have not been restated and are reported in accordance with legacy GAAP requirements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2023-07.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires public entities to disclose specific categories in the effective tax rate reconciliation, as well as additional information for reconciling items that exceed a quantitative threshold. ASU 2023-09 also requires all entities to disclose income taxes paid disaggregated by federal, state and foreign taxes, and further disaggregated for specific jurisdictions that exceed 5% of total income taxes paid, among other expanded disclosures. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2023-09.

3. Acquisition

On September 17, 2020 (the "Acquisition Date"), the Company acquired certain assets and assumed certain liabilities of CPN Biosciences, LLC ("CPN") pursuant to an asset purchase agreement dated July 24, 2020. CPN offered a physician office management solution and advanced wound care products.

The aggregate consideration amounted to $

19,024

as of the Acquisition Date, consisting of $

6,427

in cash,

2,151,438

shares of the Company's Class A common stock with a fair value of $

8,815

, and contingent consideration (the "Earnout") with a fair value of $

3,782

. On the Acquisition Date, the Company paid $

5,820

in cash and issued

1,947,953

shares of the Company's Class A common stock. The remaining consideration of $

1,436

was held back and was released in April 2022 by the Company paying $

608

in cash and issuing

203,485

shares of the Company's Class A common stock to the former equity holders of CPN.

The Company was obligated to pay the Earnout to CPN's former equity holders if CPN's legacy product revenue in the Earnout Period (July 1, 2021 to June 30, 2022), exceeded CPN's 2019 revenue. The amount of the Earnout, if any, would be equal to

70

% of the excess and would be payable 60 days after the expiration of the Earnout Period. As of the conclusion of the Earnout Period on June 30, 2022, the Company calculated the Earnout liability to be $

0

. During the Earnout Period, the Company assessed the fair value of the Earnout liability at each reporting period. Subsequent changes in the estimated fair value of the liability were reflected in earnings until the liability was settled. See Note 4, *Fair Value Measurement of Financial Assets and Liabilities.*

4. Fair Value Measurement of Financial Instruments

Earnout Liability

In connection with accounting for the CPN acquisition on September 17, 2020, the Company recorded an Earnout liability of $

3,782

on the Acquisition Date, representing the fair value of contingent consideration payable upon the achievement of a certain revenue target. The Earnout liability was classified as a Level 3 measurement within the fair value hierarchy for which fair value was derived from inputs that were unobservable and significant to the overall fair value measurement. The fair value of such Earnout liability was estimated using a Monte Carlo simulation model that utilized key assumptions including forecasted revenues and volatilities of the underlying financial metrics during the Earnout Period. The Earnout Period ended on June 30, 2022 and the Company calculated the Earnout liability to be $

0

. Before its settlement, the Company assessed the fair value of the Earnout liability at each reporting period. Any subsequent changes in the estimated fair value of the liability were reflected in selling, general and administrative expenses until the liability was settled. For more information about the Earnout liability, refer to Note 3, *Acquisition*.

The following table provides a roll-forward of the fair value of the Company's Earnout liability, for which fair value was determined using Level 3 inputs until the end of the Earnout Period on June 30, 2022.

	Earnout liability
Balance as of December 31, 2020	$ 3,985
Change in fair value	( ) 3,985
Balance as of December 31, 2021	—
Change in fair value	—
Balance as of June 30, 2022	$ —

The Company did not have any financial assets and liabilities measured at fair value on a non-recurring basis as of December 31, 2023 and 2022.

5. Accounts receivable, net

Accounts receivable consisted of the following:

	December 31, 2023	2022
Accounts receivable	$ 88,859	$ 95,812
Less - allowance for credit losses	(6,860)	(6,362)
	$ 81,999	$ 89,450

The Company's allowance for credit losses is comprised of the following:

Balance as of December 31, 2021	$ 5,153
Additions	1,781
Write-offs	(572)
Balance as of December 31, 2022	$ 6,362
Cumulative-effect adjustment from adoption of ASU 2016-13, net of tax (Note 2)	615
Additions	1,297
Write-offs	(1,414)
Balance as of December 31, 2023	$ 6,860

6. Inventories

Inventories, net of related reserves for excess and obsolescence, consist of the following:

	December 31, 2023	2022
Raw materials	$ 12,988	$ 12,282
Work in process	810	1,022

Finished goods	14,455	11,479
	$ 28,253	$ 24,783

Raw materials include various components used in the Company's manufacturing process. The Company's excess and obsolete inventory review process includes analysis of sales forecasts and historical sales as compared to inventory levels and working with operations to maximize recovery of excess inventory. During the years ended December 31, 2023, 2022, and 2021, the Company charged $ 6,580 , $ 9,648 , and $ 12,079 , respectively, for inventory excess and obsolescence to cost of goods sold within the consolidated statements of operations and comprehensive income.

7. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31, 2023	2022
Subscriptions	$ 5,866	$ 4,211
Prepaid licensing fee (Note 18)	2,368	—
Conferences and marketing expenses	945	106
Deposits	872	635
Insurance	85	54
Other	318	80
	$ 10,454	$ 5,086

Deposits are funds held by vendors which are expected to be released within twelve months and therefore they are recorded as current assets.

8. Property and Equipment, Net

Property and equipment consisted of the following:

	December 31, 2023	2022
Leasehold improvements	$ 60,819	$ 37,607
Building	4,943	4,943
Furniture, computers and equipment	64,585	57,147
	130,347	99,697
Accumulated depreciation	(73,186)	(62,798)
Construction in progress	59,067	65,564
	$ 116,228	$ 102,463

Depreciation expense was $ 10,448 , $ 5,845 and $ 5,781 , for the years ended December 31, 2023, 2022, and 2021, respectively. Construction in progress primarily represents unfinished construction work on a purchased building located on the Company's Canton, Massachusetts campus and improvements at the Company's leased facilities in Canton and Norwood, Massachusetts, as well as costs incurred to implement the company-wide enterprise resource planning ("ERP") system. During the year ended December 31, 2023, the Company incurred $ 10,891 in costs associated with the ERP implementation.

During the year ended December 31, 2022, the Company recorded a charge of $ 4,200 for the sale and donation of some equipment related to the construction in progress in one of its Canton, Massachusetts facilities. The disposal was the result of a change in the design of the construction plan for the manufacturing facility and the determination that this equipment was no longer compatible with the ongoing design. During 2022, the Company decided to temporarily pause the construction of this manufacturing facility due to inflation and market conditions that adversely impacted construction projects across the biotechnology and life sciences industries. In connection with this decision, the Company recorded a charge of $ 632 as cancellation fees to various vendors. These charges were included in selling, general and administrative expenses on the consolidated statements of operations and comprehensive income for the year ended December 31, 2022.

During the years ended December 31, 2023 and 2022, the Company identified certain impairment triggers relating to its asset groups, which included incurred expenses in excess of planned expenses for the ERP implementation in 2023, and the sale and donation of equipment and the construction pause in 2022. The impairment triggers indicated that the Company's long-lived assets might be impaired. The Company performed recoverability tests during the years ended December 31, 2023 and 2022 in accordance with ASC 360, *Property, Plant and Equipment*. The estimated undiscounted cash flows directly attributable to the asset group exceeded the carrying value of the asset group. Therefore, the Company did no

t record any impairment related to its asset group.

9. Goodwill and Intangible Assets

Goodwill was $

28,772

as of December 31, 2023 and 2022. There was

no

impairment of goodwill recorded during the years ended December 31, 2023, 2022, or 2021.

Identifiable intangible assets consisted of the following as of December 31, 2023:

	Original Cost	Accumulated Amortization	Net Book Value
Developed technology	$ 32,620	$ (24,666)	$ 7,954
Customer relationship	10,690	(3,519)	7,171
Patent	7,623	(7,623)	—
Independent sales agency network	4,500	(4,500)	—
Trade names and trademarks	2,080	(1,590)	490
Non-compete agreements	1,010	(754)	256
Total	$ 58,523	$ (42,652)	$ 15,871

Identifiable intangible assets consisted of the following as of December 31, 2022:

	Original Cost	Accumulated Amortization	Net Book Value
Developed technology	$ 32,620	$ (21,164)	$ 11,456
Customer relationship	10,690	(2,450)	8,240
Patent	7,623	(7,623)	—
Independent sales agency network	4,500	(4,500)	—
Trade names and trademarks	2,080	(1,393)	687
Non-compete agreements	1,010	(604)	406
Total	$ 58,523	$ (37,734)	$ 20,789

Amortization of intangible assets, calculated on a straight-line basis or using an accelerated method, which reflects the pattern in which the economic benefits of the intangible assets are consumed, was $ 4,918 , $ 4,883 and $ 4,949 for the years ended December 31, 2023, 2022, and 2021, respectively. Estimated future annual amortization expense related to these in tangible assets is as follows:

2024	$ 3,403
2025	3,323
2026	3,043
2027	2,283
2028	1,968

Thereafter	1,851
Total	$ 15,871

10. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31, 2023	2022
Personnel costs	$ 18,287	$ 17,113
Royalties	3,075	3,320
Accrued but unpaid lease obligations and interest	2,326	2,463
Accrued milestone payment (Note 18)	2,500	—
Accrued taxes	2,799	2,625
Other	1,087	926
	$ 30,074	$ 26,447

The accrued but unpaid lease obligations and the interest accrual on these obligations are related to the buildings in Canton, Massachusetts. See Note 17, *Leases*.

11. Restructuring

In order to reduce the Company's cost structure and improve operating efficiency, the Company consolidates its manufacturing operations in various locations into Massachusetts facilities.

On October 21, 2020, the Company committed to a plan to restructure the workforce and operations in its La Jolla, California facilities. The restructuring involved

65

employees and was substantially completed as of December 31, 2021, with certain facility and storage activities continuing through 2024. On March 9, 2022, the Company committed to a plan to restructure the workforce and operations in its Birmingham, Alabama facilities. The restructuring involved approximately

25

employees and was substantially completed as of December 31, 2022, with minimal expenses incurred in 2023.

On February 3, 2023, the Company committed to a plan to restructure its workforce to increase productivity and enhance profitability. The reduction in force reduced the Company's headcount by

71

employees, or approximately

7

% of all employees. The Company incurred total employee-related charges of $

1,609

in connection with the restructuring, primarily consisting of severance payments. It was substantially completed as of March 31, 2023.

On October 27, 2023, the Company committed to a plan to restructure its workforce to increase productivity and enhance profitability. The reduction in force reduced the Company's headcount by

49
employees, or approximately

5
% of all employees. The Company incurred a total charge of $

1,820
in the fourth quarter of 2023, primarily consisting of severance payments.

As a result of the restructuring activities, the Company incurred pre-tax charges of $

3,796
, $

2,268
and $

4,704
in the years ended December 31, 2023, 2022, and 2021, respectively. These charges were included in selling, general and administrative expenses in the consolidated statements of operations and comprehensive income. The liability related to the restructuring activities was $

904
and $

1,192
as of December 31, 2023 and 2022, respectively, and was included in accrued expenses and other current liabilities in the consolidated balance sheets. The following table provides a rollforward of the restructuring liability.

	Employee	Other	Total
Liability balance as of December 31, 2020	618	—	618
Expenses	3,513	1,191	4,704
Cash distributions	(1,614)	(540)	(2,154)
Liability balance as of December 31, 2021	2,517	651	3,168
Expenses	1,557	711	2,268
Cash distributions	(3,064)	(1,180)	(4,244)
Liability balance as of December 31, 2022	1,010	182	1,192
Expenses	3,429	367	3,796
Cash distributions and other adjustments	(3,535)	(549)	(4,084)
Liability balance as of December 31, 2023	$ 904	$ —	$ 904

12. Long-Term Debt Obligations

	December 31,	
	2023	2022
Term loan	66,563	71,250
Less debt discount and debt issuance cost	(332)	(481)
Term loan, net of debt discount and debt issuance cost	$ 66,231	$ 70,769

2021 Credit Agreement

In August 2021, the Company, as borrower, its subsidiaries, as guarantors, and Silicon Valley Bank ("SVB"), and the several other lenders thereto (collectively, the "Lenders") entered into a credit agreement, as amended (the "2021 Credit Agreement"), providing for a term loan facility not to exceed $

75,000

(the "Term Loan Facility") and a revolving credit facility not to exceed $

125,000

(the "Revolving Facility" and, together with the Term Loan Facility, the "Facilities"). The Company's obligations to the Lenders are secured by substantially all of the Company's assets, including intellectual property. Capitalized terms used herein and not otherwise defined are defined as set forth in the 2021 Credit Agreement.

Advances made under the 2021 Credit Agreement may be either SOFR Loans or ABR Loans, at the Company's option. For SOFR Loans, the interest rate is a per annum interest rate equal to the Adjusted Term SOFR plus an Applicable Margin between

2.00

% to

3.25

% based on the Total Net Leverage Ratio. For ABR Loans, the interest rate is equal to (1) the highest of (a) the Wall Street Journal Prime Rate, (b) the Federal Funds Rate plus 0.50% and (c) the Adjusted Term SOFR rate plus 1.0%, *plus* (2) an Applicable Margin between

1.00

% to

2.25

% based on the Total Net Leverage Ratio.

The 2021 Credit Agreement requires the Company to make consecutive quarterly installment payments equal to the following: (a) from September 30, 2021 through and including June 30, 2022, $

469

; (b) from September 30, 2022 through and including June 30, 2023, $

938

; (c) from September 30, 2023 through and including June 30, 2025, $

1,406

and (d) from September 30, 2025 and the last day of each quarter thereafter until August 6, 2026 (the "Term Loan Maturity Date"), $

1,875

. The Company may prepay the Term Loan Facility. Once repaid, amounts borrowed under the Term Loan Facility may not be re-borrowed.

The Company must pay in arrears, on the first day of each quarter prior to August 6, 2026 (the "Revolving Termination Date") and on the Revolving Termination Date, a fee for the Company's non-use of available funds (the "Commitment Fee"). The Commitment Fee rate is between

0.25

% to

0.45

% based on the Total Net Leverage Ratio. The Company may elect to reduce or terminate the Revolving Facility in its entirety at any time by repaying all outstanding principal and unpaid accrued interest.

Under the 2021 Credit Agreement, the Company is required to comply with certain financial covenants including the Consolidated Fixed Charge Coverage Ratio and Consolidated Total Net Leverage Ratio, tested quarterly. In addition, the Company is also required to make representations and warranties and comply with certain non-financial covenants that are customary in loan agreements of this type, including restrictions on the payment of dividends, repurchase of stock, incurrence of indebtedness, dispositions and acquisitions.

The Company recorded debt issuance costs and related fees of $

604

in connection with entering into the Term Loan Facility, which are recorded as a reduction of the carrying value of the term loan on the Company's consolidated balance sheets. In connection with entering into the Revolving Facility, the Company recorded debt issuance costs and related fees of $

1,223

, which are recorded as other assets. Both of these costs are being amortized to interest expense through the maturity date of the Facilities.

As of December 31, 2023 and 2022, the Company had outstanding borrowings of $

66,563

and $

71,250

under the Term Loan Facility, respectively, and $

0

under the Revolving Facility with $

125,000

available for future revolving borrowings.

Future payments of the 2021 Credit Agreement, as of December 31, 2023, are as follows for the calendar years ending December 31:

2024	5,625
2025	6,563
2026	54,375
Total	$ 66,563

2019 Credit Agreement

In March 2019, the Company, its subsidiaries and SVB, and the several other lenders thereto entered into a credit agreement, as amended (the "2019 Credit Agreement"), providing for a term loan facility of $

40,000

and a revolving credit facility of up to $

60,000

. Both facilities were set to mature in 2024 . The interest rate for the term loan facility was a floating per annum interest rate equal to the greater of

3.75

% above the Wall Street Journal Prime Rate and

9.25

% . The interest rate for advances under the revolving facility was a floating per annum interest rate equal to the greater of the Wall Street Journal Prime Rate and 5.50%. If the Company elected to prepay the loan or terminate the facilities, the Company was required to pay a certain percentage of the outstanding principal as a prepayment fee. A final payment fee (the "Final Payment") of

6.5

% multiplied by the original aggregate principal amount of term loan facility was due upon the earlier to occur of the maturity date of the term loan or prepayment of all outstanding principal.

In August 2021, upon entering into the 2021 Credit Agreement, the Company paid an aggregate amount of $

70,559

due under the 2019 Credit Agreement, including unpaid principal, accrued interest, the Final Payment and a prepayment fee, with proceeds from the 2021 Credit Agreement, and the 2019 Credit Agreement was terminated. Upon termination of the 2019 Credit Agreement, the Company recognized $

1,883

as loss on the extinguishment of the loan for the year ended December 31, 2021.

13. Stockholders' Equity

As of December 31, 2023 and 2022, the issued shares of Class A common stock include

728,548
treasury shares that were reacquired in connection with the redemption of redeemable shares in March 2019.

Each share of Class A common stock entitles the holder to one vote on all matters submitted to the stockholders for a vote. Class A common stockholders are entitled to receive dividends, as may be declared by the Board of Directors to the extent permissible under the 2021 Credit Agreement. Through December 31, 2023,

no
cash dividends have been declared or paid.

At December 31, 2023 and 2022, the Company reserved the following shares of Class A common stock for future issuance:

	December 31, 2023	2022
Shares reserved for issuance for outstanding options	9,340,046	5,931,742
Shares reserved for issuance for outstanding restricted stock units	3,898,331	1,381,500
Shares reserved for issuance for future grants	4,898,964	11,394,962
Total shares of authorized common stock reserved for future issuance	18,137,341	18,708,204

14. Share-Based Compensation

Stock Incentive Plans-the 2018 Plan

On November 28, 2018, the Board of Directors of the Company adopted, and on December 10, 2018, the Company's stockholders approved, the Organogenesis 2018 Equity and Incentive Plan (the "2018 Plan"). The purposes of the 2018 Plan are to provide long-term incentives and rewards to the Company's employees, officers, directors and other key persons (including consultants), to attract and retain persons with the requisite experience and ability, and to more closely align the interests of such employees, officers, directors and other key persons with the interests of the Company's stockholders.

The 2018 Plan authorizes the Company's Board of Directors or a committee of not less than two independent directors (in either case, the "Administrator") to grant the following types of awards: non-statutory stock options; incentive stock options; restricted stock awards; restricted stock units; stock appreciation rights; unrestricted stock awards; performance share awards; and dividend equivalent rights. The 2018 Plan is administered by the Company's Board of Directors.

At the adoption of the 2018 Plan, a total of

9,198,996

shares of Class A common stock was authorized to be issued (subject to adjustment in the case of any stock dividend, stock split, reverse stock split, or similar change in capitalization of the Company). In June 2022, the 2018 Plan was amended to increase the number of shares of Class A common stock reserved for issuance by

7,826,970

shares.

Stock Incentive Plans-the 2003 Plan

The Organogenesis 2003 Stock Incentive Plan (the "2003 Plan"), provided for the Company to issue restricted stock awards, or to grant incentive stock options or non-statutory stock options. Incentive stock options were granted only to the Company's employees. Restricted stock awards and non-statutory stock options were granted to employees, members of the Board of Directors, outside advisors and consultants of the Company.

Effective December 10, 2018, no additional awards may be made under the 2003 Plan and as a result (i) any shares in respect of stock options that are expired or terminated under the 2003 Plan without having been fully exercised will not be available for future awards; (ii) any shares in respect of restricted stock that are forfeited to, or otherwise repurchased by the Company, will not be available for future awards; and (iii) any shares of Class A common stock that are tendered to the Company by a participant to exercise an award will not be available for future awards.

Stock-Based Compensation Expense

Stock options awarded under the stock incentive plans expire 10 years after the grant date and typically vest over four or five years . Restricted stock units awarded typically vest over four years.

During the years ended December 31, 2023, 2022, and 2021, the Company recorded stock-based compensation expense of $

8,996

, $

6,552

and $

3,864

, respectively, within selling, general and administrative expenses on the consolidated statements of operations and comprehensive income.

Restricted Stock Units (RSUs)

During the years ended December 31, 2023 and 2022, the Company granted

3,192,372
and

979,257
time-based restricted stock units to its employees, executives and the Board of Directors. Each restricted stock unit represents the contingent right to receive one share of the Company's Class A common stock. The fair value of the restricted stock units is based on the fair market value of the Company's stock on the date of grant.

The activity of restricted stock units is set forth below:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2022	1,381,500	$ 7.62
Granted	3,192,372	$ 2.47
Vested	(522,651)	$ 7.28
Canceled/Forfeited	(152,890)	$ 5.21
Unvested at December 31, 2023	3,898,331	$ 3.54

As of December 31, 2023, the total unrecognized compensation cost related to unvested restricted stock units expected to vest was $ 7,316 and the weighted average remaining recognition period for unvested awards was 2.53 years.

Stock Options

The stock options granted during the years ended December 31, 2023 and 2022 were 3,554,528 and 1,418,224, respectively. The assumptions that the Company used to determine the grant-date fair value of stock options granted during these periods are as follows, presented on a weighted-average basis:

	Year Ended December 31, 2023	2022
Risk-free interest rate	4.00%	1.92%
Expected term (in years)	6.25	6.25
Expected volatility	51.00%	50.66%
Expected dividend yield	0.0%	0.0%
Underlying stock price	$ 2.47	$ 7.87

These assumptions resulted in an estimated weighted-average grant-date fair value per share of stock options granted during the years ended December 31, 2023 and 2022 of $

1.32
and $

3.94
, respectively.

The following table summarizes the Company's stock option activity since December 31, 2022:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	5,931,742	$ 5.91	6.14	$ 2,245
Granted	3,554,528	$ 2.51		
Canceled / forfeited	(146,224)	$ 7.09		
Outstanding as of December 31, 2023	9,340,046	$ 4.60	6.66	$ 10,267
Options exercisable as of December 31, 2023	3,999,380	$ 4.57	4.08	$ 4,681
Options vested or expected to vest as of December 31, 2023	8,488,262	$ 4.66	6.44	$ 9,227

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's Class A common stock for those stock options that have exercise prices lower than the fair value of the Company's Class A common stock.

The total fair value of options vested during the years ended December 31, 2023 and 2022 was $

3,117
and $

2,082
, respectively.

As of December 31, 2023, the total unrecognized stock compensation expense was $

6,295
and was expected to be recognized over a weighted-average period of 2.35 years.

During the year ended December 31, 2021, a former executive repaid the remaining principal balance of certain partial recourse notes, which was treated as the exercise price for

195,278

shares of associated stock options. After such repayment, a total of

675,990

shares that had previously been used to secure all of the partial recourse notes taken by the executive were considered issued and outstanding. See Note 19, *Related Party Transactions*, for additional information.

15. Income Taxes

The components of the income tax expense (benefit) consisted of the following for the years ended December 31, 2023, 2022, and 2021:

	Year Ended December 31,		
	2023	**2022**	**2021**
Income tax expense (benefit):			
Current tax expense (benefit)			
Federal	$ 1,275	$ 178	$ —
State	2,157	2,575	899
Foreign	3	17	(39)
Total current tax expense	3,435	2,770	860
Deferred tax expense (benefit)			
Federal	3,311	5,446	(30,506)
State	(1,312)	(3,466)	(1,470)
Foreign	13	—	—
Total deferred tax expense (benefit)	2,012	1,980	(31,976)
Total income tax expense (benefit)	$ 5,447	$ 4,750	$ (31,116)

On a periodic basis, the Company reassesses the valuation allowance on its deferred income tax assets, weighing positive and negative evidence to assess the recoverability of the deferred tax assets. In the fourth quarter of fiscal year 2021, the Company assessed the valuation allowance and considered positive evidence, including significant cumulative consolidated income over the three years ended December 31, 2021, revenue growth and expectations of future profitability, and negative evidence, including the impact of a negative change in the economic climate, significant risks and uncertainties in the business and restrictions on tax loss utilization in certain state jurisdictions. After assessing both the positive evidence and the negative evidence, the Company determined it was more likely than not that its deferred tax assets would be realized in the future and released the valuation allowance on its net deferred tax assets as of December 31, 2021, resulting in a benefit from income taxes of $

48,252

. The Company determined that its net U.S. deferred tax assets did not require a valuation allowance as of December 31, 2023 and 2022.

As of December 31, 2023, the Company had available for the reduction of future years' federal taxable income, net operating loss carry-forwards of approximately $

11,669

, all of which can be carried forward indefinitely, but that are subject to an

80
% taxable income limitation. The Company had state net operating loss carry-forwards of approximately $

9,430
, expiring from the year ended December 31, 2029 through 2038.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities as of December 31, 2023 and 2022 are as follows:

	December 31, 2023	2022
Net operating loss carryforwards		
Federal	$ 2,455	$ 9,327
State	665	960
Foreign	4	16
Other	6,404	5,658
Capitalized research and development	17,608	8,849
Stock-based compensation	1,699	1,453
Finance leases	—	126
Operating leases	12,503	13,164
Fixed assets	—	3,921
Net deferred tax assets before valuation allowance	41,338	43,474
Valuation allowance	—	—
Property and equipment	(1,493)	—
Right-of-use assets	(10,002)	(10,724)
Intangibles	(1,841)	(2,736)
Net deferred tax assets	$ 28,002	$ 30,014

The Company's subsidiary in Switzerland is carrying a deferred tax asset of approximately $

4

relating to a net operating loss carryover that is expected to be benefited in the next couple of years. The Company has not recorded withholding taxes on the undistributed earnings of its Swiss subsidiary because it is the Company's intent to reinvest such earnings indefinitely.

Ownership changes, as defined in the Internal Revenue Code, may limit the amount of net operating losses and research and development tax credit carryforwards that can be utilized annually to offset future taxable income. Subsequent ownership changes could further affect the limitation in future years. The Company completed an analysis in 2021 and determined that it had not experienced an ownership change during the periods 2001 through 2021.

The differences between income taxes expected at the U.S. federal statutory income tax rate of

21

% and the reported consolidated income tax benefit (expense) are summarized as follows:

	December 31,		
	2023	2022	2021
U.S. federal statutory income tax rate	21.0 %	21.0 %	21.0 %
Federal valuation allowance	—	—	(70.6 %)
State valuation allowance	—	—	(9.1 %)
Return to provision and other adjustments	(1.4 %)	(1.6 %)	—
Prior period correction	—	(8.5 %)	—
Executive compensation limited by 162(m)	12.0 %	3.1 %	—
State and local income taxes	8.8 %	6.8 %	6.8 %
Meals and entertainment	5.9 %	—	—
Nondeductible lobbying expenses	1.7 %	0.4 %	—
Stock-based compensation	1.3 %	0.3 %	—
Foreign rate differential	(0.1 %)	0.1 %	—
Uncertain tax position reserves	0.7 %	0.3 %	0.9 %
Nondeductible fringe benefits	1.0 %	0.4 %	—
State credits	1.1 %	0.9 %	—
Other nondeductible expenses	0.4 %	0.2 %	0.8 %
Research and development credits	—	—	0.9 %
Effective income tax rate	52.4 %	23.4 %	(49.3 %)

The Company recognizes the tax benefit from an uncertain tax position only if it is more-likely-than-not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being

realized upon ultimate settlement. The amount of unrecognized tax benefits is $

2,837
, $

2,642
and $

2,307
, as of December 31, 2023, 2022, and 2021, respectively.

A tabular roll forward of the Company's uncertainties in its income tax provision liability is presented below:

	Year Ended December 31,		
	2023	2022	2021
Gross balance at beginning of year	$ 1,632	$ 1,612	$ 2,123
Additions based on tax positions related to the current period	113	206	153
Reductions for tax positions of prior years	(126)	(186)	(664)
Gross balance at end of year	$ 1,619	$ 1,632	$ 1,612

The Company files income tax returns in the U.S. federal and state jurisdictions and Switzerland. With limited exceptions, the Company is no longer subject to federal, state, local or foreign examinations for years prior to December 31, 2019. However, carryforward attributes that were generated prior to December 31, 2019 may still be adjusted upon examination by state or local tax authorities if they either have been or will be used in a future period.

The Company recognizes interest and penalty-related expenses in tax expenses. The Company recorded $

500
and $

404
of interest for uncertain tax positions for the years ended December 31, 2023 and 2022, respectively, which is classified in accrued expenses and other current liabilities in the consolidated balance sheets. These amounts are not reflected in the reconciliation above.

16. Earnings per Share (EPS)

Basic EPS is calculated by dividing net income by the weighted-average number of shares outstanding during the period. Diluted EPS is calculated by dividing net income by the weighted-average number of shares outstanding plus the dilutive effect, if any, of outstanding equity awards using the treasury stock method which includes consideration of unrecognized compensation expenses as additional proceeds.

A reconciliation of the numerator and denominator used in the calculation of the basic and diluted net income attributable to the Class A common stockholders is as follows:

	Year Ended December 31,		
	2023	2022	2021
Numerator:			
Net Income	$ 4,945	$ 15,532	$ 94,202
Denominator:			
Weighted average common shares outstanding —basic	131,231,317	130,070,231	128,331,022
Dilutive effect of restricted stock units	710,813	149,215	469,123
Dilutive effect of options	804,597	2,163,706	4,862,514
Weighted-average common shares outstanding—diluted	132,746,727	132,383,152	133,662,659
Earnings per share—basic	$ 0.04	$ 0.12	$ 0.73
Earnings per share—diluted	$ 0.04	$ 0.12	$ 0.70

For the years ended December 31, 2023, 2022, and 2021, outstanding stock-based awards of

3,147,503
,

3,445,191
and

994,168
, respectively, were excluded from the diluted EPS calculation as they were anti-dilutive.

17. Leases

The Company's leases consist primarily of real estate, equipment and vehicle leases.

The Company leases real estate for office, lab, warehouse and production space under noncancelable leases that expire at various dates through 2035, subject to the Company's options to terminate or renew certain leases for an additional five to ten years .

The Company leases vehicles under operating leases for certain employees and has fleet services agreements for service on these vehicles. The minimum lease term for each newly leased vehicle is 367 days with renewal options. The Company may terminate the vehicle lease after the minimum lease term upon thirty days' prior notice.

The Company also leases other equipment under noncancelable operating leases that expire at various dates through 2025, and certain equipment required for its cleanroom facilities under finance leases that expire in 2026.

The Company determines if an arrangement is a lease at lease inception. The options to extend or terminate a lease are included in the lease terms when it is reasonably certain that the Company will exercise the options. Operating leases are included in operating lease right-of-use assets and operating lease obligations on the consolidated balance sheets. Finance lease right-of-use assets are included in property and equipment, net, and the related liabilities are included in finance lease obligations on the consolidated balance sheets.

Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the leases. Right-of-use assets and lease liabilities are recognized based on the present value of the fixed lease payments over the lease term at the commencement date. The right-of-use assets also include any initial direct costs incurred and lease payments made at or before the commencement date and are reduced by lease incentives. The Company uses its incremental borrowing rate as the discount rate to determine the present value of the lease payments for leases that do not have a readily determinable implicit discount rate. The Company's incremental borrowing rate is the rate of interest that it would have to borrow on a collateralized basis over a similar term and amount in a similar economic environment. The Company determines the incremental borrowing rates for its leases by adjusting the risk-free interest rate with a credit risk premium corresponding to the Company's credit rating.

The Company records rent expense for its operating leases on a straight-line basis from the lease commencement date until the end of the lease term. The Company records finance lease cost as a combination of the depreciation expense for the right-of-use assets and interest expense for the outstanding lease liabilities using the discount rate discussed above. Variable lease payments are primarily related to the office and fleet leases which include but are not limited to taxes, insurance, common area maintenance and maintenance programs for leased vehicles.

On January 1, 2013, the Company entered into finance lease arrangements with 65 Dan Road SPE, LLC, 85 Dan Road Associates, LLC, Dan Road Equity I, LLC and 275 Dan Road SPE, LLC for office and laboratory space in Canton, Massachusetts (the

“Related-Party Leases”). 65 Dan Road SPE, LLC, 85 Dan Road Associates, LLC, Dan Road Equity I, LLC and 275 Dan Road SPE, LLC are related parties as the owners of these entities are also directors, former directors and / or stockholders of the Company.

In August 2021, the Company purchased the building (the "275 Dan Road Building") under the lease with 275 Dan Road SPE, LLC for $

6,013

and the lease was terminated. The Company recorded an asset of $

4,943

to buildings within property and equipment, net in accordance with ASC 842-20-40-2, *Purchase of the Underlying Asset*, to account for the purchase of the leased asset.

The remaining three Related-Party Leases were set to terminate on December 31, 2022 and each contained a renewal option for a five-year period with a rental rate at the greater of (i) rent for the last year of the prior term, or (ii) the then fair market value. In November 2021, the Company exercised the option to extend the leases for an additional five years, and at such time, remeasured the right of use assets and lease liabilities based on its best estimate of the market rental rate in the renewal period and reassessed the classification for these leases. As a result, these leases were reclassified from finance leases to operating leases on the consolidated balance sheets as of December 31, 2021. In December 2022, the Company and the landlord finalized the market rental rate in the renewal period for these properties, resulting in an additional $

8,060

to be recorded as variable lease expenses over the renewal period.

In May 2023, the Company amended its lease of its research and development facility in Birmingham, Alabama. The lease amendment extended the term of the lease through September 30, 2031 and was accounted for as a modification to the existing lease contract.

In June 2023, the Company amended a contract with a contract manufacturing organization, which had previously been determined to contain an embedded operating lease for dedicated manufacturing space. The lease amendment extended the term of the lease through July 31, 2026. The Company accounted for the lease amendment as a modification to the existing lease, and accordingly increased the associated right-of-use asset and lease liability by $

2,106

.

During the year ended December 31, 2023, the Company terminated an existing agreement for the rental of certain medical garments. The Company recorded a loss of $

559

in connection with the lease termination.

During the year ended December 31, 2023, the Company executed agreements for the rental of certain medical garments. The Company classified these rental agreements as finance leases and the leases commenced in April 2023 and September 2023. At each lease commencement date, the Company recorded equipment within property and equipment and associated lease liabilities of $

750

and $

2,701

, respectively.

Effective April 1, 2019, the Company agreed to accrue interest on accrued but unpaid lease obligations owed for rent in arrears to the owners of the buildings subject to the Related-Party Leases, at an interest rate equal to the rate charged under the 2019 Credit Agreement. In connection with the purchase of the 275 Dan Road Building in August 2021, the Company paid

50

% of the accrued but unpaid lease obligations, including accrued interest, associated with the 275 Dan Road Building. The remaining accrued but unpaid lease obligation for this building was paid in five quarterly installments through January 3, 2023, and accordingly at December 31, 2023, there is no remaining balance or accrued interest associated with the 275 Dan Road Building. The accrued but unpaid lease obligations as well as the related accrued interest with respect to the remaining three Related-Party Leases are shown below:

	December 31,	
	2023	2022
Principal portion of rent in arrears	$ 5,273	$ 5,779
Accrued interest on accrued but unpaid lease obligations	$ 2,326	$ 1,956

The accrued but unpaid lease obligations owed for rent in arrears was included in current portion of operating lease obligations, other than the balance related to the 275 Dan Road Building, which was included in accrued expenses and other current liabilities on the consolidated balance sheets, as of December 31, 2023 and 2022. The accrued interest on the accrued but unpaid lease obligations was included in accrued expenses and other current liabilities on the consolidated balance sheets as of December 31, 2023 and 2022.

The components of lease cost were as follows:

	Classification	Year Ended December 31, 2023	Year Ended December 31, 2022
Finance lease			
Amortization of right-of-use assets	COGS and SG&A	$ 479	$ 213
Interest on lease liabilities	Interest Expense	137	7
Total Finance lease cost		616	220
Operating lease cost	COGS, R&D, SG&A	10,052	9,570
Short-term lease cost	COGS, R&D, SG&A	2,921	2,951
Variable lease cost	COGS, R&D, SG&A	5,595	5,082
Total lease cost		$ 19,184	$ 17,823

Supplemental balance sheet information related to finance leases was as follows:

	December 31, 2023	December 31, 2022
Property and equipment, gross	$ 3,454	$ 1,174
Accumulated depreciation	(479)	(1,174)
Property and equipment, net	$ 2,975	$ —
Current portion of finance lease obligations	$ 1,081	$ —
Finance lease obligations, net of current portion	1,888	—
Total finance lease liabilities	$ 2,969	$ —

Supplemental cash flow information related to leases was as follows:

	Year Ended December 31, 2023	Year Ended December 31, 2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	$ 10,401	$ 9,273

Operating cash flows for finance leases	$ 137	$ 7
Financing cash flows for finance leases	$ 485	$ 200

	December 31, 2023	December 31, 2022
Weighted-average remaining lease term		
Finance leases	2.58	—
Operating leases	6.49	7.54

	December 31, 2023	December 31, 2022
Weighted-average discount rate		
Finance leases	7.91 %	—
Operating leases	4.71 %	4.61 %

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

	Operating leases	Finance leases
2024	$ 9,799	$ 1,278
2025	8,823	1,278
2026	7,542	737
2027	13,275	—
2028	3,570	—
Thereafter	15,108	—
Total lease payments	58,117	3,293
Less: interest	(7,966)	(324)
Total lease liabilities	$ 50,151	$ 2,969

18. Commitments and Contingencies

License and Manufacturing Agreement

In November 2023, the Company entered into a trademark license and manufacturing agreement with Vivex Biologics, Inc. ("Vivex") to sell its CYGNUS Dual ("Dual") and CYGNUS Matrix ("Matrix") products, with the option to license the VIA Matrix ("VIA") products.

The Company paid an upfront licensing fee to Vivex to sell Dual and Matrix, and also agreed to pay a fixed milestone payment for Dual in the event that its average sales price ("ASP") is published by certain government agencies for a specified period of time. In addition, the Company is required to pay a low double digit royalty and a high single-digit royalty on the Net Sales of Dual and Matrix, respectively, during the royalty term, as defined in the agreement with Vivex. The royalty term is commensurate with the initial term of the contract and will continue for each subsequent renewal period. The initial term of the agreement expires on December 31, 2026 and can be renewed for up to five additional one-year terms.

The Company recorded $ 5,000 in prepaid and other current assets and other assets for the payment of the upfront licensing fee, which will be recognized as expense on a straight-line basis over the estimated life of the arrangement, which the Company determined to be three years , commensurate with the initial term of the contract. In December 2023, the Company recorded $ 2,500 in prepaid and other current assets, other assets, and accrued expenses and other current liabilities for the milestone payment, as the Company determined it is probable of owing such payment to Vivex. As of December 31, 2023, $ 2,368 and $ 4,737 are recorded in prepaid and other current assets and other assets in the accompanying consolidated balance sheets, respectively, for the upfront licensing fee and expected milestone payment.

Royalties

The Company entered into a license agreement with a university for certain patent rights related to the development, use and production of one of its advanced wound care products. Under this agreement, the Company incurred a royalty based on a percentage of net product sales, for the use of these patents until the patents expired, which was in November 2006. Accrued royalties totaled $ 1,187 as of December 31, 2023 and 2022, respectively, and were classified as part of accrued expenses and other current liabilities on the Company's

consolidated balance sheets. There was

no

royalty expense incurred during the years ended December 31, 2023, 2022, and 2021, related to this agreement.

In October 2017, the Company entered into a license agreement with a third party. Under the license agreement, the Company is required to pay royalties based on a percentage of net sales of the licensed product that occur, after December 31, 2017, through the expiration of the underlying patent in October 2026, subject to minimum royalty payment provisions. The Company recorded royalty expense of $

5,456

, $

7,279

and $

5,929

, during the years ended December 31, 2023, 2022, and 2021, respectively, within selling, general and administrative expenses on the consolidated statements of operations and comprehensive income.

Legal Matters

In conducting its activities, the Company, from time to time, is subject to various claims and also has claims against others. In management's opinion, the ultimate resolution of such claims would not have a material effect on the financial position, operating results or cash flows of the Company. The Company accrues for these claims when amounts due are probable and estimable.

Other Commitments

As of December 31, 2023, we had commitments totaling $

34,915

that are legally binding and enforceable. These commitments include purchase obligations for goods and services.

19. Related Party Transactions

Lease obligations to affiliates, including accrued but unpaid lease obligations, purchase of an asset under a finance lease with an affiliate, and renewal of leases with affiliates are further described in Note 17, *Leases*.

In 2010, the Company's Board of Directors approved a loan program that permitted the Company to make loans to three executives of the Company (the "Employer Loans") to (i) provide them with liquidity ("Liquidity Loans") and (ii) fund the exercise of vested stock options ("Option Loans"). Two of the executives left the Company in 2014. The Employer Loans matured with all principal and accrued interest due on the tenth anniversary of the issuance date of each subject loan. Interest on the Employer Loans was at various rates ranging from

2.30

%—

3.86

% per annum, compounded annually. The Employer Loans were secured by shares of the Company's Class A common stock held by the former executives. With respect to the Liquidity Loans, the Company had no personal recourse against the borrowers beyond the pledged shares. As of December 31, 2020, Liquidity Loans and Option Loans to one former executive were outstanding with an aggregate principal balance of $

100

and $

334

, respectively. During the three months ended March 31, 2021, this former executive paid off the outstanding principal balance of his Employer Loans and the related interest receivable. As a result, the Company recorded $

179

as a recovery of the previously reserved related party receivables within selling, general and administrative expenses on the consolidated statements of operations and comprehensive income for the year ended December 31, 2021. The $

334

of the repaid principal balance of the Option Loans was recorded to equity. See Note 14, *Share-Based Compensation*.

20. Employee Benefit Plan

The Company maintains a 401(k) Savings Plan (the "Plan") for the U.S. employees. Under the Plan, eligible employees may contribute, subject to statutory limitations, a percentage of their salary to the Plan. Contributions made by the Company are made at the discretion of the Board of Directors and vest immediately. During the years ended December 31, 2023, 2022, and 2021, the Company made employer contributions of $

7,430

, $

6,601

and $

3,092

, respectively.

21. Subsequent Events

The Company has performed an evaluation of subsequent events through the time of filing this Annual Report on Form 10-K with the SEC.

Exhibit 21.1

SUBSIDIARIES OF ORGANOGENESIS HOLDINGS INC.

NAME OF ORGANIZATION	JURISDICTION
Organogenesis Inc.	Delaware
Prime Merger Sub, LLC	Delaware
Organogenesis Switzerland GmbH	Switzerland

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in this Registration Statement on Forms S-3 (No. 333-229003 and 333-233621) and Forms S-8 (No. 333-229601 and No. 333-268736) of our reports dated February 29, 2024, relating to the consolidated financial statements of Organogenesis Holdings Inc. and its subsidiaries (the Company), and the effectiveness of the Company's internal control over financial reporting (on which our report expresses an adverse opinion on the effectiveness of the Company's internal control over financial reporting because of a material weakness), appearing in the Annual Report on Form 10-K of the Company for the year ended December 31, 2023.

/s/ RSM US LLP

Boston, Massachusetts
February 29, 2024

EXHIBIT 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gary S. Gillheeney, Sr., certify that:

1. I have reviewed this Annual Report on Form 10-K of Organogenesis Holdings Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statement made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: February 29, 2024

/s/ Gary S. Gillheeney, Sr.

Gary S. Gillheeney, Sr.
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David Francisco, certify that:

1. I have reviewed this Annual Report on Form 10-K of Organogenesis Holdings Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statement made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: February 29, 2024

/s/ David Francisco

David Francisco
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

Certification of Periodic Financial Report
Pursuant to 18 U.S.C. Section 1350
as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Each of the undersigned officers of Organogenesis Holdings Inc. (the "Company") certifies, to his knowledge and solely for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report on Form 10-K of the Company for the year ended December 31, 2023 complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 29, 2024

/s/ Gary S. Gillheeney, Sr.

Gary S. Gillheeney, Sr.
Chief Executive Officer
(Principal Executive Officer)

Dated: February 29, 2024

/s/ David Francisco

David Francisco
Chief Financial Officer
(Principal Financial and Accounting Officer)

ORGANOGENESIS HOLDINGS INC.

Compensation Recovery Policy

November 1, 2023

This Compensation Recovery Policy (the "**Policy**") has been adopted by the Board of Directors (the "**Board**") of Organogenesis Holdings Inc. (the "**Company**"). Certain capitalized terms used in this Policy are defined at the end of this Policy.

1.**Introduction**. This Policy is intended to support the Company's pay-for-performance practices by addressing circumstances in which the Company may directly or indirectly pay compensation that was not earned. For example, the Company might pay unearned compensation by miscalculating the amount of compensation to be paid to an employee or by paying compensation for results achieved through misconduct. It is the policy of the Company to recover unearned compensation as set forth in this Policy. This Policy imposes legally binding obligations on each Executive Officer.

2.**Intent**. This Policy is intended to comply with Section 10D of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), Rule 10D-1 under the Exchange Act and Nasdaq Stock Market Rule 5608. This Policy is also intended to facilitate compliance with Section 304 of the Sarbanes-Oxley Act of 2002, as amended (15 U.S.C. § 7243). This Policy shall be interpreted and administered to facilitate compliance with applicable laws, rules and regulations, including interpretations thereof promulgated or issued by the Securities and Exchange Commission (the "**Commission**") or Nasdaq, as applicable.

3.**Administration**. This Policy shall be administered by the Board or, if so designated by the Board, the Compensation Committee of the Board (the "**Compensation Committee**"), in which case references herein to the Board shall be deemed references to the Compensation Committee. Administration of the Policy shall include the authority to (a) exercise all of the powers granted to the Board under the Policy, (b) construe, interpret, and implement this Policy in the Board's sole discretion, and (c) make all determinations necessary or advisable in administering this Policy and for the Company's compliance with applicable laws, rules and regulations with respect to this Policy, (d) engage counsel and other advisors at the expense of the Company to advise and assist the Board in connection with the interpretation, implementation and enforcement of this Policy, and (e) recommend amendments to this Policy. Any determinations made by the Board under this Policy shall be final and binding on all persons, including the Company, its affiliates, its shareholders and employees, and need not be uniform with respect to every individual covered by the Policy.

4.**Dissemination and Acknowledgement of this Policy**. A copy of this Policy shall be provided to each Executive Officer upon inception of the Policy, upon commencement of employment, upon any amendment of the Policy and otherwise at regular intervals. Continued employment for more than two (2) weeks after receipt of a copy of this Policy shall constitute an agreement to be bound by the terms of this Policy. It shall be a condition of employment or

continued employment of each Executive Officer that he, she or they shall execute and deliver to the Company, upon request, a copy of the Acknowledgement and Agreement attached to this Policy as Exhibit A, provided that failure to obtain such Acknowledgement and Agreement shall not affect the enforceability of this Policy.

5.**Recovery of Erroneously Awarded Incentive-Based Compensation**.

(a)In the event that the Company is required to prepare an Accounting Restatement, the Company shall recover reasonably promptly from each Executive Officer the amount of Erroneously Awarded Incentive-Based Compensation, regardless of fault or responsibility and regardless of whether the Company actually files the required Accounting Restatement with the Commission.

(b)Under this Policy, each Executive Officer is legally obligated, both during and after employment, to reimburse the Company reasonably promptly for any Erroneously Awarded Incentive-Based Compensation.

(c)Any employment agreement, equity award agreement, compensation plan or other compensatory agreement or arrangement with any Executive Officer shall be deemed to include, as a condition to the receipt of any Incentive-Based Compensation from or on behalf of the Company, an agreement by the Executive Officer to be bound by this Policy.

6.**Recovery for Misconduct**. In accordance with Section 304 of the Sarbanes-Oxley Act of 2002 (15 U.S.C. § 7243), in the absence of an exemption from the Commission, if the Company is required to prepare an accounting restatement (which may include an Accounting Restatement) due to the material noncompliance of the Company, as a result of misconduct, with any financial reporting requirement under applicable securities laws, the Chief Executive Officer and Chief Financial Officer of the Company shall reimburse the Company for (a) any bonus or other incentive-based or equity-based compensation received by that person from or on behalf of the Company during the 12-month period following the first public issuance or filing with the Commission (whichever first occurs) of the financial document embodying such financial reporting requirement, and (b) any profits realized from the sale of securities of the Company during that 12-month period (collectively, "**Misconduct-related Compensation**"). For purposes of administering this Policy, the Board may treat any Misconduct-related Compensation as Erroneously Awarded Incentive-Based Compensation but may elect such other recovery procedures as it deems necessary or appropriate.

7.**Recovery Procedure**.

(a)If the Company is required to prepare an Accounting Restatement, the Board shall reasonably promptly determine the amount of any Erroneously Awarded Incentive-Based Compensation and shall deliver written notice of the determination to the relevant Executive Officer(s), together with a demand for repayment of such compensation in the manner determined by the Board pursuant to Section 7(d).

(b)For Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Incentive-Based Compensation is

not subject to mathematical recalculation directly from the information in an Accounting Restatement:

(i)the Board shall make a reasonable estimate of the effect of the Accounting Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received; and

(ii)the Company shall maintain documentation of the Board's determination of that reasonable estimate and provide such documentation to Nasdaq.

(c)For long-term disability plans, life insurance plans, supplemental executive retirement plans or other plans or arrangements that take into account Incentive-Based Compensation, the Company shall recover the amount contributed to the notional account based on Erroneously Awarded Incentive-Based Compensation and any earnings accrued to date on that notional amount.

(d)The Board shall have the discretion to determine the appropriate timing and means of recovery of Erroneously Awarded Incentive-Based Compensation based on the facts and circumstances of each recovery, which may include one or more of the following (in each case to the extent permitted by law):

(i)repayment in cash of the amount of Erroneously Awarded Incentive-Based Compensation;

(ii)offsets against unpaid incentive compensation, nonqualified deferred compensation, future compensation or dividends on Company stock;

(iii)cancellation of outstanding equity awards, whether vested or unvested;

(iv)surrender of outstanding shares of Company stock;

(v)non-cancellable promissory notes bearing a commercially reasonable rate of interest;

(vi)a deferred payment plan that allows the Executive Officer to repay Erroneously Awarded Incentive-Based Compensation as soon as possible without unreasonable economic hardship to the Executive Officer; or

(vii)any other remedial action permitted by law, as determined by the Board in its sole discretion.

Notwithstanding the foregoing, except as provided in Section 8, the Company shall not accept an amount less than the amount of the Erroneously Awarded Incentive-Based Compensation in satisfaction of an Executive Officer's obligations under this Policy.

(e)If an Executive Officer fails to repay all Erroneously Awarded Incentive-Based Compensation to the Company when due, (i) the Company shall seek, subject only to the

exceptions provided in Section 8, to recover such Erroneously Awarded Incentive-Based Compensation from the Executive Officer and (ii) the Executive Officer shall reimburse the Company for any and all expenses reasonably incurred (including legal fees) by the Company or any of its subsidiaries in recovering such Erroneously Awarded Incentive-Based Compensation.

8.**Exceptions**. The Company need not recover Erroneously Awarded Incentive-Based Compensation in the following circumstances if a majority of the independent directors serving on the Board has made a determination that recovery would be impracticable:

(a)the direct expense paid to a third party to assist in enforcing the Policy would exceed the amount to be recovered; *provided, however*, that, before concluding that it would be impracticable to recover any amount of Erroneously Awarded Incentive-Based Compensation based on expense of enforcement, the Company must make a reasonable attempt to recover such Erroneously Awarded Incentive-Based Compensation, document such reasonable attempt(s) to recover, and provide that documentation to Nasdaq; or

(b)recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. § 401(a)(13) or 26 U.S.C. § 411(a) and regulations thereunder.

9.**Disclosure**. The Company shall file all disclosures with respect to this Policy in accordance with the requirements of federal securities laws, including the disclosure required by applicable Commission filings.

10.**Prohibition of Indemnification**. Notwithstanding the terms of any insurance policy or any indemnification agreement or other contractual arrangement with any Executive Officer to the contrary, the Company shall not insure or indemnify any Executive Officer against (a) the loss of any Erroneously Awarded Incentive-Based Compensation that is required to be repaid, returned or recovered pursuant to this Policy, or (b) any claims relating to the Company's enforcement of its rights under this Policy. Although Executive Officers may purchase insurance to cover their potential recovery obligations, the Company shall not pay or reimburse the Executive Officer for premiums or deductibles for any such policy. Further, the Company shall not agree to exempt any Incentive-Based Compensation from the application of this Policy or to waive the Company's right to recover any Erroneously Awarded Incentive-Based Compensation. This Policy shall supersede any such agreement or waiver (whether entered into before, on, or after the Effective Date), including any indemnification agreement.

11.**Other Recovery Rights; Credit for Recovery**. This Policy shall not be construed to limit in any way the Company's right to recover any Erroneously Awarded Incentive-Based Compensation or other Incentive-Based Compensation from any Executive Officer, or any other rights or remedies that the Company may have, under any other policy, plan or agreement or any applicable law, rule or regulation. If the Company shall recover from any Executive Officer any Erroneously Awarded Incentive-Based Compensation through any means outside this Policy, the amount recovered shall be credited against the amount owed by the Executive Officer under this Policy with respect to such Erroneously Awarded Incentive-Based Compensation.

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12.**Binding Effect**. This Policy shall be binding on and enforceable against all Executive Officers and their beneficiaries, heirs, executors, administrators and other legal representatives.

13.**Survival; No Release or Waiver of Claims**. Neither the termination of employment of an Executive Officer nor ceasing to serve as an Executive Officer shall affect the Executive Officer's obligations under this Policy, which shall survive such termination or change in service. Each Executive Officer agrees that no general or limited release or waiver by the Company of any claims or rights shall release or waive, or be deemed to release or waive, any of the Company's rights under this Policy (or any obligations of the Executive Officer under this Policy) unless, and only to the extent that, and subject to Section 10, such release or waiver expressly refers to this Policy by name and expressly states that the Company intends to release its rights under this Policy.

14.**Severability**. If any provision of this Policy or the application of such provision is adjudicated to be invalid, illegal or unenforceable in any respect, that invalidity, illegality or unenforceability shall not affect any other provision of this Policy, and the invalid, illegal or unenforceable provision shall be deemed to be amended to the minimum extent necessary to render that provision or the application thereof enforceable.

15.**Governing Law**. This Policy shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to its conflicts of laws.

16.**Amendment; Termination; Waiver**. This Policy may be amended, modified or terminated at any time by the Board of Directors of the Company. The Board shall have the discretion to waive any provision of this Policy, but only to the extent that such waiver would not result in a violation by the Company of any applicable law, rule or regulation, including Rule 10D-1 under the Exchange Act and Nasdaq Rule 5608.

17.**Definitions**. For purposes of this Policy, the following terms shall have the respective meanings set forth below:

"**Accounting Restatement**" means any accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under applicable securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"**Effective Date**" means October 2, 2023.

"**Erroneously Awarded Incentive-Based Compensation**" means the amount of Recoverable Incentive-Based Compensation Received that exceeds the amount of Recoverable Incentive-Based Compensation that otherwise would have been Received had it been determined based on the restated amounts. The amount of Erroneously Awarded Incentive-Based Compensation must be computed without regard to any taxes paid.

"**Executive Officer**" means the Company's principal executive officer, president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy making functions for the Company. All executive officers identified by the Company pursuant to Item 401(b) of Regulation S-K shall be deemed to be Executive Officers.

"**Financial Reporting Measure**" means any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and total shareholder return (whether absolute or relative) are also Financial Reporting Measures. A Financial Reporting Measure need not be presented within the financial statements or included in a filing with the Commission.

"**Incentive-Based Compensation**" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

Incentive-Based Compensation is deemed "**Received**" in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant of the Incentive-Based Compensation occurs after the end of that period.

"**Recoverable Incentive-Based Compensation**" means all Incentive-Based Compensation Received by a person:

(a) after the later of (i) beginning service as an Executive Officer and (ii) the Effective Date;

(b) who served as an Executive Officer at any time during the performance period for that Incentive-Based Compensation;

(c) while the Company has a class of securities listed on a national securities exchange or a national securities association; and

(d) during the Recovery Period.

"**Recovery Period**" means the three completed fiscal years immediately preceding the Restatement Date. The Recovery Period also includes any transition period (that results from a change in the Company's fiscal year) within or immediately following those three completed fiscal years. A transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months shall be deemed a completed fiscal year.

"**Restatement Date**" means the date that the Company is required to prepare an Accounting Restatement, which is the earlier to occur of:

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(a) the date the Company's Board of Directors, a committee of the Board of Directors, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement; or

(b) the date a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement.

Exhibit A

ORGANOGENESIS HOLDINGS INC.

Compensation Recovery Policy Acknowledgement and Agreement

The undersigned has received a copy of the Compensation Recovery Policy (as amended from time to time, the "**Policy**") of Organogenesis Holdings Inc. (the "**Company**").

The undersigned has read and understands the Policy. To the extent that the undersigned considered appropriate, the undersigned has consulted with the undersigned's own tax, legal, financial and other advisors regarding the Policy.

The undersigned hereby acknowledges and agrees that the undersigned is an "Executive Officer" within the meaning of the Policy and that the Policy applies in full to the undersigned. The undersigned hereby agrees to comply with all of the obligations of the undersigned under the Policy as an Executive Officer of the Company. The undersigned acknowledges that the Policy imposes legally binding obligations on the undersigned, including the obligation to reimburse the Company for "Erroneously Awarded Incentive-Based Compensation" within the meaning of the Policy. The undersigned hereby acknowledges and agrees that that these obligations will continue even if the undersigned ceases to serve as an Executive Officer or the employment of the undersigned terminates for any reason.

Executive Officer:

_

Signature

_

Print Name

_

Date

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