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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, 2020

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 class	Trading Symbol(s)	Name of 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. ☐

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 $43.3 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, 2020, 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 28, 2021 was 127,985,190.

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 2020 Annual Meeting of Stockholders (the "Proxy Statement") to be filed with the Securities and Exchange Commission on or before April 30, 2021.

ORGANOGENESIS HOLDINGS INC.
ANNUAL REPORT ON FORM 10-K
FOR FISCAL YEAR ENDED DECEMBER 31, 2020

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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.

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 and smoking. 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 service 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 PMA approval, BLA approval 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 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; PuraPly AM as an antimicrobial barrier for a broad variety of wound types; and the Affinity and NuShield wound coverings to address a variety of wound sizes and types. We have a highly trained and specialized direct wound care sales force paired with exceptional customer support services.

In the Surgical & Sports Medicine market, we focus on products that support the healing of musculoskeletal injuries, including degenerative conditions such as OA and tendonitis. We are leveraging our regenerative medicine capabilities in this attractive, adjacent market. Our Surgical & Sports Medicine products include ReNu for in-office knee osteoarthritis treatment; NuCel for bony fusion in the lumbar spine; NuShield and Affinity barrier products for surgical application in targeted soft tissue repairs; and PuraPly AM for management of open wounds in the surgical setting. We currently sell these products through independent agencies and our growing direct sales force.

On December 10, 2018, Avista Healthcare Public Acquisition Corp., our predecessor company ("AHPAC"), consummated the previously announced business combination (the "Business Combination") pursuant to that certain Agreement and Plan of Merger, dated as of August 17, 2018 (as amended, the "Avista Merger Agreement"), by and among AHPAC, Avista Healthcare Merger Sub, Inc., a Delaware corporation and a direct wholly-owned subsidiary of AHPAC ("Avista Merger Sub") and Organogenesis Inc., a Delaware corporation. As a result of the Business Combination and the other transactions contemplated by the Avista Merger Agreement, Avista Merger Sub merged with and into Organogenesis Inc., with Organogenesis Inc. surviving the merger (the "Avista Merger"). In addition, in connection with the Business Combination, AHPAC redomesticated as a Delaware corporation (the "Domestication"). After the Domestication, AHPAC changed its name to "Organogenesis Holdings Inc." As a result of the Avista Merger, Organogenesis Inc. became a wholly-owned direct subsidiary of Organogenesis Holdings Inc.

As of December 31, 2020, we had approximately 910 full-time employees worldwide. For the year ended December 31, 2020, we generated revenue of $338.3 million and we incurred operating expenses of $223.6 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 amniotic products NuCel, NuShield, ReNu and Affinity. 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 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 VLU market. In addition, our product, Dermagraft, has been on the market since it received FDA approval in 2001 and is a well-known brand in the global regenerative medicine market. NuTech Medical has an established track record in the regenerative medicine category of the Surgical & Sports Medicine market and its products have a strong presence in this 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, and cardiovascular and peripheral vascular disease and smoking. 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 amniotic wound coverings customizable for various sizes and types of wounds. The breadth of our portfolio gives us the flexibility to offer products at various prices to accommodate both the clinical and economic factors that may impact purchasing decisions. Our products can address varying reimbursement levels depending on the type of wound, the payer, and geographic differences in payer payment rates. Our experienced wound care sales force is highly trained to assist clinicians to effectively deploy 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 200 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, BLA 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 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 including hospitals, wound care centers, government facilities, ASCs and physician offices to sell our broad portfolio of products. We serve more than 3,000 health care facilities, hospital systems, IDNs and GPOs. In addition, we have developed important relationships with physicians, 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, medical and technical support. We believe our customer support capabilities differentiate us from many of our competitors who may outsource these critical services to third parties.
- **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, BLA approval and 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 70 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. In addition, with the acquisition of NuTech Medical, we acquired products that give us access to the rapidly growing amniotic category of the 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, 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, 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 amniotic products in 2017. We plan to continue to accelerate penetration into this market by leveraging our established commercial and operational infrastructure and building out our direct sales force to supplement our 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 potential of regenerative medicine in the Surgical & Sports Medicine market, particularly with respect to chronic inflammatory and degenerative conditions, continues to present a strong long-term opportunity. 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 near term. 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 Expand Sales Force and Increase Sales Productivity and Geographic Reach.** We plan to continue to expand the reach and penetration of our products by growing our sales organization to serve the Advanced Wound Care and Surgical & Sports Medicine markets. This expansion 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 amniotic products from NuTech Medical. We believe TransCyte has the ability to address a $200 million burn market, which includes 500,000 burns that require medical attention and 40,000 burns that require hospitalization annually in the United States. 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 may 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 and Surgical & 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 $14.9 billion in 2018, which included an estimated $8.9 billion addressable market for Advanced Wound Care and an estimated $6.0 billion addressable market for Surgical & Sports Medicine. Within the Advanced Wound Care market in 2018, 54% of treatments were used in advanced wound dressings, 17% were used in biologics, 20% were used in negative pressure wound therapy and 9% were used in other treatments. The skin substitute market, within biologics, is expected to grow from $1.1 billion in 2019 to $1.4 billion in 2024. Within the Surgical & Sports Medicine market, the bone fusion sub-market accounted for approximately $2.7 billion in 2017, the tendon and ligament injuries sub-market accounted for approximately $1.0 billion in 2015 and the chronic inflammatory and degenerative condition sub-market accounted for approximately $2.4 billion in 2017.

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 smoking; 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 treatment with traditional treatment such as dressings. Chronic wounds include:

- *VLUs:* wounds that occur in the leg veins when blood does not circulate properly to the heart.
- *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 growth factors secreted by cells that are critical to healing, and that result in disrupted cell signaling pathways.

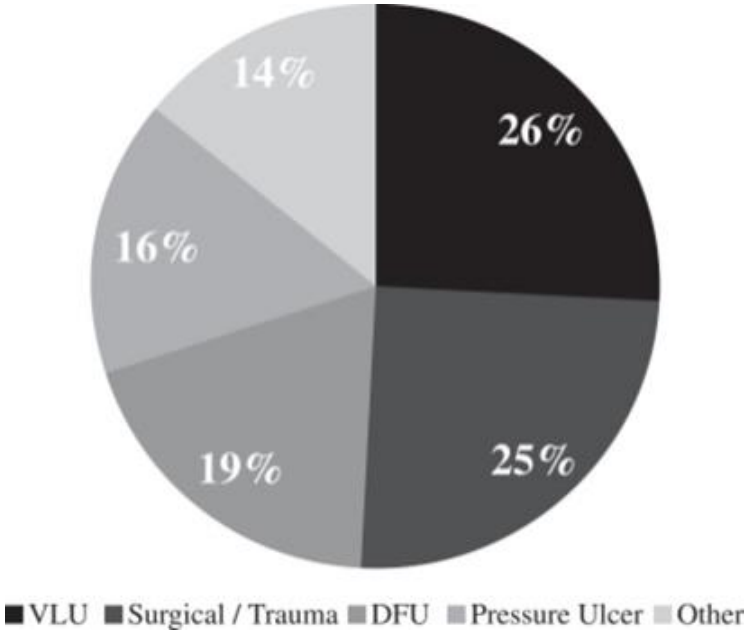
Acute Wounds

An 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 and burns, or surgical wounds from surgical incisions. In contrast to chronic wounds, which would normally heal but stall due to biologic factors, acute wounds are 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 BioMed GPS, in 2016 there were approximately 430,000 open traumatic wounds. In 2016, it is estimated that there were more than 500,000 burns that required medical treatment and approximately 40,000 burns required hospitalization.

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.

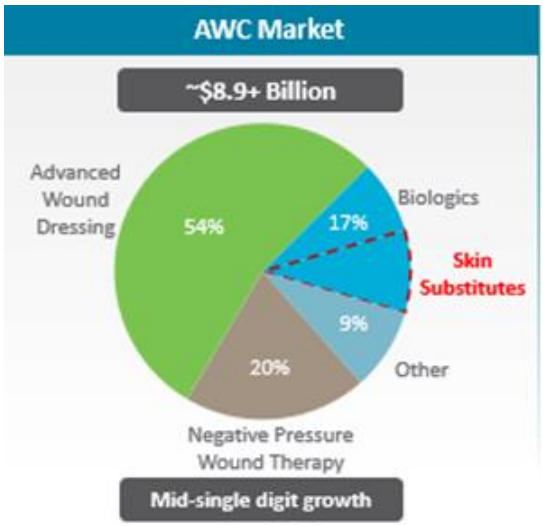
Due to the breadth of our wound care portfolio, our products are able to address both chronic and acute wounds across all of these wound types.

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 BIS Research, the global Advanced Wound Care market was estimated to be approximately $8.9 billion in 2018 and is expected to grow at a compound annual growth rate, or CAGR, of 3.6% through 2024. This market consists of several product categories including advanced wound dressings, devices such as negative pressure wound therapy, or NPWT, and biologics such as skin substitute and growth factors. The approximate breakdown for these product categories in 2018 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 BIS Research, the worldwide wound biologics market, which includes skin substitutes and growth factors, was estimated to be approximately $1.5 billion in 2018, of which skin substitute products are estimated to represent approximately 64%. 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 2019 to $1.4 billion in 2024. 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, over 8.3 million wounds require medical care in the United States each year, and over 3.3 million of those wounds are difficult to heal wounds where traditional therapies are unlikely to succeed. Despite this vast need and the proven advantages of advanced wound care products in general and skin substitutes in particular, only 135,000 patients, or less than five percent, are treated with skin substitutes each year. Our internal estimates indicate that if the potentially addressable market were completely penetrated today, annual skin substitute revenue in the United States alone could exceed $9 billion.

We believe that we are well positioned in the skin substitute market as adoption continues to increase. According to BioMed GPS, we are one of the three largest skin substitute companies 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

The same demographic trends that are driving the growth of the wound care market are also driving growth in the Surgical & Sports Medicine market. This 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 OA and tendonitis. This volume increase is fostering increased interest in regenerative medicine products, as they can help support healing and improve outcomes in older and more challenging patient populations.

While our products have applicability across a wide variety of surgical specialties, our immediate surgical focus in addition to wound care is in regenerative orthobiologics. Orthobiologics are substances that orthopedic surgeons use to help injuries to bones, tendons and ligaments heal more quickly. Orthobiologic products are used to treat people with long-term disabling musculoskeletal disorders and injuries.

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. We also plan to leverage these platforms to expand into adjacent surgical markets in the near term. In the long-term, we plan to deepen our focus on chronic inflammatory and degenerative conditions, in particular OA. We intend to address patient needs in the inpatient hospital, ASC and clinic settings. We estimate the immediate addressable Surgical & Sports Medicine market for our products to be approximately $6.1 billion and is expected to grow at a CAGR of 8%. This market is growing rapidly due to an increase in spinal fusions, bone reconstruction surgeries and musculoskeletal injuries and degenerative conditions.

Bone Fusion

Spine fusion surgery involves the use of grafting material to cause two vertebral bodies to grow together into one. In the United States, medical facilities performed 667,400 spinal fusion surgeries in 2013, of which 398,300 were lumbar operations. Trauma and extremities applications, including ankle arthrodesis, now represent a bone fusion market nearly as large as the spine market. With improving fixation methods, success rates have improved across these applications. However, nonunion due to inadequate bone healing remains one of the leading causes of failure for fusion procedures. Fusion is especially challenging in patients with comorbidities such as diabetes, obesity, and smoking who have underlying healing deficiencies. According to Technavio, the annual market for orthobiologic products to aid in fusion exceeds $2.7 billion worldwide.

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 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. According to Technavio, the annual regenerative tissue scaffold market is estimated to exceed $1 billion.

Chronic Inflammatory and Degenerative Conditions

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, or HA. According to Technavio, the global chronic inflammatory and degenerative orthopedic market exceeded $2.4 billion in 2018.

Our Solution

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.

In the case of bony fusion, autograft bone marrow has historically been used as a biologic to support bone healing. However, the use of autograft suffers from a number of short-comings that include donor site morbidity and varied outcomes due to the underlying health condition of the patient. Furthermore, it is a more invasive procedure leading to potentially slower healing times and side effects for the patient.

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 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 DBM and allograft. The majority of our current and planned products in the Surgical & Sports Medicine space are based on amniotic technologies. There is a rapidly growing body of clinical and scientific evidence indicating the potential of these products in surgical applications, particularly in orthobiologics, resulting in increased adoption of these products. According to estimates from BioMed GPS, the amniotic orthobiologics market was $88 million in 2016 and is projected to grow at a CAGR of more than 22% through 2021.

Our Products

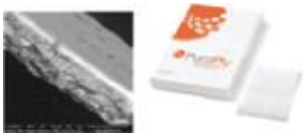
Advanced Wound Care

In the Advanced Wound Care 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 wounds, including, but not limited to, chronic wounds such as VLUs, DFUs, and pressure ulcers and acute wounds such as traumatic wounds and burns.

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 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 often 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 amniotic wound coverings tailored for a wide variety of wound sizes and types.

Our advanced wound care products are used predominantly 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 wound covering 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 produce human collagen, ECM, proteins, cytokines, and growth factors	PMA	DFUs
NuShield (2010)† 	Dehydrated placental tissue wound covering preserved to retain 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 with broad-spectrum polyhexamethylene biguanide, or PHMB, antimicrobial agent. 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.	510(k)	Chronic and acute wounds (except 3rd degree burns)

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

Affinity

Affinity is a fresh, amniotic allograft wound covering and surgical barrier for application in the care of chronic and acute wounds or surgical implantation in spine, orthopedic and sports medicine applications. We believe Affinity is one of only a few amniotic tissue products containing viable amniotic cells, and is unique in that it undergoes our proprietary AlloFresh process that hypothermically stores the product in its fresh state, never dried or frozen, which retains its native benefits and structure. Regulated as a human cells, tissues, and cellular and tissue-based product, or HCT/P, under Section 361 of 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.

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 approximately 960,000 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 electronic health records 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 does not need to be removed from the wound during this period because it contains a temporary mesh fabric that is dissolvable and becomes part of the body's own healing processes. As part of our long-term plan to consolidate manufacturing operations in Massachusetts, we anticipate that manufacturing of Dermagraft will be suspended in the fourth quarter of 2021 and that sales of Dermagraft will be suspended in the first quarter of 2022. We currently plan to transition our Dermagraft manufacturing to our Massachusetts based manufacturing facilities following the expiration of the lease for our California based manufacturing facility, which we expect will result in substantial long-term cost savings. In the period when Dermagraft is not available, we expect our sales force will be able to drive substitution from Dermagraft to Apligraf and our amnion products and that the suspension of Dermagraft sales will not have a material impact on our net revenue.

NuShield

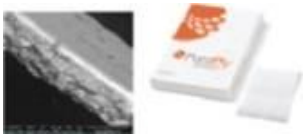
NuShield is a dehydrated placental tissue wound covering and surgical barrier that is topically or surgically applied to the target tissue to support native healing. Regulated as a 361 HCT/P, NuShield is processed using our proprietary LayerLoc process, which preserves the native structure of the amnion 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 wound covering 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. We also developed and received 510(k) clearance for PuraPly without PHMB, which we refer to as "PuraPly," for those patients who do not require an antimicrobial agent. 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.

Surgical & Sports Medicine

In the Surgical & Sports Medicine market, we focus on the development and commercialization of products that support the healing of musculoskeletal injuries, including chronic degenerative conditions such as OA and tendonitis. 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
Affinity (2014)† 	Fresh amniotic membrane barrier membrane in which native viable cells, growth factors/cytokines, and ECM proteins are preserved	361 HCT/P	Barrier membrane to support repair of tendon, ligament and other soft tissue injuries
NuCel (2009)†* 	Cellular suspension product, with cells derived from amniotic fluid combined with micronized amniotic tissue	361 HCT/P	Orthopedic surgical procedures including lumbar intervertebral bony fusion
NuShield (2010)† 	Dehydrated placental tissue barrier membrane preserved to retain 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
PuraPly AM (2016) 	Purified native collagen matrix with broad-spectrum PHMB antimicrobial agent. 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.	510(k)	Antimicrobial barrier for management of open wounds in the surgical setting
ReNu (2015)†* 	Cryopreserved suspension of amniotic fluid cells and morselized amnion tissue from the same donor	361 HCT/P	Chronic inflammatory and degenerative conditions; target indication is knee osteoarthtitis

† Launched by NuTech Medical; acquired by Organogenesis in 2017.

* Initially commercialized as a 361 HCT/P but may require BLA approval pursuant to recent 361 HCT/P Guidance from the FDA.

NuCel

NuCel is a surgically implanted allograft derived from human amniotic tissue and cells derived from amniotic fluid. NuCel is used primarily in spinal and orthopedic surgical applications to support tissue healing, including bone growth and fusion. The target indication for NuCel is lumbar spine interbody fusion. The amniotic tissue harvesting process protects key biologic characteristics of the tissue that support healing. Several published clinical studies have provided preliminary evidence of the clinical efficacy of NuCel. While NuCel is currently marketed as a 361 HCT/P, efforts are ongoing to initiate a clinical program to secure BLA approval for the product. NuCel was launched in 2009 by NuTech Medical and acquired by us in 2017.

ReNu

ReNu is a cryopreserved suspension derived from human amniotic tissue 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 fasciitis. The target indication for ReNu is for the treatment of Knee Osteoarthritis. A pilot clinical study of ReNu for knee OA has been published, which we believe is indicative of its safety. The results of this study also suggest potential efficacy for a period of more than a year. While ReNu is currently marketed as a 361 HCT/P, efforts are ongoing to secure BLA approval for the product, with a Phase 3 pivotal study currently underway. Management believes BLA approval may facilitate a significant incremental sales opportunity for ReNu. ReNu was launched in 2015 by NuTech Medical and acquired by us in 2017.

Affinity, NuShield and PuraPly AM

We also market our Affinity and NuShield products for surgical and orthopedic applications. These products may be used as a surgical barrier or as an on-lay or wrap barrier to support soft tissue repairs. The native biological characteristics of these amniotic tissues when used as barrier membranes may help support the healing of soft tissue defects, particularly in difficult-to-heal locations or challenging patient populations. In addition, we market our PuraPly AM product as an antimicrobial barrier for the management of open wounds in the surgical setting.

Bone Allograft Products

Our bone allograft products, which are derived from donated human cadaveric bone, include FiberOS and OCMP. Each of these products is used as a bone void filler, primarily in orthopedic and neurosurgical applications requiring bony fusion, such as spinal fusions and foot and ankle fusions. FiberOS is a blend of demineralized cortical fibers, mineralized cortical powder, and demineralized cortical powder and OCMP is a freeze-dried allograft cancellous (spongy or mesh-like) and demineralized cortical mixture. These products are typically sold as an ancillary product together with our amniotic product NuCel.

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 six ongoing 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.

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Advanced Wound Care

Product	Wound Type	Design	Completion Date	Estimated/Actual Data Presentation Date[4]
PuraPlyAM	All Wounds	PuraPly AM RESPOND Registry Evaluating Real World Effectiveness of PPAM=Pooled Analysis (N=434 wounds)	Q2 2020[3]	Q4 2020 SAWC[5] Fall Q1 2021
	Diabetic Foot Ulcers (DFU)	Comparative Effectiveness Analysis (CEA), NetHealth EMR Database of PPAM vs Theraskin (NI) (N=1032)	Q1 2020[3]	Q2 2020 ISPOR[6], Q2 2021 SAWC Spring[5] Q2 2021 Publication
	Venous Leg Ulcers (VLU)	Comparative Effectiveness Analysis (CEA), NetHealth EMR Database of PPAM vs Grafix (NI) (N=856)	Q3 2019[3]	Q3 2020-SAWC[5] Spring Q2 2021 Publication
	Pressure Injuries (PRI)	Prospective Multi-center Randomized Controlled Trial (RCT) PPAM vs Standard of Care (SOC) (N=38)	Q4 2019[2]	Additional Publication TBD
Apligraf	PRI	Comparative Effectiveness Analysis (CEA), NetHealth EMR Database of Apligraf vs Primatrix (N=1296)	Q4 2019[3]	Q3 SAWC[5] Spring Q2 2021 Publication
	PRI	Comparative Effectiveness Analysis (CEA), NetHealth EMR Database of Apligraf vs Epifix (N=1189)	Q1 2020[3]	Q2 2020 ISPOR[6] Q3 2021 Publication
	PRI	Comparative Effectiveness Analysis (CEA), NetHealth EMR Database of Apligraf vs Grafix (N=1330)	Q2 2020[3]	Q4 2020 SAWC[5] Fall Q3 2021 Publication
	VLU	Comparative Effectiveness Analysis (CEA), NetHealth EMR Database of Apligraf vs Primatrix (N=9552)	Q4 2019[3]	Q3 2020 SAWC[5] Spring Q4 2021 Publication
NuShield	DFU	Prospective Multicenter RCT, Nushield vs SOC (N=60)- Interim Analysis	Q2 2020[3]	Q4 2020 DFCON[7], SAWC[5] Fall Q1 2021 Publication
	DFU[1]	Prospective Multicenter RCT, Nushield vs SOC (N=200)	Q3 2021	Q4 2022
Affinity	VLU[1]	Prospective, Multicenter RCT Affinity vs SOC (N=200)	Q4 2022	Q1 2023

1. In development or Actively Enrolling
2. Based on last patient last visit in the study
3. Data analysis complete
4. Estimated date of first external presentation of primary data
5. SAWC: Symposium of Advanced Wound Care.
6. ISPOR: Int Soc for Pharmacoeconomics and Outcomes
7. DFCON: Diabetic Foot Conference

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Surgical & Sports Medicine

Product	Indication	Design	Completion Date[1]	Estimated/Actual Data Presentation Date[2]
ReNu	Knee OA	Investigation of ReNu Knee Injection: Response of Knee Function and Pain in patients with Osteoarthritis for 12 months (N=200)	Q3 2018	Q2 2020 TOBI[3] Q3 2021
	Knee OA	Rescue Arm- Investigation of ReNu Knee Injection: Response of Knee Function and Pain in patients with Osteoarthritis (N=200)	Q3 2018	Q3 2021
	Hip OA	Prospective Pilot Study Amniotic Suspension Allograft for Treatment of Moderate Hip OA: A Prospective Pilot Study (N=10)	Q3 2020	Q1 2021
	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)	Q3 2023	Q4 2023
	Plantar Fasciitis	Comparative Study of Injectable human amniotic allograft (ReNu) versus corticosteroids for Plantar Fasciitis: A Prospective, Randomized, Blinded Study (N=132)	Q1 2021	Q3 2021
NuCel	Lumbar Spine Vertebral Fusion	A Single-Arm Prospective, study of NuCel in patients undergoing fusion for one, two or three level degenerative disease of the lumbar spine (N=57)	Q2 2020	Q3 2021
	Lumbar Spine Vertebral Fusion	A Single-Arm Prospective, multi-center study of Nucel in patients receiving interbody fusion for one- and two-level degenerative disease of the lumbar spine (N=200)	Q4 2023	Q3 2024
NuShield	Peroneal Tendon Repair	Single-Arm Clinical Evaluation of the Safety and Efficacy of the NuShield® Allograft for Peroneal Tendon Repair	Q3 2021	Q2 2022

1. Based on last patient last visit in the study
2. Estimated date of first external presentation of primary data
3. TOBI: The Orthobiologic Institute Conference

Organogenesis Inc.

Recently Published Clinical Studies

PuraPly AM

In a published 24-week study of the use of PuraPly AM in the management of bioburden and treatment of chronic, non-healing wounds (n=63), 90% of wounds demonstrated a reduction in area and 68% of wounds achieved complete closure (mean time to complete closure of 5.0 weeks). The wounds studied included 29% venous ulcers, 22% trauma and laceration, 16% post-surgical wounds, 13% pressure ulcers and 10% diabetic ulcers. The median wound area was 6.5cm^2 and the mean wound duration was 4 months.

Affinity

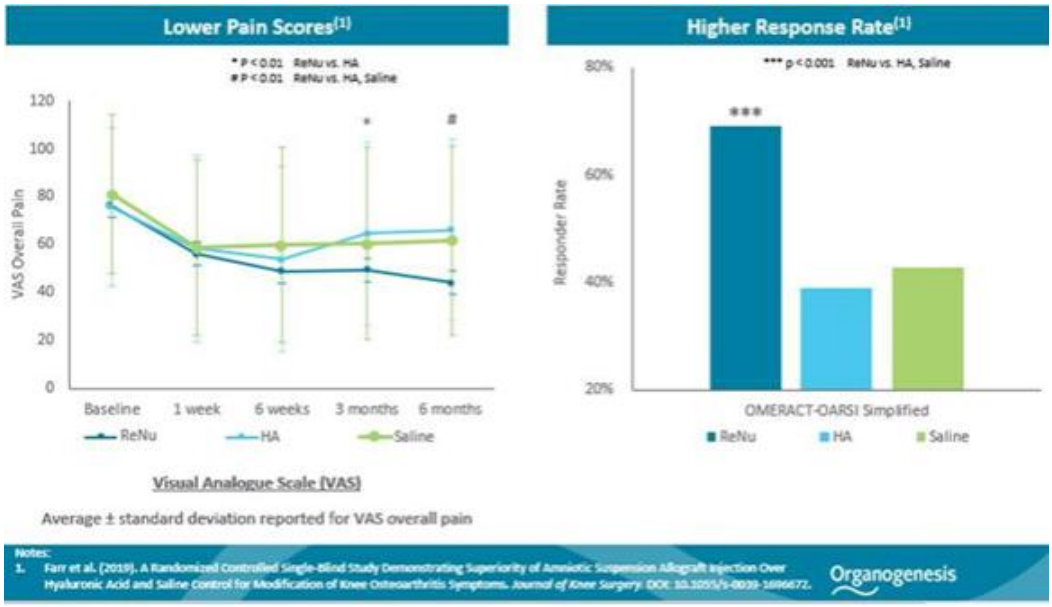
In a published randomized controlled clinical trial of Affinity for use in diabetic foot ulcers comparing the use of Affinity and the standard of care (n=38) to the use of the standard of care alone (n=38), 60% of wounds in the Affinity and standard of care group achieved wound closure at 12 weeks compared to 38% of wounds in the standard of care group 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. 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; 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; 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.

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 statistically significant reduction in pain and higher OMERACT-OARSI responder rate at 6 months follow-up than patients treated with HA or saline.



NuCel

Published preliminary results of a study examining the use of NuCel to achieve one and two-level lumbar interbody fusion demonstrated that 97% of patients in the one-level lumbar interbody fusion group (n=38) achieved kinematic fusion and 100% of patients in the two-level lumbar interbody fusion group (n=34) achieved kinematic fusion. Baseline comorbidities were present in 90% of patients in the one-level lumbar interbody fusion group and 88% of patients in the two-level interbody fusion group and no adverse events related to NuCel were reported.

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.

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.

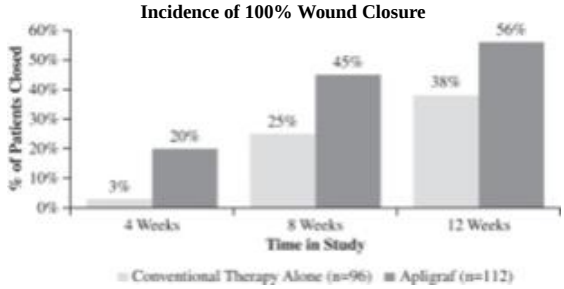
Pivotal FDA Registration Trials

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. Mean duration of the ulcer was 12 months in the Apligraf group and 11 months in the control group.

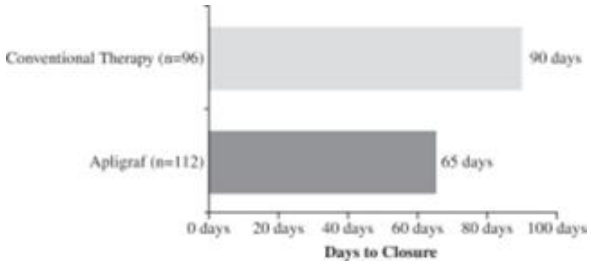
Apligraf was significantly more effective than conventional therapy for the incidence of complete wound closure over time. By 12 weeks of treatment, 56% (63 of 112 patients) of DFUs treated with Apligraf plus conventional therapy (debridement, saline dressings, total off-loading) were 100% closed, compared 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.

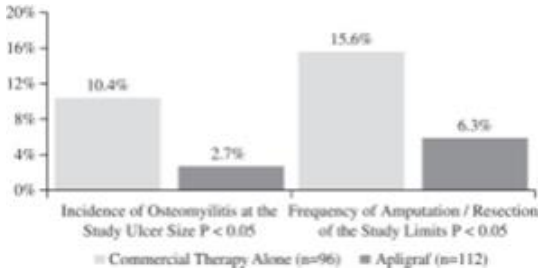
Incidence of 100% Wound Closure



Median Time to 100% Wound Closure

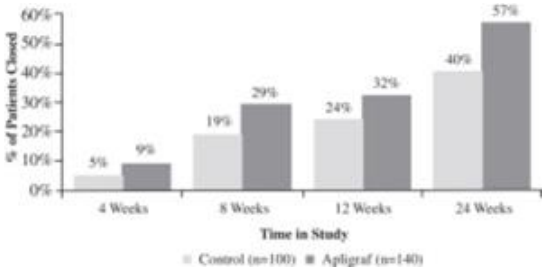


Reduction in Osteomyelitis and Amputation / Resection



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 three comparative effectiveness studies with Apligraf utilizing our proprietary access to data collected in Net Health's WoundExpert® 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 Misonix, Inc.) and Oasis (owned by Smith & Nephew). All three 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 three 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 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.

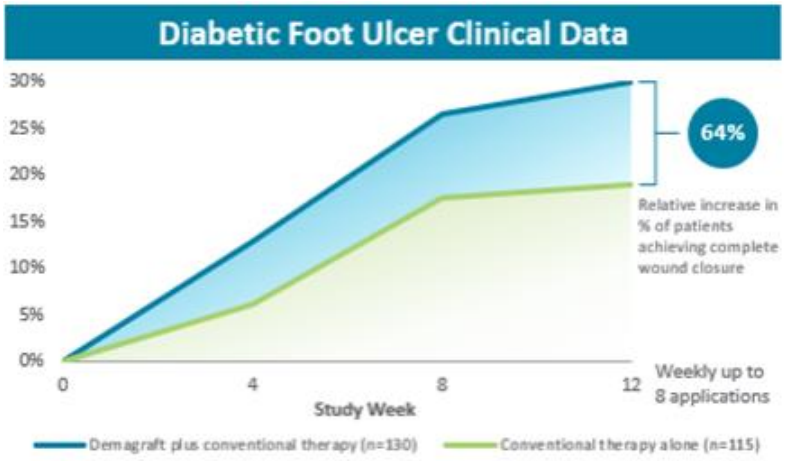
Dermagraft

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

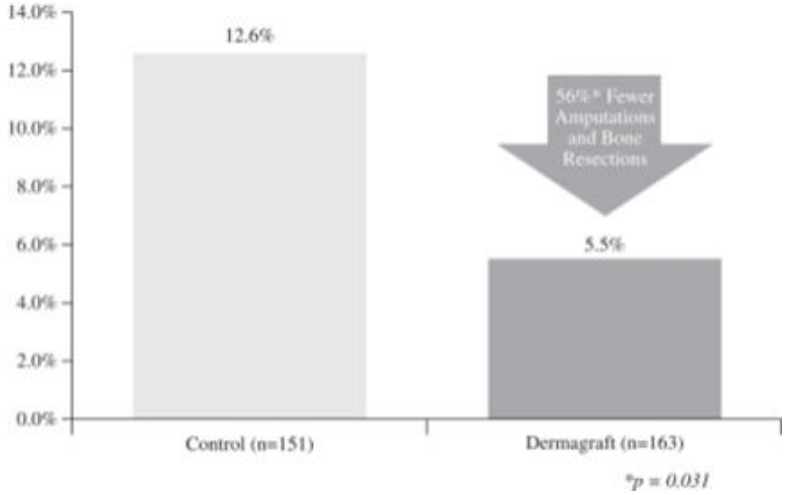
In the pivotal clinical trial, the weekly application of Dermagraft and conventional therapy for up to eight weeks increased the proportion of DFUs that achieved 100% closure at 12 weeks by 64%, when compared to the use of conventional therapy alone. Patients treated in the Dermagraft group were 1.7 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



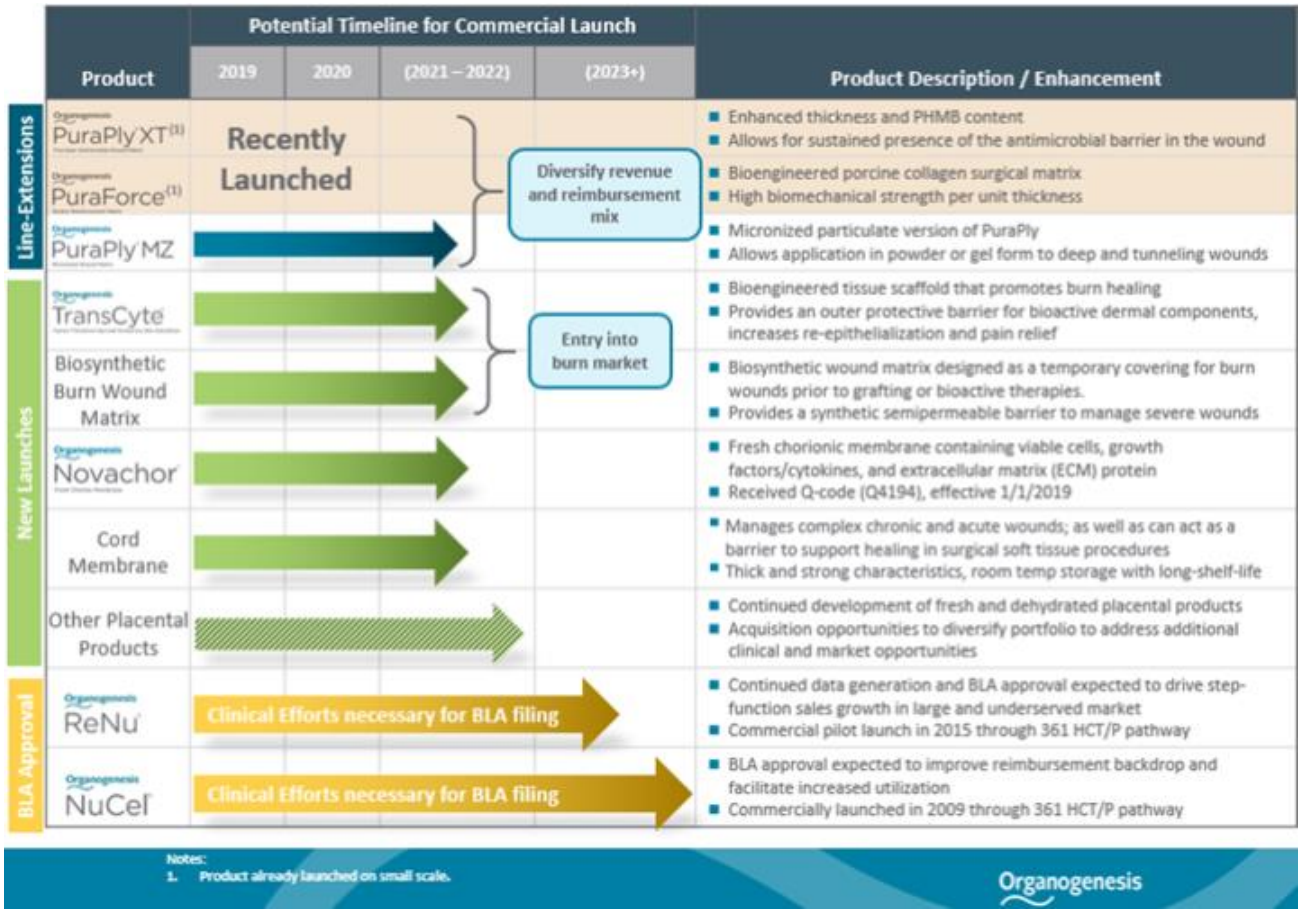
Comparative Effectiveness and Economic Studies

We have conducted one comparative effectiveness study with Dermagraft, which utilizes our proprietary access to data collected in the EMR database. This study, which was published in a peer-reviewed journal, compared Dermagraft outcomes to EpiFix (owned by MiMedx), and 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.

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 XT

PuraPly XT is a version of PuraPly AM with enhanced thickness and PHMB content that allows for sustained presence of the antimicrobial barrier in the wound. Like PuraPly AM, PuraPly XT is intended for 510(k) indications for the treatment of chronic and acute wounds (other than 3rd degree burns) and the surgical treatment of open wounds. We commercially launched this product in 2020.

PuraForce

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. We commercially launched this product in 2019.

PuraPly MZ

PuraPly MZ is a micronized particulate version of PuraPly that allows application in powder or gel form to deep and tunneling wounds. Like PuraPly, PuraPly MZ is intended for indications for the management of chronic and acute wounds (other than 3rd degree burns) and in conjunction with the surgical treatment of open wounds. A 510k application has been filed, and FDA has requested additional preclinical biocompatibility testing which is ongoing. Following successful 510k Clearance, we plan to commercially launch this product in late 2021 or early 2022.

Novachor

Novachor is a fresh chorionic membrane wound covering in which native tissue elements are preserved, including viable cells, growth factors/cytokines, and extracellular matrix (ECM) proteins. The product is regulated as a 361 HCT/P when promoted and utilized clinically for homologous use as a wound covering or surgical barrier. We expect to commercially launch this product in 2021 or early 2022, following technology transfer of production to our contract manufacturer.

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 one other PMA approved product that would be directly competitive to TransCyte currently on the market. We plan to initiate a market re-introduction program in late 2021, and will target a full commercial launch in late 2023. We also plan to launch in the same timeframe a complementary biosynthetic wound product, a Class II Medical Device for the management of burns, for which we plan to seek 510(k) clearance in the second half of 2021.

Gintuit

Gintuit is a surgically applied bioengineered bi-layered living cellular tissue that supports the healing of oral soft tissue. It is currently the only BLA approved product based on cultured allograft cells and it is indicated for the treatment of mucogingival conditions in adults. We are not currently marketing Gintuit.

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, TransCyte and Gintuit 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. We commercially launched our PuraForce product from this platform in 2019.
- ***Amniotic and Placental Products:*** Our current amniotic 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 technology preserves the native structure of the amnion and chorion membranes, optimized to provide excellent strength, flexibility, and handling.

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, 2020, we had approximately 300 direct sales representatives and approximately 175 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 on the United States, but we have obtained marketing registrations, developed commercial and distribution capabilities, and we 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 La Jolla, 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 physicians aid us in our research and development process.

The majority of our product portfolio, including Apligraf, our PuraPly product family, Gintuit, our collagen biomaterial technology platform product family and all of our amniotic products, were developed by our legacy and NuTech Medical research and development team. 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-amniotic products and use third-party manufacturers for our amniotic 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.

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.

Reimbursement

Overview

Our customers primarily consist of hospitals, wound care centers, government facilities, ASCs and physician offices, all of whom rely on coverage and reimbursement for our products by Medicare, Medicaid and other third-party payers. Governmental insurance 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 and also may require prior authorization for the products and services that a member receives. Coverage and reimbursement from government and commercial payers is not assured and is subject to change.

Medicare, the federally funded program that provides healthcare coverage for senior citizens and the disabled, is the largest third-party payer in the United States. CMS, administers the Medicare program and uses MACs to process claims, develop coverage policies and make payments within designated geographic jurisdictions. Our products fall under the jurisdiction of the Part A/B MACs. Medicare coverage for our products is established by each MAC for its specific jurisdiction. CMS does not have a national coverage determination related to skin substitutes. Currently, all the MACs cover our products in the outpatient hospital, physician office and ASC settings.

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, most of those payers do not cover many of our other products, such as PuraPly, PuraPly AM, NuShield, and Affinity.

Currently, Medicare makes a separate payment for our products when used in the physician office at a payment rate of average sales price (ASP) plus 6%. Legislation was recently enacted that temporarily discontinued the sequestration rate of 2% of the government portion which resulted in a final payment rate of ASP+4.3%. The sequestration will begin again on April 1, 2021. In the outpatient hospital and ASC settings, Medicare payment for all our products is bundled into the payment for the application procedure.

All skin substitute products administered in the hospital outpatient department and ASC settings are bundled, except for those products that have been approved by CMS for 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. The amount of the pass-through payment for PuraPly AM and PuraPly was equal to ASP + 6% for the applicable calendar quarter.

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; for example, sixty percent of the hospital payment rate is adjusted to take into account the region's wage-index, which can vary widely from one region to another. The wage-index adjustment 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.

All skin substitute products administered in the hospital outpatient department and ASC settings are bundled, except for those products that have been approved by CMS for pass-through status. In order to encourage the development of innovative medical devices, drugs and biologics, Congress created pass-through payments to allow payment for new innovative medical products to be added to the current Medicare rate. For a limited period of time, products with pass-through status are reimbursed through an additional reimbursement amount known as a "pass through payment," for the medical device, drug or biologic on top of the bundled payment amount the hospital would receive for performing the service. The additional payment amount is the hospital's charge for the pass-through product reduced to cost using the hospital's specific cost to charge ratio, less an offset for the amount of money already included in the bundle for skin substitute products.

PuraPly AM and PuraPly were included in the "bundled" payment structure from January 1, 2018 through September 30, 2018. Section 1301 of the Consolidated Appropriations Act of 2018, which was enacted on March 23, 2018, restored the pass-through status of PuraPly AM and PuraPly effective October 1, 2018 through September 30, 2020. Beginning on October 1, 2018, Medicare resumed making pass-through payments when PuraPly AM and PuraPly were used in outpatient hospital and ASC settings. All other skin substitute products, including all of our other products, remained in the bundled payment structure. The amount of the pass-through payment for PuraPly AM and PuraPly was equal to ASP + 6% for the applicable calendar quarter. The Consolidated Appropriations Act applied only to Medicare, and does not apply to Medicaid or any commercial payers. As noted above, as of October 1, 2020, payment for PuraPly and PuraPly AM is once again bundled into the payment rate for the application procedure.

Furthermore, Medicare has signaled that it may revise its two-tiered bundled payment policy for skin substitutes. Medicare solicited comments in calendar year 2019 proposed rule related to proposed updates and policy changes under the Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (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. It is possible that Medicare will revise its payment policy in calendar year 2022 or calendar year 2023. Any revised policy 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 skin substitutes (including ours) is calculated based on the manufacturer's ASP 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 skin substitutes (including ours) are updated quarterly based on manufacturer reported ASP and are not geographically adjusted. The actual payment rate for skin substitutes is ASP plus 6%, which will be adjusted for the statutorily mandated sequestration starting on April 1, 2021 resulting in an actual payment of ASP plus 4.3%. This payment methodology applies only to physician offices. Medicare does not require us to report ASP for our products because they are regulated by the FDA as medical devices. However, starting in January 2022, we will be 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. Currently, 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 discretion to pay for such products based on invoices submitted by providers, Wholesale Acquisition Cost ("WAC") + 6%, or they may contact CMS to determine if there is unpublished ASP data.

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, 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.

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, or 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 diagnoses that affect the patient's condition and the provision of certain surgical procedures. In addition, 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 the only regenerative medicine company offering PMA approved and 510(k) cleared products in addition to our 361 HCT/Ps.

Our products compete primarily with skin substitute products, amniotic technology products, orthobiologics products, other advanced wound care and traditional wound care products, among others. Our competitors include 3M, Incorporated, Amniox Medical, Inc., Arthrex, Inc., Integra LifeSciences Holdings Corporation, Medtronic plc, MiMedx Group, Inc., Smith & Nephew plc, Misonix, Inc. and Stryker Corporation.

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, 2020, we owned 28 issued patents globally, of which 12 were U.S. patents. As of December 31, 2020, we owned 10 pending patent applications, of which 6 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 2021 and 2036. 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, containers for shipping frozen products, bioreactor culture dish systems having an accessible sealing port, methods for preparing multi-layer stacks of living tissue, cultured three-dimensional tissues comprising a scaffold of a biocompatible non-living material, 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, 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, visco-supplement compositions and musculoskeletal inflammatory treatment methods using same, uses of human amniotic fluid for treating chronic wounds and joint diseases. Our pending patent applications may not result in issued patents and we can give no assurance that any patents that have issued or might issue 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 11 U.S. trademark registrations and 6 foreign trademark registrations, as of December 31, 2020.

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; approval of a PMA for a Class III medical device; or approval of a BLA for a biological product. 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, 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 wound coverings, 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 amniotic or chorion-based sheet product we presently or may 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 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 which 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 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 osteoarthritis (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 need. 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 osteoarthritis (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 benefit, 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, including prohibiting activities that might result in fraud and abuse. 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 improper claims 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. Almost any financial interaction with a healthcare provider, patient or customer will implicate the Anti-Kickback Statute. Statutory exceptions and regulatory safe harbors protect certain interactions if specific requirements are met. However, only those interactions that represent fair market value exchanges generally are protected by a safe harbor or exception. 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, establishes pricing methodologies for government health insurance programs and requires 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 patient 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.

Employees

As of December 31, 2020, we had approximately 910 employees worldwide. None of our employees are represented by a collective bargaining agreement and we have never experienced a work stoppage. We believe our employee relations are good.

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.

ITEM 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 since our inception and, while we reported positive net income in 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 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 or, if such reimbursement is available, the rate at which it will be available. The rate of reimbursement and coverage for the purchase of our products has been and may continue to be unstable, unpredictable and subject to changes in government and private payer policies that could adversely affect our business, results of operations and financial condition. Currently, not all of our products are covered by all payers.
- 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 amount for most of our products and the products of our competitors targeting the same indication 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.
- We have identified a material weaknesses in our internal control over financial reporting, and our management has concluded that our disclosure controls and procedures are not effective. While we are working to remediate any material weakness or significant deficiencies in our internal controls over financial reporting, 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.
- 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, NuCel, NuShield and ReNu, 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.
- Because we depend upon a limited group of suppliers and manufacturers for our Apligraf, Affinity, Dermagraft and NuShield 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 the global COVID-19 pandemic, or other factors, in a manner that could materially adversely affect our business, financial condition or results of operations.
- 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.
- We are a “controlled company” within the meaning of Nasdaq Global Market rules and, as a result, qualify for exemptions from certain corporate governance requirements. The Controlling Entities, which include affiliates of certain members of our board of directors, will effectively control the outcome of all matters requiring shareholder approval, including charter amendments, mergers, consolidations and asset sales.

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 health benefit programs and private health plans to cover our products or to timely and adequately reimburse the users of our products;
- the rate of reimbursement for purchases of our products by government and private insurers;
- any change in Medicare payment policy which provides a competitive advantage to our competitor's products;
- any change in government health benefit programs' and private health plans' policies regarding sales and reimbursement of durable medical equipment, 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 incurred significant losses since our inception, and 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 year ended December 31, 2020, in which we are reporting net income of $17.9 million, we have incurred losses from operations in many years since our inception. Our loss was $40.5 million and $64.8 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $153.1 million. We expect to incur significant sales and marketing costs as we expand our operations to support the sale of our products. Our prior losses, combined with any potential future losses, may have an adverse effect on our business, results of operations and financial condition.

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 are working to remediate any material weakness or significant deficiencies in our internal controls over financial reporting, 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.

We have historically had a small internal accounting and finance staff. This lack of adequate accounting resources has resulted in the identification of a material weakness in our internal controls over financial reporting. 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.

As disclosed in the Company’s annual report for the fiscal year ended December 31, 2019, our management team identified the following material weakness in our internal control over financial reporting: we did not design and maintain formal accounting, business operations, and information technology policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including (i) formalized policies and procedures for reviews over account reconciliations, journal entries, and other accounting analyses and memos and procedures to ensure completeness and accuracy of information used in these review controls and (ii) controls to support the objectives of proper segregation of the initiation of transactions, the recording of transactions, and the custody of assets.

Although we have made significant progress in remediating this material weakness, we concluded that the material weakness described above continued to exist as of December 31, 2020. Specifically, we are unable to conclude that the controls were operating effectively for a reasonable period of time. We commenced remediation efforts during 2018 that continued through 2020. We added additional accounting resources with requisite background and knowledge; we engaged external experts to complement internal resources; we began implementation of a new companywide enterprise resource planning system and we have designed more effective controls that should remediate these deficiencies once they have been implemented and have had sufficient time for them to operate effectively. We plan to continue to take additional steps to remediate the material weakness and improve our financial reporting systems and implement new policies, procedures and controls. 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 health benefit 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 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, 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. Although our supplier has implemented certain corrective measures, we have determined that the current process does not meet our production standards. As a result, we identified an alternate supplier, and were only able to resume commercial-scale production in the second quarter of 2020. 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 (including in connection with the expected suspension of manufacturing of Dermagraft in the fourth quarter of 2021) 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.

Because we depend upon a limited group of suppliers and manufacturers for our products, including our NuShield, Affinity, Apligraf, Puraply Antimicrobial and Dermagraft 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. For us to be successful, our 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, 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. Due to our substantial indebtedness, 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 or 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 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 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 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 in expanding our internal sales force, and there can be no assurance that these efforts will result in significant increases in sales.

We are committed to building and further expanding our internal sales and marketing capabilities, including the expansion of our sales force to 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 a direct sales force 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 expanding 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 and personnel, we must both modify our existing operational and financial systems, procedures and controls and implement new systems, procedures and controls. We must also expand our finance, administrative, and operations staff. Management may be unable to hire, train, retain, motivate and manage necessary personnel or to identify, manage and exploit existing and potential strategic relationships and market opportunities.

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. 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, or synergies from additional sales of existing or newly acquired products;
- be unable to successfully integrate, operate, maintain and manage our newly acquired operations;
- 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. 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 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.

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.

We rely to a large extent upon sophisticated information technology systems to operate our business. 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). 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. Any interruption or breach in our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us or allow third parties to gain material, inside information that they use to trade in our securities.

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.

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 or the President 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, which could adversely affect our business, results of operations and financial condition.

Our long-term assets include property, plant and equipment of $60.1 million and $47.2 million as of December 31, 2020 and 2019, respectively. Approximately $21.7 million of each of these amounts is attributable to certain leasehold improvements that we made to the buildings we lease at 275 Dan Road as part of our Canton, Massachusetts corporate headquarters. 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. The build out to this property was suspended prior to completion and we are currently evaluating our future use of this property. If we decide that we do not intend to complete this buildout, either due to insufficient funding for this purpose or other business reasons, then these assets would be impaired. 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, 2020, 2019 and 2018, we did not recognize an impairment charge in relation to these leasehold improvements. 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 investments become impaired.

We are required under generally accepted accounting principles 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.

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 the global COVID-19 pandemic, or other factors, in a manner that could materially adversely affect our business, financial condition or results of operations.

Our ability to manufacture products may be materially adversely impacted by the coronavirus.

COVID-19 is continuing to impact worldwide economic activity. Estimates for economic growth have been reduced and may have a corresponding effect on our sales activity. The virus has been declared a pandemic by the World Health Organization and has spread globally to over 180 countries, including the United States. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. We, like many employers in the United States, have required (with limited exceptions) employees to work from home or not come into their offices or facilities. We manufacture our non-amniotic products and use third-party manufacturers for our amniotic products and we use third-party raw material suppliers to support our internal manufacturing processes. Our manufacturing facilities have, thus far, remained operational as "essential" services under applicable regulatory orders. If our manufacturing capabilities or the manufacturing capabilities of our suppliers are impacted as a result of COVID-19, it may not be possible for us to timely manufacture relevant products at the required levels or at all. A reduction or interruption in any of our manufacturing processes could have a material adverse effect on our business, results of operations, financial condition and cash flows. Further, remote work may disrupt our operations or increase the risk of a cybersecurity incident.

We also may be unable to obtain the raw materials necessary to support our internal manufacturing processes due to the additional constraints on suppliers created by COVID-19. Any delays in the delivery of these raw materials and delay manufacturing of our products may result in the cancellation of orders for our products.

In addition, 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 COVID-19, will interfere with our ability to effectively meet 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 sales may be materially adversely impacted by the coronavirus.

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. 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. We may also find that the independent agencies that we use will have to prioritize their workload and may be forced to slow their activities as a result of COVID-19. As a result, 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. The support for our sales force may also be impacted, thereby reducing the effectiveness of our sales force.

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 providers prioritizing resources to address the COVID-19 pandemic.

The impact of COVID-19 on economic activity, and its effect on our manufacturing facilities, supply chain and sales force is uncertain at this time and could have a material adverse effect on our results, especially to the extent theses effects persist or exacerbate over an extended period of time.

Our ability to comply with financial covenants under our credit agreement and raise capital may be materially adversely impacted by COVID-19.

We have funded our operations and capital spending, in part, through third-party debt and proceeds from the sale of our Class A common stock. Our 2019 Credit Agreement requires that we comply with certain financial covenants that include maintaining Minimum Trailing Twelve Month Consolidated Revenue and Non-PuraPly Revenue, each tested quarterly. If we are unable to meet these financial covenants due to the economic impact of COVID-19 or otherwise, the borrowings under the 2019 Credit Agreement may become due and payable immediately unless we obtain an amendment from our lenders and we would be prohibited from making additional borrowings under the Revolving Facility if we have availably under that facility in the future. There can be no assurance that our lenders would agree to any such amendment on acceptable terms, or at all. In addition, any sustained disruption in the capital markets from the COVID-19 pandemic could negatively impact our ability to raise capital from the offering of equity or debt securities.

Risks Related to Regulation of Our Products and Other Government Regulations

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 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;
- 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;
- 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. Simultaneously efforts are ongoing to initiate a clinical program to secure BLA approval for NuCel. 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 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 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 Public Health Service Act (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 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 unmet medical need. 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 June 2021, we announced RMAT designation for ReNu for the management of symptoms associated with knee osteoarthritis (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 timeframe. 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 NDA.

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 do not qualify for regulation solely under Section 361 of the PHSA, and may require that the products be removed from the market until we obtain premarket clearance or approval.

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. In light of the 361 HCT/P Guidance, our labeling and marketing claims for our amniotic membrane products, including our Affinity and NuShield products, clarify that they are intended as wound coverings, 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 amniotic or chorion-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. Cell- or tissue-based product that we distribute is deemed not to be an HCT/P or a Section 361 HCT/P, it will be subject to premarket clearance or approval requirements, as well as additional, more stringent post-market regulatory requirements. 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 have begun enrolling patients in a Phase 3 trial for ReNu for the management of symptoms associated with knee OA. Simultaneously, efforts are ongoing to initiate a clinical program to secure BLA approval for NuCel.

Compliance with applicable pre- and post-market regulatory requirements will involve significant time and substantial costs. We may also be required to suspend sales of NuCel and ReNu until FDA approval is obtained. Thus, 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. 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 2021 as a result of the challenges presented by the COVID-19 public health emergency. If we are unable to obtain BLA approvals for NuCel and ReNu within the enforcement grace period, we may be required to suspend sales of those products until FDA approval is obtained. The ability to obtain approval for the uses for which the product is currently marketed cannot be assured. We cannot guarantee that the FDA will not take enforcement action during or after the grace period. Moreover, even for those products that will 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.

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 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. Additionally, the FDA may not grant the necessary clearances or approvals or require us to suspend sales of NuCel and ReNu until FDA approval is obtained.

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 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, approved and cleared products are subject to continuing obligations to comply with other substantial regulatory requirements, including the FDA's cGTP regulations, the FDA's QSR and/or the FDA's Current Good Manufacturing Practices, or cGMP regulations, adverse event reporting, and FDA inspections. 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 disease, 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.

As a condition of our Gintuit BLA, a pediatric study was required to be conducted, and we did not complete this study by the deadline set forth in the BLA approval letter. Gintuit could therefore be subject to enforcement action if marketing is resumed without completion of the required pediatric study.

Sponsors of products for which the FDA has approved a BLA are obligated by the Pediatric Research Equity Act, or PREA, to carry out clinical trials of the products in pediatric populations, unless those requirements are waived. In 2012, we obtained FDA approval of a BLA for an oral tissue-engineered product to be marketed under the trade name Gintuit. Although Gintuit was not intended to be used in pediatric populations, the FDA imposed a requirement to conduct a pediatric study following approval. We originally planned to complete these studies within the timeframes established in the Gintuit approval letter. However, in 2014, we made a business decision to suspend commercialization of Gintuit; all manufacturing, commercial and clinical activities for the product were discontinued. At that time, we informed the FDA of this decision and requested suspension of the pediatric study requirement, at which time the FDA placed Gintuit on its discontinued products list. Notwithstanding our request that the pediatric study requirement be suspended, we were notified by the FDA on June 29, 2017 that the FDA had determined that we had not

complied with our PREA obligations. We responded and submitted a formal request for an extension for the pediatric study requirement for Gintuit. However, on October 5, 2017, the FDA advised that our request had been denied. Although we believe that we are not currently subject to penalties for noncompliance because Gintuit is not on the market and there is accordingly no foreseeable use of the product in pediatric populations, the product could be viewed as misbranded and subject to seizure or other enforcement action if marketing is resumed without completion of the required pediatric study.

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. 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;
- 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, 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;
- Section 242 of HIPAA codified at 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 so-called federal "sunshine" law, 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.

In particular, 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 past activities may not always be consistent with current industry best practices. Further, there is a lack of government guidance as to whether various 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. If the government declines to intervene, the whistleblower may proceed on her own and, if she is successful, she 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. 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. 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%. Beginning on April 1, 2021, Medicare will again withhold 2% of the government's payment portion, which is 80% of the total payment amount. Currently, we are not required to report ASP for our products because they are regulated as medical devices by the FDA, although we have chosen to report ASP for some of our products. Starting in January 2022, we will be required to report ASP for all our products as a result of provisions included in the Consolidated Appropriations Act of 2020. Government price reporting requirements are complex. If we do not report ASP correctly, 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 Patient Protection and Affordable Care Act of 2010 ("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 are ongoing efforts 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 *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 held oral argument on November 10, 2020. The Biden Administration has repealed executive acts that curtailed PPACA under the preceding administration and has declared its intent to vigorously defend the law against new and persisting legal challenges. The administration has also committed to seek legislative and administrative reforms that will build on innovations relating to health care reimbursement, coordinated care and law enforcement introduced by PPACA. We cannot predict the ultimate results of the *Texas* case or whether additional legislative reform proposals will be adopted, when they will be adopted, or what impact they may have on us, but any such proposals could have a negative impact on our business and provide incentives for hospitals and physicians to not use 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 2025. However, the sequestration was suspended by Congressional action in the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which suspended the payment adjustment percentage of 2% applied to all Medicare Fee-For-Service (FFS) claims from May 1 through December 31, 2020. The Consolidated Appropriations Act of 2021, signed into law on December 27, 2020, further extended the suspension period through March 31, 2021. Congressional action will be required to suspend the sequestration after March 31, 2021. These or other similar reductions in government healthcare spending could result in reduced demand for our products or additional pricing pressure.

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 than 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 health benefit programs such as Medicare and Medicaid and from other global government authorities. Government health benefit programs and private health plans continuously seek to reduce healthcare costs. For example, in 2014, Medicare unexpectedly 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. As of January 1, 2018, our PuraPly AM and PuraPly products no longer qualified for separate payments under Medicare and this change resulted in a reduction in our revenue as compared to prior periods.

In March 2018, the United States Congress passed, and the President signed into law, the Consolidated Appropriations Act of 2018, or the Appropriations Act. The Appropriations Act restored the pass-through status effective October 1, 2018 for drugs or biologicals whose period of pass-through payment status ended on December 31, 2018 and for which payment was packaged into a covered hospital outpatient service furnished beginning on January 1, 2018; PuraPly and PuraPly AM met these conditions. As a result, PuraPly and PuraPly AM were included in the "bundled" payment structure from January 1, 2018 through September 30, 2018 after which time Medicare resumed making pass-through payments to hospitals when they use PuraPly and PuraPly AM in the outpatient hospital setting and in ASCs. PuraPly and PuraPly AM retained this "pass-through" reimbursement status through September 30, 2020. After September 30, 2020, PuraPly and PuraPly AM are bundled as are all of our other products. 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, Affinity 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.

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, 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 because it solicited comments on alternatives in its calendar year 2019 rulemaking. Changes in the policy could occur as early as calendar year 2022 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 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 Average Sales Price ("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 based on the manufacturer's reported ASP on a per square centimeter basis. These rates are adjusted quarterly based on manufacturer ASP reporting, and the payment amount is ASP plus 6%; starting on April 1, 2021, the payment rate will be adjusted to ASP plus 4.3% under the statutorily-mandated sequestration. Currently, the Medicare statute does not require us to report ASP for our products because they are regulated by the FDA as medical devices. However, starting in January 2022, we may be 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 for newer products), 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.

Our PuraPly AM and PuraPly products transitioned off "pass-through" reimbursement status to a "bundled" reimbursement structure beginning on January 1, 2018, which has resulted in a decline in our PuraPly AM and PuraPly revenues as compared to prior periods. Although new legislation restored pass-through status for these products beginning on October 1, 2018, they again lost this preferred status on October 1, 2020, which could have a material adverse effect on our PuraPly revenue.

Under Medicare, our PuraPly AM and PuraPly products had pass-through reimbursement status through December 31, 2018 when used in the hospital outpatient and ASC setting. Hospitals and ASCs that use products with "pass-through" status receive a separate payment for the product in addition to the bundled payment, known as a "pass through" payment, resulting in a higher total reimbursement for procedures that use these products. "Pass through" status is typically granted for a two to three year period in order to encourage the development of innovative medical devices, drugs and biologics. As of January 1, 2018, PuraPly AM and PuraPly transitioned to the "bundled" payment structure applicable to other skin substitutes, which provides for a two-tiered payment system in the hospital outpatient and ASC setting and results in a single payment to the provider that covers both the application of the product and the product itself. Under the Appropriations Act, the pass-through status of certain products, including PuraPly AM and PuraPly, was restored effective October 1, 2018 and they retained that status through September 30, 2020. As a result of the transition to the bundled payment structure, total Medicare reimbursement for procedures using our PuraPly AM and PuraPly products decreased substantially during the first nine months of 2018. This reduction in reimbursement resulted in a substantial decrease in revenue from our PuraPly AM and PuraPly products, which are key products in our portfolio, during the first nine months of 2018 and had a negative effect on our business, results of operations and financial condition. Although Medicare resumed making pass through payments for PuraPly AM and PuraPly products in the outpatient hospital and ASC setting on October 1, 2018 pursuant to the Appropriations Act, all other skin substitute products, including all of our other products, remain in the bundled payment structure. PuraPly AM and PuraPly transitioned back into the bundled payment structure on October 1, 2020. The loss of the pass-through payment status on October 1, 2020 may once again result in lower revenue for PuraPly AM and PuraPly which could have a material adverse effect on our business, results of operations and financial condition.

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 (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. Based on the statements made in the proposed rule, it is possible that Medicare will revise its payment policy in calendar year 2022 or calendar year 2023. Any revised policy 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.

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 are 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 which 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 continue, 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 substantial indebtedness may have a material adverse effect on our business, results of operations and financial condition.

We have a significant amount of indebtedness. As of December 31, 2020, we had approximately $70 million of aggregate principal amount of indebtedness outstanding under our 2019 Credit Agreement. Our substantial level of indebtedness increases the risk that we may be unable to generate cash sufficient to pay amounts due in respect of our indebtedness. Our substantial indebtedness 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 and subordinated 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

There can be no assurance that the Company's Class A common stock will continue to be listed on Nasdaq or that that the Company will be able to comply with the continued listing standards of Nasdaq.

Our Class A common stock is listed on Nasdaq under the symbol "ORGO". Trading of our Class A common stock and public warrants was suspended as a result of the redemption on October 31, 2018 of all of AHPAC's public shares. On November 2, 2018, as a result of the redemption of the public shares, Nasdaq issued a delisting notice in respect of the AHPAC units, AHPAC Class A ordinary shares and AHPAC warrants to purchase Class A ordinary shares. On November 9, 2018, AHPAC submitted a request for an oral hearing before the Hearings Panel to appeal the delisting determination pursuant to the procedures set forth in the Nasdaq rules. That hearing occurred on December 13, 2018 and on January 4, 2019, Nasdaq notified us that the Hearings Panel granted our request for the continued listing of our Class A common stock and lifted the trading suspension at the open of the market on January 8, 2019. Pursuant to the Hearing Panel's decision, on or before March 31, 2019, we were required to demonstrate to the satisfaction of Staff and the Hearings Panel that we had a minimum of 300 round lot stockholders and that we otherwise meet all applicable requirements for listing on Nasdaq. The Hearings Panel determined to delist our public warrants due to our non-compliance with the minimum 400 round lot holder requirement for initial listing on Nasdaq, as required by Nasdaq Listing Rule 5515(a)(4). On March 12, 2019, the Nasdaq Stock Market LLC filed a Form 25 with the SEC to delist the public warrants. The delisting became effective on March 22, 2019 (ten days after the Form 25 was filed). In connection with our exchange offer in the summer of 2019, we issued an aggregate of 2,925,731 shares of our Class A commons stock in exchange for all outstanding public warrants, which, until such time, traded "over-the-counter" under the trading symbol "ORGOW." Even though the Company was able to regain compliance with the Nasdaq listing standards with respect to its Class A common stock, the Company can provide no assurance that it can maintain compliance with those standards.

If Nasdaq delists the Company's Class A common stock from trading on its exchange for failure to meet the listing standards, the Company's stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for the Company's securities;
- reduced liquidity for the Company's securities;
- a determination that the Company's Class A common stock is a "penny stock" which will require brokers trading in the Company's Class A common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for the Company's securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

We are a "controlled company" within the meaning of Nasdaq rules and, as a result, qualify for exemptions from certain corporate governance requirements.

Alan A. Ades, Albert Erani and Glenn H. Nussdorf, members of our Board of Directors, together with Dennis Erani, Starr Wisdom and certain of their respective affiliates, who we refer to collectively as the Controlling Entities, control a majority of the voting power of the Company's outstanding Class A common stock. Such Controlling Entities entered into a Controlling Stockholders Agreement providing for nomination rights of the Controlling Entities with respect to four directors of the Company and qualifying the Company as a "controlled company" under the Nasdaq listing rules. Under the Nasdaq rules, a listed company of which more than 50.0% of the voting power for the election of directors is held by any person or group of persons acting together is a "controlled company" and may elect not to comply with certain Nasdaq corporate governance requirements, including the requirement (i) that a majority of the Board of Directors consist of independent directors, (ii) to have a governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities, (iii) to have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities, (iv) that the compensation committee consider certain independence factors when engaging legal counsel and other committee advisors and (v) for an annual performance evaluation of the governance and compensation committees. We expect to continue to be treated as a "controlled company" for the foreseeable future. Accordingly, you may not have the same protections afforded to stockholders of companies that are subject to all of the Nasdaq corporate governance requirements.

The Controlling Entities control us, and their interests may conflict with yours in the future.

As of February 28, 2021, the Controlling Entities collectively beneficially own approximately 54% of the Company's Class A common stock. As a result of this voting control, the Controlling Entities 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 (subject to any contractual designation rights), 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 Controlling Entities and their affiliates continue to own a significant amount of the Company's combined voting power, even if less than 50.0%, they may continue to be able to strongly influence or effectively control its decisions. The interests of the Controlling Entities 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 Controlling Entities and their affiliates may engage in activities where their interests conflict with our interests or those of our other stockholders. In addition, the Controlling Entities 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.

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 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.

We are an "emerging growth company" and a "smaller reporting company" which permits us to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies or smaller reporting companies.

The Company qualifies as an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, which we refer to as the "JOBS Act." As such, the Company takes advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as it continues to be an emerging growth company, including (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act, (ii) the exemptions from say-on-pay, say-on-frequency and say-on-golden parachute voting requirements and (iii) reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements. As a result, the Company's stockholders may not have access to certain information they deem important. the Company will remain an emerging growth company until the earliest of (i) the last day of the fiscal year (a) following October 14, 2021, the fifth anniversary of the IPO, (b) in which the Company has total annual gross revenue of at least $1.07 billion or (c) in which the Company is deemed to be a large accelerated filer, which means the market value of the Company Class A common stock that is held by non-affiliates exceeds $700.0 million as of the last business day of the Company's prior second fiscal quarter, and (ii) the date on which the Company has issued more than $1.0 billion in non-convertible debt during the prior three-year period.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the exemption from complying with new or revised accounting standards provided in Section 7(a)(2)(B) of the Securities Act as long as the Company is an emerging growth company. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies, but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. For example, the Company will adopt ASU 2016-02, *Leases (Topic 842)* on January 1, 2021 and ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326) on* January 1, 2023. This may make comparison of the Company's financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

The Company is also a "smaller reporting company" as defined in the Exchange Act. The Company may continue to be a smaller reporting company even after it is no longer an emerging growth company. The Company may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that its voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of its second fiscal quarter, or its annual revenues are more than $100 million during the most recently completed fiscal year and its voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of its second fiscal quarter.

The Company cannot predict if investors will find the Company Class A common stock less attractive because the Company will rely on these exemptions. If some investors find the Company Class A common stock less attractive as a result, there may be a less active trading market for the Company Class A common stock and the Company's stock price may be more volatile.

General Risk Factors

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 acquisition of NuTech Medical, 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.

Business or economic disruptions or global health concerns could seriously harm our business.

Broad-based business or economic disruptions could adversely affect our business and the sale of our products. For example, in December 2019 an outbreak of a novel strain of coronavirus originated in Wuhan, China, and has since spread to a number of other countries, including the United States. To date, this outbreak has already resulted in extended shutdowns of certain businesses in the Wuhan region and has had ripple effects to businesses around the world. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the suppliers, clinical trial sites, regulators, health care providers and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business could be materially and negatively impacted. It is also possible that global health concerns such as this one could disproportionately impact the hospitals, clinics and healthcare providers to whom we sell our products, which could have a material adverse effect on our business and our results of operation and financial condition.

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.

Generally accepted accounting principles 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;
- 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 do not currently, and may never, publish research on the Company. If no securities or industry analysts commence coverage of the Company, the Company's stock price and trading volume would likely be negatively impacted. If any of the analysts who may 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. If any analyst who may cover 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.

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 will be subject to laws, regulations and rules enacted by national, regional and local governments and Nasdaq. In particular, the Company will be required to comply with certain SEC, Nasdaq and other legal or regulatory requirements. Compliance with, and monitoring of, applicable laws, regulations and rules may be 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters is located on our four-building campus in Canton, Massachusetts. Comprising approximately 300,000 square feet of leased space devoted to manufacturing, shipping, operations, and research and development, the leases for all four buildings expire on December 31, 2022. We have an option to renew these leases for an additional five-year term. We lease the buildings in Canton from entities that are controlled by Alan A. Ades, Albert Erani, Dennis Erani and Glenn H. Nussdorf, who together control a majority of the voting power of our outstanding Class A common stock. In addition, Messrs. Ades, Albert Erani and Nussdorf are current or former members of our Board of Directors.

In Norwood, Massachusetts, we have a leased facility of approximately 43,850 square feet for office and laboratory 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, with an early option to extend the term for a period of five years if exercised within twenty-four months of the rent commencement date and an option to extend the term for a period of ten years (in addition to the five-year early extension period, if exercised).

In La Jolla, California, we have leased facilities of approximately 92,000 square feet devoted to operations, research and development, and manufacturing. As La Jolla leases expire on December 31, 2021, we entered into a lease in August 2020 for approximately 23,000 square feet in San Diego, California for office and laboratory use. The lease commences on the date when certain landlord's work is substantially completed, which is expected to be at the beginning of April 2021. The initial lease term is ten years from the lease commencement date, with an option to extend the term for a period of five years.

In Birmingham, Alabama, we have a leased facility of approximately 25,000 square feet to support our amniotic products. It was initially leased through December 31, 2020 and was subsequently extended to December 31, 2022 in the first quarter of 2021.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any 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 28, 2021, a total of 127,985,190 shares of our Class A common stock were outstanding and we had 102 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 2019 Credit Agreement restrict our ability to pay cash dividends on our capital stock without the bank's consent.

Securities authorized for issuance under equity compensation plans

For information regarding securities authorized for issuance under our equity compensation plans, see Part III, Item 12, "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

CPN Acquisition

On September 17, 2020, the Company issued 1,947,953 shares of its Class A common stock to CPN Biosciences, LLC as partial consideration for the acquisition of substantially all of the assets of CPN Biosciences, LLC pursuant to an asset purchase agreement. For purposes of the acquisition, the agreed upon value of our Class A common stock was $4.78 per share. No underwriters were used in the foregoing transaction. This sale of securities was made in reliance upon the exemption from registration provided by Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder for transactions by an issuer not involving a public offering.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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," "the Company," "Organogenesis" or "our company" 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 and smoking. 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 service 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 PMA approval, BLA approval 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 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; PuraPly AM to address biofilm across a broad variety of wound types; and Affinity and NuShield to address a variety of wound sizes and types. We have a highly trained and specialized direct wound care sales force paired with exceptional customer support services.

In the Surgical & Sports Medicine market, we focus on products that support the healing of musculoskeletal injuries, including degenerative conditions such as osteoarthritis and tendonitis. We are leveraging our regenerative medicine capabilities in this attractive, adjacent market. Our Surgical & Sports Medicine products include ReNu for in-office joint and tendon applications; NuCel for bony fusion in the spine and extremities; NuShield and Affinity for surgical application in targeted soft tissue repairs; and PuraPly AM for surgical treatment of open wounds. We currently sell these products through independent agencies and our growing direct sales force.

We generated net revenue of $338.3 million, $261.0 million and $193.4 million for the years ended December 31, 2020, 2019 and 2018, respectively. We had net income of $17.9 million and net loss of $40.5 million and $64.8 million for the years ended December 31, 2020, 2019 and 2018, respectively. While we reported net income for the year ended December 31, 2020, 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, 2020, we had an accumulated deficit of $153.1 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 in one segment of regenerative medicine.

Items Affecting Comparability

Avista Merger. On December 10, 2018, Avista Healthcare Public Acquisition Corp., our predecessor company ("AHPAC"), consummated the previously announced business combination pursuant to that certain Agreement and Plan of Merger, dated as of August 17, 2018 (as amended, the "Avista Merger Agreement"), by and among AHPAC, Avista Healthcare Merger Sub, Inc., a direct wholly-owned subsidiary of AHPAC ("Avista Merger Sub") and Organogenesis Inc.. As a result of the transactions contemplated by the Avista Merger Agreement, Avista Merger Sub merged with and into Organogenesis Inc., with Organogenesis Inc. surviving the merger (the "Avista Merger"). In addition, in connection with the business combination, AHPAC redomesticated as a Delaware corporation (the "Domestication"). After the Domestication, AHPAC changed its name to "Organogenesis Holdings Inc." As a result of the Avista Merger, Organogenesis Inc. became a wholly-owned subsidiary of Organogenesis Holdings Inc. For periods prior to the closing of the Avista Merger on December 10, 2018, the disclosure in Management's Discussion and Analysis of Financial Condition and Results of Operations has been updated to give effect to the Avista Merger.

Management's Use of Non-GAAP Measures

Our management uses financial measures that are not in accordance with generally accepted accounting principles in the United States, or 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, loss on the extinguishment of debt and mark to market adjustments on our warrant liabilities and our contingent assets and liabilities, write-off of IPO costs, transaction costs related to Avista Merger, a warrant exchange transaction, and CPN acquisition, gain on settlement of deferred acquisition consideration, recovery of certain notes receivable from related parties and restructuring charges. 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:

- Adjusted EBITDA excludes stock-based compensation expense as it 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 excludes depreciation and amortization expense and, although these are non-cash expenses, the assets being depreciated may have to be replaced in the future;
- Adjusted EBITDA excludes net interest expense, or the cash requirements necessary to service interest, which reduces cash available to us;
- Adjusted EBITDA excludes the impact of the changes in the fair value of our warrant liability, our contingent consideration forfeiture asset and Earnout liability;
- Adjusted EBITDA excludes the write-off of the costs in connection with an abandoned public offering and the costs incurred in connection with the Avista Merger;
- Adjusted EBITDA excludes certain transactions expenses such as the Company's warrant exchange transaction and the CPN acquisition transaction;
- Adjusted EBITDA excludes loss on the extinguishment of debt;
- Adjusted EBITDA excludes charges related to restructuring activities;

- Adjusted EBITDA excludes certain income associated with the settlement of deferred acquisition consideration and recovery of certain notes receivable from related parties;
- Adjusted EBITDA excludes income tax expense (benefit); 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 and Key Factors Influencing our 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.

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.

Included within our product revenue is our PuraPly product portfolio that consists of PuraPly and PuraPly AM. We launched PuraPly in mid-2015 and introduced PuraPly AM in 2016. In order to encourage the development of innovative medical devices, drugs and biologics, CMS can grant new products an additional “pass-through payment” in addition to the bundled payment amount for a limited period of no more than three years. Our PuraPly products were granted pass-through status from launch through December 31, 2017, which created an economic incentive for practitioners to use PuraPly over other skin substitutes. As a result, we saw increases in revenue related to our PuraPly portfolio in 2017. Beginning January 1, 2018, PuraPly AM and PuraPly transitioned to the bundled payment structure for skin substitutes, which provides for a two-tiered payment system in the hospital outpatient and ASC setting. The two-tiered Medicare payment system bundles payment for our Advanced Wound Care products (and all skin substitutes) into the payment for the procedure for applying the skin substitute, resulting in a single payment to the provider that includes reimbursement for both the procedure and the product itself. As a result of the transition to the bundled payment structure, total Medicare reimbursement for procedures using our PuraPly AM and PuraPly products decreased substantially. This reduction in reimbursement resulted in a substantial decrease in revenue from our PuraPly AM and PuraPly products during the first nine months of 2018 and had a negative effect on our business, results of operations and financial condition. On March 23, 2018, Congress passed, and the President signed into law, the Consolidated Appropriations Act of 2018, or the Act. The Act restored the pass-through status of PuraPly and PuraPly AM effective October 1, 2018. As a result, effective October 1, 2018, Medicare resumed making pass-through payments to hospitals using PuraPly and PuraPly AM in the outpatient hospital setting and in ASCs. PuraPly and PuraPly AM had pass-through reimbursement status through September 30, 2020. With the expiration of the pass-through reimbursement status, our net revenue from PuraPly and PuraPly AM may decrease as they transition to the bundled payment structure. While we expect our net revenue from Non-PuraPly products will continue to increase, we cannot be certain that any such revenue increase will fully offset the revenue decrease from PuraPly products if such a decrease occurs. We are not able to estimate the extent of the changes in revenue due to the uncertainties related to the impact of the COVID-19 pandemic, which could have material adverse effects on our revenue, especially to the extent that the pandemic persists or exacerbates over an extended period of time.

Cost of goods sold, gross profit and gross profit margin

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 increases in our cost of goods sold correspond with the increases in sales units driven by the expansion of our sales force and sales territories, expansion of our product portfolio offerings, and the number of healthcare facilities that offer our products. We expect our cost of goods sold to increase due primarily to increased sales volumes.

Gross profit is calculated as net revenue less cost of goods sold and generally increases as revenue increases. Gross profit margin is calculated as gross profit divided by total net revenue. Our gross profit and gross profit margin are 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 and gross profit margin.

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 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 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. Our research and development expenses also include expenses for clinical trials. 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.

Write-off of deferred offering costs

We deferred costs incurred related to a proposed initial public offering, or IPO, of Organogenesis Inc. that included legal, audit, and other professional fees. During the quarter ended June 30, 2018, the IPO process was abandoned and as a result, we recorded a write-off to expense the accumulated costs.

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.

Change in fair value of warrant liability. In connection with the 2016 Loans, we issued warrants to purchase our Class A common stock to the lenders, who are affiliates of ours. We classified the warrants as a liability on our consolidated balance sheets because these warrants provided for down-round protection which would cause the exercise price of the warrants to be adjusted if future equity issuances were below the current exercise price of the warrants. The warrant liability was initially recorded at fair value upon issuance and was subsequently remeasured to fair value at each reporting date until the warrants were net exercised in December 2018 in connection with the Avista Merger. Changes in the fair value of the warrant liability were recognized as a component of other income (expense), net in the consolidated statements of operations.

Loss on the extinguishment of debt. In connection with the consummation of the Avista Merger in December 2018, outstanding principal of $45.7 million related to the affiliate debt was exchanged for 6,502,679 shares of our Class A common stock and a cash payment of $35.6 million, including $22.0 million of principal and $13.6 million of accrued interest and accrued affiliate loan fees as of and through the closing date of the Avista Merger. Following the consummation of these transactions, the affiliate debt was deemed fully paid and was discharged and terminated. We incurred a loss of $2.1 million on the extinguishment of the affiliate debt in connection with the write off of unamortized debt issuance costs and the difference in the carrying value of the affiliate debt converted to Class A common stock and the fair value of the Class A common stock issued in the conversion.

In March 2019, upon entering into the 2019 Credit Agreement, we paid an aggregate amount of $17.6 million associated with the termination of the ML Agreement (as defined below), including unpaid principal, accrued interest and an early termination penalty. We recognized $1.9 million as loss on the extinguishment of the loan.

Gain on settlement of deferred acquisition consideration—In February 2020, we settled the dispute on the $5.0 million deferred purchase acquisition consideration with the sellers of NuTech Medical for $4.0 million and assumed from the sellers of NuTech Medical the responsibilities related to a legacy lawsuit of NuTech Medical which was settled in October 2020. In connection with the settlement of this dispute and the legacy lawsuit, we recorded a gain of $2.2 million for the year ended December 31, 2020.

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 and inherent in that, assess the likelihood of sufficient future taxable income. We also consider the expected reversal of deferred tax liabilities and analyze the period in which these liabilities would be expected to reverse to determine whether the taxable temporary difference amounts serve as an adequate source of future taxable income to support the realizability of the deferred tax assets. 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. Based on a consideration of the factors discussed above, including the fact that through the period ended December 31, 2020, our results reflected a three-year cumulative loss position, we have determined that a valuation allowance is necessary against the full amount of our net deferred tax assets, excluding alternative minimum tax credits. As a result of the 2017 Tax Cuts and Jobs Act ("Tax Act") and the 2020 CARES Act, alternative minimum tax credits were refunded on the 2018 and 2019 tax returns in full.

Results of Operations

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

	Year Ended December 31		
	2020	2019	2018
	(in thousands)		
Net revenue	$338,298	$260,981	$193,449
Cost of goods sold	87,319	75,948	68,808
Gross profit	250,979	185,033	124,641
Operating expenses:			
Selling, general and administrative	203,478	199,693	161,961
Research and development	20,086	14,799	10,742
Write-off of deferred offering costs	—	—	3,494
Total operating expenses	223,564	214,492	176,197
Income (loss) from operations	27,415	(29,459)	(51,556)
Other expense, net:			
Interest expense, net	(11,279)	(8,996)	(10,789)
Change in fair value of warrants	—	—	(469)
Gain on settlement of deferred acquisition consideration	2,246	—	—
Loss on the extinguishment of debt	—	(1,862)	(2,095)
Other income, net	97	13	162
Total other expense, net	(8,936)	(10,845)	(13,191)
Net income (loss) before income taxes	18,479	(40,304)	(64,747)
Income tax expense	(530)	(150)	(84)
Net income (loss)	$ 17,949	$ (40,454)	$ (64,831)

EBITDA and Adjusted EBITDA

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

	Year Ended December 31,		
	2020	2019	2018
	(in thousands)		
Net income (loss)	$17,949	$(40,454)	$(64,831)
Interest expense, net	11,279	8,996	10,789
Income tax expense	530	150	84
Depreciation	3,723	3,388	3,309
Amortization	3,745	6,043	3,669
EBITDA	37,226	(21,877)	(46,980)
Stock-based compensation expense	1,661	936	1,075
Restructuring charge (1)	618	—	—
Gain on settlement of deferred acquisition consideration (2)	(2,246)	—	—
Recovery of certain notes receivable from related parties (3)	(1,516)		
Change in contingent consideration forfeiture asset (4)	—	—	589
Change in fair value of warrant liability (5)	—	—	469
Change in fair value of Earnout (6)	203		
Write-off of deferred offering costs (7)	—	—	3,494
Loss on extinguishment of debt (8)	—	1,862	2,095
Avista merger transaction costs (9)	—	—	3,072
Exchange offer transaction costs (10)	—	916	—
CPN transaction costs (11)	929	—	—
Adjusted EBITDA	$36,875	$(18,163)	$(36,186)

(1) Amount reflects employee retention and other benefit-related costs related to the Company's restructuring activities in the fourth quarter ended December 31, 2020. See Note "11. Restructuring".

(2) Amount reflects the gain recognized related to the settlement of the deferred acquisition consideration dispute with the sellers of NuTech Medical in February 2020 as well as the settlement of the assumed legacy lawsuit from the sellers of NuTech Medical in October 2020. See Note "18. Commitments and Contingencies".

(3) Amount reflects the collection of certain notes receivable from related parties previously reserved. See Note "19. Related Party Transactions".

(4) Amount reflects the change in fair value of the common shares issued in connection with the acquisition of NuTech Medical that were forfeitable upon the occurrence of the FDA requiring approval of certain products acquired from NuTech Medical. The forfeiture rights expired in March 2018 because there was no adverse FDA event and the related expenses resulting from the write-off of the forfeiture rights were recorded within selling, general and administrative expenses in the quarter ended March 31, 2018.

(5) In connection with our 2016 Loans, we classified the warrants issued to purchase our Class A common stock to the lenders, who are affiliates of ours, as a liability on our consolidated balance sheet. The warrants were net exercised in December 2018 in connection with the Avista Merger. Amount reflects the change in the fair value of the warrant liability.

(6) Amount reflects the change in the fair value of the Earnout liability in connection with the CPN acquisition. See Note "3. Acquisition".

(7) Amount reflects a one-time write-off in the quarter ended June 30, 2018 of costs accumulated in connection with an abandoned public offering which was replaced with the Avista Merger transaction.

(8) Amounts reflect the amount of loss recognized on the extinguishment of the Master Lease Agreement upon repayment in 2019 and the amount of loss recognized on the repayment and conversion to equity of the affiliated debt in December 2018.

(9) Amount reflects legal and professional fees incurred primarily in the second half of the year ended December 31, 2018 related directly to the Avista Merger which were expensed as incurred.

(10) Amount reflects legal, advisory and other professional fees incurred in the quarter ended September 30, 2019 related directly to the warrant exchange transactions. See Note "14. Stockholders' Equity".

(11) Amount reflects the legal, advisory and other professional fees incurred in the nine months ended September 30, 2020 related directly to the CPN acquisition. See Note "3. Acquisition".

Comparison of the Year Ended December 31, 2020, 2019 and 2018

Revenue

	Years Ended December 31,			Change			
	2020	2019	2018	2020 to 2019		2019 to 2018	
	(in thousands, except for percentages)						
Advanced Wound Care	$294,624	$220,744	$164,332	$73,880	33%	$56,412	34%
Surgical & Sports Medicine	43,674	40,237	29,117	3,437	9%	11,120	38%
Net revenue	$338,298	$260,981	$193,449	$77,317	30%	$67,532	35%

For the year ended December 31, 2020, net revenue from our Advanced Wound Care products increased by $73.9 million, or 33%, as compared to the year ended December 31, 2019. The increase in Advanced Wound Care net revenue was primarily attributable to the expanded sales force, increased sales to existing and new customers and increased adoption of our amniotic product portfolio, including our Affinity product.

For the year ended December 31, 2020, net revenue from our Surgical & Sports Medicine products increased by $3.4 million, or 9%, as compared to the year ended December 31, 2019. The increase in Surgical & Sports Medicine net revenue was primarily attributable to the expanded sales force and penetration of existing and new customer accounts, partially offset by postponement or cancellation of medical procedures as a result of COVID-19.

For the year ended December 31, 2019, net revenue from our Advanced Wound Care products increased by $56.4 million, or 34%, as compared to the year ended December 31, 2018. The increase in Advanced Wound Care net revenue was primarily attributable to the expanded sales force and increased sales to existing and new customers, PuraPly regaining pass-through reimbursement status for the two-year period effective October 1, 2018 and the continued growth in adoption of our amniotic products.

For the year ended December 31, 2019, net revenue from our Surgical & Sports Medicine products increased by $11.1 million, or 38%, as compared to the year ended December 31, 2018. The increase in Surgical & Sports Medicine net revenue was primarily due to the expanded sales force and penetration of existing and new customer accounts.

Included within net revenue is PuraPly revenue of $147.3 million, $126.8 million, and $69.8 million for the years ended December 31, 2020, 2019 and 2018, respectively. PuraPly had pass-through status from October 1, 2018 to September 30, 2020, causing the increase in PuraPly revenue in the year ended December 31, 2019 as compared to the year ended December 31, 2018. The continued increase in PuraPly revenue in the year ended December 31, 2020 was due to the expanded sales forces, expanded product offerings, and increased sales to existing and new customers.

Cost of Goods Sold, Gross Profit and Gross Margin

	Years Ended December 31,			Change			
	2020	2019	2018	2020 to 2019		2019 to 2018	
	(in thousands, except for percentages)						
Cost of goods sold	$ 87,319	$ 75,948	$ 68,808	$11,371	15%	$ 7,140	10%
Gross profit	$250,979	$185,033	$124,641	$65,946	36%	$60,392	48%
Gross profit %	74%	71%	64%				

For the year ended December 31, 2020, cost of goods sold increased by $11.4 million, or 15%, as compared to the year ended December 31, 2019. The increase in cost of goods sold was primarily due to increased unit volumes, additional manufacturing and quality control headcount.

For the year ended December 31, 2020, gross profit increased by $65.9 million, or 36%, as compared to the year ended December 31, 2019. The increase in gross profit resulted primarily from increased sales volume due to the strength in our Advanced Wound Care and Surgical & Sports Medicine products as well as a shift in product mix to our higher gross margin products.

For the year ended December 31, 2019, cost of goods sold increased by $7.1 million, or 10%, as compared to the year ended December 31, 2018. The increase in cost of goods sold was primarily due to increased unit volumes, additional manufacturing and quality control headcount, and facilities improvement projects.

For the year ended December 31, 2019, gross profit increased by $60.4 million or 48%, as compared to the year ended December 31, 2018. The increase in gross profit resulted primarily from increased sales volume due to the strength in our Advanced Wound Care and Surgical & Sports Medicine products, PuraPly regaining pass-through reimbursement status for the two-year period effective October 1, 2018, and the resulting higher margins realized as a result of manufacturing efficiencies associated with our Advanced Wound Care products.

Selling, General and Administrative Expenses

	Years Ended December 31,			Change			
	2020	2019	2018	2020 to 2019		2019 to 2018	
	(in thousands, except for percentages)						
Selling, general and administrative	$203,478	$199,693	$161,961	$3,785	2%	$37,732	23%
Selling, general and administrative as a percentage of net revenue	60%	77%	84%				

For the year ended December 31, 2020, selling, general and administrative expenses increased by $3.8 million, or 2%, as compared to the year ended December 31, 2019. The increase in selling, general and administrative expenses was primarily due to a $15.3 million increase related to additional headcount, primarily in our direct sales force and increased sales commissions due to increased sales, a $2.0 million cancellation fee for certain product development and consulting agreements, and a $1.7 million increase in credit card processing fees due to increased collection. These increases were partially offset by a $10.0 million decrease related to reduced travel and marketing programs amid travel restrictions in place due to the COVID-19, a $2.3 million decrease in legal, consulting fees and other costs associated with the ongoing operations of our business, a $2.3 decrease in amortization associated with the intangible assets amortized using an accelerated method and a $1.1 million decrease in bad debt primarily due to the collection of the previously reserved related party receivables. We expect our selling, general and administrative expenses to continue to increase throughout 2021.

For the year ended December 31, 2019, selling, general and administrative expenses increased by $37.7 million, or 23%, as compared to the year ended December 31, 2018. The increase in selling, general and administrative expenses is primarily due to an increase of $30.6 million related to additional headcount, primarily in our direct sales force and increased sales commissions due to increased sales, an increase of $2.6 million in legal, consulting fees and other costs associated with the ongoing operations of our business, an increase of $2.4 million in amortization associated with intangible assets amortized using an accelerated method, an increase of $1.7 million associated with marketing and promotional materials for our products, and an increase of $1.7 million in royalties attributable to certain product sales. These increases are partially offset by a decrease of $1.5 million associated with transaction advisory fees incurred in 2018.

Research and Development Expenses

	Years Ended December 31,			Change			
	2020	2019	2018	2020 to 2019		2019 to 2018	
	(in thousands, except for percentages)						
Research and development	$20,086	$14,799	$10,742	$5,287	36%	$4,057	38%
Research and development as a percentage of net revenue	6%	6%	6%				

For the year ended December 31, 2020, research and development expenses increased by $5.3 million, or 36%, as compared to the year ended December 31, 2019. The increase in research and development expenses was primarily due to an increase in process development costs associated with a new contract manufacturer, 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. We expect our research and development costs to continue to increase throughout 2021.

For the year ended December 31, 2019, research and development expenses increased by $4.1 million, or 38%, as compared to the year ended December 31, 2018. The increase in research and development expenses is primarily due to the increase in clinical research costs and increased headcount associated with our existing Advanced World Care and Surgical & Sports Medicine products and an increase in product costs associated with our pipeline products not yet commercialized.

Write-off of Deferred Offering Costs

	Years Ended December 31,			Change			
	2020	2019	2018	2020 to 2019		2019 to 2018	
	(in thousands, except for percentages)						
Write-off of deferred offering costs	$ —	$ —	$ 3,494	$ —	**	$ (3,494)	**
Write-off of deferred offering costs as a percentage of net revenue	0%	0%	2%				

** not meaningful

During the year ended December 31, 2018, there was a one-time write-off of costs accumulated in connection with a proposed initial public offering by Organogenesis Inc. that was abandoned and was replaced with the Avista Merger.

Other Expense, Net

	Years Ended December 31,			Change			
	2020	2019	2018	2020 to 2019		2019 to 2018	
	(in thousands, except for percentages)						
Interest expense, net	$(11,279)	$ (8,996)	$(10,789)	$(2,283)	25%	$ 1,793	(17%)
Change in fair value of warrants	—	—	(469)	—	**	469	(100%)
Gain on settlement of deferred acquisition consideration	2,246	—	—	2,246	**	—	**
Loss on the extinguishment of debt	—	(1,862)	(2,095)	1,862	(100%)	233	(11%)
Other income (expense), net	97	13	162	84	646%	(149)	(92%)
Total other expense, net	$ (8,936)	$(10,845)	$(13,191)	$ 1,909	(18%)	$ 2,346	-18%

** not meaningful

For the year ended December 31, 2020, other expense, net, decreased by $1.9 million or 18%, as compared to the year ended December 31, 2019. Interest expense, net, increased by $2.3 million or 25% primarily due to the increased borrowings under the 2019 Credit Agreement. The loss on the extinguishment of debt of $1.9 million in 2019 reflected the write-off of unamortized debt discount upon repayment of the Master Lease Agreement as well as early payment penalties in March 2019. The gain of $2.2 million in 2020 was related to the settlement of the deferred acquisition consideration dispute with the sellers of NuTech Medical in February 2020 as well as the settlement in October 2020 of a legacy lawsuit which we assumed from the sellers of NuTech Medical as part of the resolution of the aforementioned dispute.

For the year ended December 31, 2019, other expense, net, decreased by $2.3 million, or 18%, as compared to the year ended December 31, 2018. Interest expense, net, decreased by $1.8 million, or 17 %, primarily due to the repayment and conversion to equity of affiliate debt in connection with the Avista Merger. Change in fair value of warrant liability decreased by $0.5 million due to the exercise of the underlying warrants in connection with the Avista Merger. The loss on extinguishment of debt of $1.9 million in 2019 reflects the write-off of unamortized debt discount upon repayment of the Master Lease Agreement as well as early payment penalties in March 2019. The loss on extinguishment of debt of $2.1 million in the year ended December 31, 2018 reflects the write off of unamortized debt issuance costs upon repayment of affiliate debt and the difference in the carrying value of the affiliate debt converted to Class A common stock and the fair value of the Class A common stock issued in the conversion in December 2018.

Income Tax Expense

	Years Ended December 31,			Change			
	2020	2019	2018	2020 to 2019		2019 to 2018	
	(in thousands, except for percentages)						
Income tax expense	$ (530)	$ (150)	$ (84)	$(380)	253%	$(66)	79%

For the year ended December 31, 2020, income tax expense increased by $0.4 million, or 253%, as compared to the year ended December 31, 2019. The increase is primarily due to the cash tax expected in states where net operating loss utilization is limited.

For the year ended December 31, 2019, income tax expense increased by $0.1 million, or 79%, as compared to the year ended December 31, 2018. The increase is primarily due to increased revenue for gross receipts-based U.S. state income taxes and the Swiss subsidiary’s profits.

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, 2020, we had $106.1 million in working capital which includes $84.4 million in cash. We expect that our cash on hand and other components of working capital as of December 31, 2020, 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. We continue to closely monitor ongoing developments in connection with the COVID-19 pandemic, which may negatively impact our commercial prospects, cash position and access to capital in fiscal 2021 or beyond. We will continue to assess our cash and other sources of liquidity and, if circumstances warrant, we will make appropriate adjustments to our operating plan. Please see “Item 1A. Risk Factors” in this Annual Report on Form 10-K for an additional discussion of risks and potential risks of the COVID-19 pandemic on our business, financial condition and results of operations.

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, computer hardware and software.

To the extent additional funds are necessary to meet our long-term liquidity needs as we continue to execute 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, particularly in light of the adverse impacts of the COVID-19 pandemic on the capital markets. Any failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations, and financial condition. Our current borrowings under the 2019 Credit Agreement are subject to compliance with certain financial covenants regarding Minimum Trailing Twelve Month Consolidated Revenue and Non-PuraPly revenue. If we are not able to comply with these covenants, due to the impacts of COVID-19 or otherwise, the borrowings under the 2019 Credit Agreement may become due and payable immediately unless we obtain an amendment from our lenders. There can be no assurance that our lenders would agree to any such amendment on acceptable terms, or at all.

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

	December 31,		
	2020	2019	2018
	(in thousands)		
Cash(1)	$ 84,394	$ 60,174	$ 21,291
Line of credit	$ 10,000	$ 33,484	$ 26,484
Term loan	59,710	49,634	—
Notes payable	—	—	15,123
Capital lease obligations	15,061	17,488	17,654
Total debt	$ 84,771	$ 100,606	$ 59,261

(1) Under the line of credit or the Revolving Faciltiy, we have up to $30,000 available (subject to Borrowing Base) for future revolving borrowings.

Cash Flows

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

	Year Ended December 31,		
	2020	2019	2018
	(in thousands)		
Net cash provided by (used in) operating activities	$ 6,801	$(33,528)	$(60,635)
Net cash used in investing activities	(24,833)	(6,234)	(1,856)
Net cash provided by financing activities	42,468	78,727	81,538
Net increase in cash and restricted cash	$ 24,436	$ 38,965	$ 19,047

Operating Activities

During the year ended December 31, 2020, net cash provided by operating activities was $6.8 million, resulting from our net income of $17.9 million and non-cash charges of $15.0 million, partially offset by net cash used in connection with changes in our operating assets and liabilities of $26.2 million. Net cash used in changes in our operating assets and liabilities included an increase in accounts receivable of $18.8 million, an increase in inventory of $6.7 million, an increase in prepaid expenses and other current assets of $1.0 million, and a decrease in accounts payable and other liabilities of $1.1 million, all of which were partially offset by an increase in accrued expenses and other current liabilities of $1.4 million.

During the year ended December 31, 2019, net cash used in operating activities was $33.5 million, resulting from our net loss of $40.5 million and net cash used in connection with changes in our operating assets and liabilities of $9.7 million partially offset by non-cash charges of $16.6 million. Net cash used in connection with changes in our operating assets and liabilities includes an increase in inventory of $11.1 million, an increase in accounts receivable of $4.7 million, an increase in prepaid expenses and other current assets of $0.6 million and a decrease in other liabilities of $0.9 million, all of which were partially offset by an increase in accounts payable of $4.7 million and an increase of accrued expenses and other current liabilities of $2.9 million.

During the year ended December 31, 2018, net cash used in operating activities was $60.6 million, resulting from our net loss of $64.8 million and net cash used in connection with changes in our operating assets and liabilities of $16.7 million partially offset by non-cash charges of $20.9 million. Net cash used in connection with changes in our operating assets and liabilities includes a decrease in accrued interest on affiliate debt of $9.2 million, an increase in accounts receivable of $7.1 million, an increase in inventory of $1.5 million, an increase in prepaid expenses and other current assets of $1.4 million, all of which were partially offset by an increase in accrued expenses and other liabilities of $2.7 million.

Investing Activities

During the year ended December 31, 2020, we used $24.8 million of cash in investing activities consisting of capital expenditures of $21.1 million, payment of $5.8 million related to the acquisition of CPN, partially offset by notes receivable repayment of $2.1 million from our former executives.

During the year ended December 31, 2019, we used $6.2 million of cash in investing activities consisting primarily of capital expenditures and an intangible asset purchase.

During the year ended December 31, 2018, we used $1.9 million of cash in investing activities consisting primarily of capital expenditures.

Financing Activities

During the year ended December 31, 2020, net cash provided by financing activities was $42.5 million. This consisted primarily of $59.1 million in net proceeds from the issuance of Class A common stock and $2.8 million in proceeds from the exercise of options. The net cash provided by financing activities was partially offset by the payment of capital lease obligations of $2.4 million, the payment of $3.5 million related to the NuTech Medical deferred acquisition consideration and the net debt repayment of $13.5 million under our 2019 Credit Agreement.

During the year ended December 31, 2019, net cash provided by financing activities was $78.7 million that consisted primarily of $56.1 million in net proceeds from the 2019 Credit Agreement, $47.4 million in net proceeds from the issuance of Class A common stock and $0.9 million in proceeds from the exercise of warrants and options. The net cash provided by financing activities was partially offset by the payment of the put option on redeemable Class A common stock of $6.8 million, repayment of the ML Agreement of $17.6 million, and payment of capital lease obligations of $1.3 million.

During the year ended December 31, 2018, net cash provided by financing activities was $81.5 million that consisted primarily of $91.7 million in net proceeds from the issuance of Class A common stock, $15 million proceeds from affiliate debt, $8.7 million in net borrowings under our 2017 Credit Agreement and $0.1 million in proceeds from the exercise of stock options. The net cash provided by financing activities was partially offset by payment of recapitalization costs of $11.2 million, affiliate debt repayments of $22.7 million, and the payment of capital lease obligations of $0.1 million.

Indebtedness

2019 Credit Agreement

On March 14, 2019, we and our subsidiaries entered into a credit agreement with SVB and several other lenders, which we refer to as the 2019 Credit Agreement. Capitalized terms used herein and not otherwise defined are defined as set forth in the 2019 Credit Agreement.

The 2019 Credit Agreement, as amended, provides for a revolving credit facility (the “Revolving Facility”) of up to the lesser of $40.0 million and the amount determined by the Borrowing Base. Additionally, we entered into a $60.0 million term loan (the “Term Loan Facility”) structured in three tranches. The first tranche of $40.0 million was made available to us and fully funded on March 14, 2019; (ii) the second tranche of $10.0 million was made available to us and fully funded in September 2019; and (iii) the third tranche of $10.0 million was made available to us and fully funded in March 2020.

We are required to comply with certain covenants and restrictions under the 2019 Credit Agreement. If we fail to comply with these requirements, the lenders will be entitled to exercise certain remedies, including the termination of the lending commitments and the acceleration of the debt payments under either or both of the Revolving Facility and the Term Loan Facility. We are also required to achieve certain financial covenants, including Minimum Trailing Twelve Month Consolidated Revenue and Non-PuraPly Revenue, tested quarterly. The Minimum Trailing Twelve Month Consolidated Revenue thresholds for the year ending December 31, 2020 were agreed to and the covenant requiring Trailing Twelve Month Non-PuraPly Revenue beginning with the quarter ending September 30, 2020 was added in connection with the third amendment to the 2019 Credit Agreement entered into on March 26, 2020. The Minimum Trailing Twelve Month Consolidated Revenue requirements for the year ending December 31, 2020 were set at the following levels: $235.0 million for the trailing twelve months ending March 31, 2020; $253.0 million for the trailing twelve months ending June 30, 2020; $260.0 million for the trailing twelve months ending September 30, 2020; and $262.0 million for the trailing twelve months ending December 31, 2020. The Trailing Twelve Month Non-PuraPly Revenue requirements were set at the following levels: $136.5 million for the trailing twelve months ending September 30, 2020; and $145.0 million for the trailing twelve months ending December 31, 2020. The minimum revenue covenant levels for the periods ending March 31, 2021 and thereafter shall be determined with the lenders no later than March 31 of each applicable fiscal year. We are also required to maintain Minimum Liquidity equal to the greater of (i) 6 months Monthly Burn and (ii) $10.0 million.

As of December 31, 2020, we were in compliance with the financial covenants under the 2019 Credit Agreement and we had outstanding borrowings under the Revolving Facility and Term Loan Facility of the 2019 Credit Agreement of $10.0 million and $60.0 million, respectively.

2017 Credit Agreement

In March 2017, we entered into a credit agreement with SVB, which we refer to as the 2017 Credit Agreement. The 2017 Credit Agreement, as amended, provided for a revolving credit facility of up to $30.0 million and a term loan of up to $5.0 million. The term loan was repaid in full in December 2018. Upon entering into the 2019 Credit Agreement, the outstanding amount due under the 2017 Credit Agreement was fully repaid and terminated.

Master Lease Agreement

In April 2017, we entered into the Master Lease Agreement (the "ML Agreement") with Eastward Fund Management LLC. In March 2019, upon entering into the 2019 Credit Agreement, we paid an aggregate amount of $17.6 million due under the ML Agreement with proceeds from the 2019 Credit Agreement, and the ML Agreement was terminated. Upon termination of the ML Agreement, we recognized $1.9 million as loss on the extinguishment of the loan.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2020 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years
	(in thousands)				
Operating lease obligations (1)	$ 34,951	$ 5,640	$ 7,734	$ 6,046	$ 15,531
Capital lease obligations (2)	19,541	4,786	4,945	9,810	—
Debt obligations (3)	89,526	23,579	48,351	17,596	—
Purchase commitments (4)	16,921	12,457	4,464	—	—
Deferred acquisition consideration (5)	1,919	1,919	—	—	—
Acquisition of intangible assets (6)	250	250	—	—	—
Total	$163,108	$48,631	$65,494	$33,452	$ 15,531

(1) Amounts in the table reflect minimum payments due for our leased space and vehicles under operating leases that expire between 2021 and 2031.

(2) Amounts in the table reflect the total cash payments on our capital lease obligations primarily related to the office and laboratory space in Canton, Massachusetts, including accrued interest of $2.9 million for rent in arrears discussed in Note "18. Commitments and Contingencies". The leases have a ten-year term and expire in December 2022 but due to the subordination agreement, rent in arrears will be paid in 2024 upon maturity of the 2019 Credit Agreement.

(3) Amounts in the table reflect the contractually required principal and interest payable as of December 31, 2020 pursuant to outstanding borrowings under the 2019 Credit Agreement. For the Term Loan Facility, the table reflects interest-only payments through February 2021 at an interest rate of 9.25%, as well as a final payment of $3.9 million due upon repayment of all outstanding amounts. For the Revolving Facility, the table reflects interest payments relating to the outstanding principal due in March 2024, calculated using an interest rate of 5.5%, which was the applicable interest rate as of December 31, 2020.

(4) Amounts in the table reflect purchase commitments to suppliers for raw materials and consumables to be utilized in the manufacturing process.

(5) Amount in the table reflects the remaining settlement payments to sellers of NuTech Medical for the settlement of deferred acquisition consideration dispute according to the settlement agreement reached in February 2020. See Note "18. Commitments and Contingencies."

(6) Amount in the table reflects the remaining payments due related to the acquisition of an intangible asset.

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 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, especially given the risks and uncertainties related to COVID-19, 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

Accounts receivable are stated at invoice value less estimated allowances for sales returns and doubtful accounts. We estimate the allowance for sales returns based on a historical percentage of returns over a twelve-month trailing average of sales. 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, 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.

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. We operate 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*, we 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, we determine 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. The quantitative goodwill impairment test requires us 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.

Application of the goodwill impairment test requires judgments, including identification of the reporting units, assigning goodwill to reporting units, a qualitative assessment to determine whether there are any impairment indicators, and determining the fair value of each reporting unit which often involves the use of significant estimates and assumptions, including assumptions with respect to future cash inflows and outflows, discount rates, asset lives and market multiples, among other items. There is no assurance that the actual future earnings or cash flows of the reporting unit will not decline significantly from the projections used in the impairment analysis. Goodwill impairment charges may be recognized in future periods to the extent changes in factors or circumstances occur, including deterioration in the macroeconomic environment and industry, deterioration in the Company's performance or its future projections, or changes in plans for its reporting unit.

There were no impairments of goodwill recorded during 2020, 2019, and 2018.

Impairment of Long-Lived Assets

We review other long-lived assets (including identifiable definite lived intangible assets) for impairment whenever events or changes in circumstances indicate that the useful life is shorter than originally estimated or the carrying amount of an asset or asset group may not be recoverable. If such facts and circumstances exist, we assess the recoverability of the identified assets by comparing the projected undiscounted net cash flows associated with the related asset or group of assets over their remaining lives to their respective carrying amounts. Impairments, if any, are based on the excess of the carrying amount over the fair value of those assets and occur in the period in which the impairment determination is made.

There were no impairments of long-lived assets recorded during 2020, 2019, and 2018.

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. Deferred taxes are determined using enacted tax rates in effect in the year in which the differences are expected to settle. 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 and inherent in that, assess the likelihood of sufficient future taxable income. We also consider the expected reversal of deferred tax liabilities and analyze the period in which these liabilities would be expected to reverse to determine whether the taxable temporary difference amounts serve as an adequate source of future taxable income to support the realizability of the deferred tax assets. 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. Based on a consideration of the factors discussed above, including the fact that through the year ended December 31, 2020, our results reflected a three-year cumulative loss position, we have determined that a valuation allowance is necessary against the full amount of our net deferred tax assets, excluding alternative minimum tax credits. As a result of the 2017 Tax Cuts and Jobs Act and the 2020 CARES Act, alternative minimum tax credits were refunded on the 2018 and 2019 tax returns in full.

Valuation of Contingent Purchase Earnout

In connection with our acquisition of CPN Biosciences, LLC ("CPN"), we recognized a non-current liability of $3,782, for the fair value of the contingent consideration (the "Earnout"). The Earnout liability is classified as a Level 3 measurement for which fair value is derived from inputs that are unobservable and significant to the overall fair value measurement. The fair value of such Earnout liability is estimated using a Monte Carlo simulation model that utilizes key assumptions including forecasted revenues and volatilities of the underlying financial metrics during the Earnout period. We assess the fair value of the Earnout liability at each reporting period. Any subsequent changes in the estimated fair value of the liability are reflected in selling, general and administrative expenses until the liability is settled.

Stock-Based Compensation

We measure stock-based awards granted based on the fair value of the awards on the date of grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Generally, we issue stock-based awards with only service-based vesting conditions and record the expense for these awards using the straight-line method. We have not issued any stock-based awards with performance-based vesting conditions.

We recognize stock-based compensation expense within selling, general and administrative expenses in the consolidated statement of operations 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 is based on the fair market value of our 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. We have been a public company for a short period of time, have limited public float and lack company-specific historical and implied volatility information for our Class A common stock. Therefore, we estimate our expected stock price volatility based on the historical volatility of publicly traded peer companies and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our own traded stock price. The expected term of our 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 we have never paid cash dividends on Class A common stock and do not expect to pay any cash dividends in the foreseeable future.

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, 2020, we had $60.0 million and $10.0 million of borrowings outstanding under the Term Loan Facility and the Revolving Facility, respectively. Borrowings under our 2019 Credit Agreement bear interest at variable rates. Based on the principal amount outstanding as of December 31, 2020, 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-31 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

Evaluation of the Company's Disclosure Controls

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, 2020. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the Securities and Exchange Commission (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 concluded that, as of December 31, 2020, our disclosure controls and procedures were not effective because our internal control over financial reporting has not been operating effectively for a reasonable period of time.

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 Securities Exchange Act of 1934 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 and 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;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the issuer are being made only in accordance with authorizations of management and directors; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the issuer's assets that could have a material effect on the issuer's consolidated financial statements.

Because of its inherent limitations, our 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. Accordingly, even effective internal control over financial reporting can only provide reasonable assurance of achieving their control objectives.

Management assessed the effectiveness of the Company's internal control over financial reporting based on the criteria established 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, 2020, our internal control over financial reporting was not effective based on those criteria.

As disclosed in the Company's annual report for the fiscal year ended December 31, 2019, our management team identified the following material weakness in our internal control over financial reporting: we did not design and maintain formal accounting, business operations, and information technology policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including (i) formalized policies and procedures for reviews over account reconciliations, journal entries, and other accounting analyses, memos and procedures to ensure completeness and accuracy of information used in these review controls and (ii) controls to support the objectives of proper segregation of the initiation of transactions, the recording of transactions, and the custody of assets.

Although management has made significant progress in remediating this material weakness, management concluded that the material weakness described above continued to exist as of December 31, 2020. Specifically, we are unable to conclude that the controls were operating effectively for a reasonable period of time.

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 associated with the above-mentioned material weakness. Management is committed to finalizing the remediation of the material weakness during 2021. Management's internal control remediation efforts include the following:

- In 2019, we began the implementation of a new company-wide enterprise resource planning system to provide additional systematic controls and segregation of duties for our accounting processes. We anticipate that the enterprise resource planning system will go live during the first half of 2021.
- We have designed and implemented more effective controls throughout 2019 and 2020.
- We completed the risk assessment activities by evaluating whether the design of our internal controls appropriately addresses changes in the business (including changes to people, processes and systems) that could impact our system of internal controls.
- We designed controls that address the completeness and accuracy of any key reports utilized in the execution of internal controls.
- We reported regularly to the audit committee on the progress and results of control remediation.
- We developed and executed upon a monitoring protocol that allows the Company to validate the operating effectiveness of certain controls over financial reporting to gain assurance that such controls are present and functioning as designed.

We will also continue to engage an outside firm in 2021 to assist management with performing sufficient testing throughout the year to validate the operating effectiveness of certain controls over financial reporting.

As management continues to evaluate and work to improve its internal control over financial reporting, management may determine it is necessary to take additional measures to address the material weakness. Until the controls have been operating for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively, the material weakness described above will continue to exist.

The Company acquired CPN Biosciences, LLC ("CPN") on September 17, 2020. Management excluded this business from its assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2020. This exclusion was in accordance with SEC guidance that an assessment of a recently acquired business's internal control over financial reporting may be omitted from management's report on internal control over financial reporting in the year of acquisition of the business. CPN represented, in aggregate, approximately 6% of the Company's total consolidated assets and less than 1% of total consolidated revenues, as of and for the year ended December 31, 2020.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting other than those described above related to remediation efforts. However, as the implementation of the new ERP system continues, we will 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.

ITEM 9B. OTHER INFORMATION

None.

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 2019 Annual Meeting of Stockholders which will be filed to 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
2.1	Merger Agreement, dated August 17, 2018, by and among Avista Healthcare Public Acquisition Corp., Avista Healthcare Merger Sub, Inc. and Organogenesis Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on August 17, 2018)
2.2	Amendment No. 1 to Merger Agreement, dated October 5, 2018, by and among Avista Healthcare Public Acquisition Corp., Avista Healthcare Merger Sub, Inc. and Organogenesis Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on October 9, 2018)
2.3	Agreement and Plan of Merger dated as of March 18, 2017 by and among Organogenesis Inc., Prime Merger Sub, LLC, Nutech Medical, Inc., Howard P. Walthall, Jr., Gregory J. Yager, Kenneth L. Horton and Kenneth L. Horton, as representative (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
3.1	Certificate of Incorporation of ORGO (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	Bylaws of ORGO (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 ORGO, 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	Stockholders Agreement dated as of December 10, 2018 among ORGO, 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 10.2 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.3†	License and Services Agreement, dated as of September 14, 2011, by and between Organogenesis Inc. and Net Health Systems, Inc., as amended by that certain First Amendment dated as of March 31, 2013, Second Amendment dated as of July 22, 2014, Third Amendment dated as of March 13, 2015 and Fourth Amendment dated as of August 17, 2017 (incorporated by reference to Exhibit 10.3 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 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)
10.5	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)

Exhibit No.	Exhibit
10.6	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)
10.7	Lease dated as of January 1, 2013 by and between Organogenesis Inc. and 275 Dan Road SPE, LLC (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.8	Lease Agreement dated as of March 6, 2017 by and between Organogenesis Inc. and ARE-10933 North Torrey Pines, LLC (incorporated by reference to Exhibit 10.8 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.9	Sublease Agreement dated as of March 18, 2014 by and between Organogenesis Inc. and Shire Holdings US AG, as amended by that certain First Amendment to Sublease dated as of January 13, 2017, as amended by that certain Second Amendment to Sublease dated as of January 25, 2017 (incorporated by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.10	Lease Agreement, dated as of June 5, 2012, by and between Organogenesis Switzerland GmbH and Stiftung Regionales Gründerzentrum Reinach, as amended by that certain Supplement No. 1 dated May 9, 2017 and that certain Supplement No. 2 dated May 9, 2017 (incorporated by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.11	Lease Agreement, dated as of January 1, 2014, by and between Oxmoor Holdings, LLC and Prime Merger Sub, LLC (as successor-in-interest to Nutech Medical, Inc.) (incorporated by reference to Exhibit 10.11 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.12	Standard Industrial/Commercial Multi-Tenant Lease—Net, dated as of March 7, 2011, by and among Liberty Industrial Park and Organogenesis Inc., as amended by that certain First Amendment dated as of April, 2013, Second Amendment dated as of April 19, 2015, and Third Amendment dated as of March 9, 2017 (incorporated by reference to Exhibit 10.12 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.13‡	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)
10.14‡	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)
10.15‡	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)
10.16‡	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)
10.17‡	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)
10.18	Credit Agreement dated March 14, 2019 between the Company, Organogenesis Inc. and Prime Merger Sub, LLC, collectively as borrower, and Silicon Valley Bank, in its capacity as Administrative Agent, and Silicon Valley Bank and the other lenders listed therein, 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 March 14, 2019)
10.19	Amended and Restated Subordination Agreement dated as of August 6, 2019 by and among Dan Road Associates LLC, 85 Dan Road Associates LLC, 275 Dan Road SPE LLC, 65 Dan Road SPE LLC and Silicon Valley Bank (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on August 8, 2019)
10.20	Letter Agreement dated as of August 6, 2019 by and among Organogenesis Inc., Dan Road Associates LLC, 85 Dan Road Associates LLC, 275 Dan Road SPE LLC and 65 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 8, 2019)

Exhibit No.	Exhibit
10.21‡	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)
10.22‡	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)
10.23‡	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)
10.24‡	2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.30 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.25‡	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)
10.26‡	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)
10.27‡	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)
10.28†	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)
10.29	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)
10.30	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)
10.31	Exchange Agreement, dated August 17, 2018, by and among Avista Healthcare Public Acquisition Corp. and certain lenders listed on Schedule A therein (incorporated by reference to Exhibit 10.37 to the Company's Annual Report on Form 10-K (File No. 001-37906) filed with the SEC on March 18, 2019)
10.32	First Amendment to Credit Agreement dated November 12, 2019 among Organogenesis Holdings Inc., Organogenesis Inc. and Prime Merger Sub, LLC, collectively as borrower, and Silicon Valley Bank, in its capacity as the Issuing Lender and Swingline Lender, Silicon Valley Bank, as Administrative Agent, and Silicon Valley Bank and the other lenders listed therein, collectively as lenders (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on November 15, 2019)
10.33	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)
10.34	Form of Indemnity Agreement (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-213465) filed with the SEC on September 2, 2016)
10.35	Fourth Amendment to Lease dated February 14, 2020 by and between Liberty Industrial Park and Organogenesis Inc. (incorporated by reference to Exhibit 10.41 to the Company's Annual Report on Form 10-K (File No. 001-37906) filed with the SEC on March 9, 2020)
10.36	Second Amendment to Lease dated February 7, 2020 by and between Oxmoor Holdings, LLC and Organogenesis Inc. (incorporated by reference to Exhibit 10.42 to the Company's Annual Report on Form 10-K (File No. 001-37906) filed with the SEC on March 9, 2020)
10.37	Second Amendment to Credit Agreement entered into on February 14, 2020 and dated and effective as of February 13, 2020 among Organogenesis Holdings Inc., Organogenesis Inc. and Prime Merger Sub, LLC, collectively as borrower, and Silicon Valley Bank, in its capacity as the Issuing Lender and Swingline Lender, Silicon Valley Bank, as Administrative Agent, and Silicon Valley Bank and the other lenders listed therein, 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 February 19, 2020)

Exhibit No.	Exhibit
10.38	Separation Letter Agreement, dated March 13, 2020, between Organogenesis Holdings Inc. and Howard P. Walthall, Jr. (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 16, 2020)
10.39	Third Amendment to Credit Agreement dated March 26, 2020 among Organogenesis Holdings Inc., Organogenesis Inc. and Prime Merger Sub, LLC, collectively as borrower, and Silicon Valley Bank, in its capacity as the Issuing Lender and Swingline Lender, Silicon Valley Bank, as Administrative Agent, and Silicon Valley Bank and the other lenders listed therein, 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 March 30, 2020)
10.40	Separation Letter Agreement, dated August 24, 2020, between Organogenesis Holdings Inc. and Timothy M. Cunningham (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 24, 2020)
10.41	Fee Letter Agreement dated November 12, 2020 by and among the Company, the Avista Funds and the Management Company (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 November 18, 2020)
10.42‡	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)
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
101*	The following materials from the Annual Report of Organogenesis Holdings Inc. on Form 10-K for the year ended December 31, 2020, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2020 and December 31, 2019 of Organogenesis Holdings Inc., (ii) Consolidated Statements of Operations for the years ended December 31, 2020, 2019, and 2018 of Organogenesis Holdings Inc., (iii) Consolidated Statements of Redeemable Common Stock and Stockholders' Equity (Deficit) for the years ended December 31, 2020, 2019, and 2018 of Organogenesis Holdings Inc., (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2020, 2019, and 2018 of Organogenesis Holdings Inc., and (v) Notes to Consolidated Financial Statements of Organogenesis Holdings Inc.

* 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.
President and Chief Executive Officer
Date: March 16, 2021

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 Director (Principal Executive Officer)	March 16, 2021
/s/ David Francisco **David Francisco**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2021
/s/ Alan A. Ades **Alan A. Ades**	Director	March 16, 2021
/s/ Robert Ades **Robert Ades**	Director	March 16, 2021
/s/ David Erani **David Erani**	Director	March 16, 2021
/s/ Arthur S. Leibowitz **Arthur S. Leibowitz**	Director	March 16, 2021
/s/ Wayne D. Mackie **Wayne D. Mackie**	Director	March 16, 2021
/s/ Glenn H. Nussdorf **Glenn H. Nussdorf**	Director	March 16, 2021
/s/ Joshua Tamaroff **Joshua Tamaroff**	Director	March 16, 2021

ORGANOGENESIS HOLDINGS INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors
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, 2020 and 2019, the related consolidated statements of operations, redeemable common stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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.

/s/ RSM US LLP

We have served as the Company's auditor since 2004.

Boston, Massachusetts
March 16, 2021

ORGANOGENESIS HOLDINGS INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash	$ 84,394	$ 60,174
Restricted cash	412	196
Accounts receivable, net	56,804	39,359
Inventory	27,799	22,918
Prepaid expenses and other current assets	4,935	2,953
Total current assets	174,344	125,600
Property and equipment, net	60,068	47,184
Notes receivable from related parties	—	556
Intangible assets, net	30,622	20,797
Goodwill	28,772	25,539
Deferred tax asset, net	18	127
Other assets	670	884
Total assets	$ 294,494	$ 220,687
Liabilities and Stockholders' Equity		
Current liabilities:		
Deferred acquisition consideration	$ 483	$ 5,000
Current portion of term loan	16,666	—
Current portion of capital lease obligations	3,619	3,057
Current portion of deferred rent and lease incentive obligation	95	—
Accounts payable	23,381	28,387
Accrued expenses and other current liabilities	23,973	23,450
Total current liabilities	68,217	59,894
Line of credit	10,000	33,484
Term loan, net of current portion	43,044	49,634
Deferred acquisition consideration, net of current portion	1,436	—
Earnout liability	3,985	—
Deferred rent and lease incentive obligation, net of current portion	2,315	1,012
Capital lease obligations, net of current portion	11,442	14,431
Other liabilities	7,971	6,649
Total liabilities	148,410	165,104
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; 128,460,381 and 105,599,434 shares issued; 127,731,833 and 104,870,886 shares outstanding at December 31, 2020 and 2019, respectively.	13	10
Additional paid-in capital	299,129	226,580
Accumulated deficit	(153,058)	(171,007)
Total stockholders' equity	146,084	55,583
Total liabilities and stockholders' equity	$ 294,494	$ 220,687

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

ORGANOGENESIS HOLDINGS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2020	2019	2018
Net revenue	$ 338,298	$ 260,981	$ 193,449
Cost of goods sold	87,319	75,948	68,808
Gross profit	250,979	185,033	124,641
Operating expenses:			
Selling, general and administrative	203,478	199,693	161,961
Research and development	20,086	14,799	10,742
Write-off of deferred offering costs	—	—	3,494
Total operating expenses	223,564	214,492	176,197
Income (loss) from operations	27,415	(29,459)	(51,556)
Other expense, net:			
Interest expense, net	(11,279)	(8,996)	(10,789)
Change in fair value of warrants	—	—	(469)
Gain on settlement of deferred acquisition consideration	2,246	—	—
Loss on the extinguishment of debt	—	(1,862)	(2,095)
Other income, net	97	13	162
Total other expense, net	(8,936)	(10,845)	(13,191)
Net income (loss) before income taxes	18,479	(40,304)	(64,747)
Income tax expense	(530)	(150)	(84)
Net income (loss)	17,949	(40,454)	(64,831)
Non-cash deemed dividend to warrant holders	—	(645)	—
Net income (loss) attributed to common shareholders	$ 17,949	$ (41,099)	$ (64,831)
Net income (loss) attributed to common shareholders, per share:			
Basic	$ 0.17	$ (0.44)	$ (0.94)
Diluted	$ 0.16	$ (0.44)	$ (0.94)
Weighted-average common shares outstanding			
Basic	107,737,936	92,840,401	69,318,456
Diluted	111,360,831	92,840,401	69,318,456

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

ORGANOGENESIS HOLDINGS INC.

CONSOLIDATED STATEMENTS OF REDEEMABLE COMMON STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(in thousands, except share amounts)

	Redeemable Common Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance as of December 31, 2017	728,548	$ 6,762	66,983,139	$ 6	$ 50,086	$ (65,409)	$ (15,317)
Proceeds from equity financing, net of issuance costs of $270	—	—	15,561,473	2	91,728	—	91,730
Recapitalization costs	—	—	—	—	(11,206)	—	(11,206)
Exercise of stock options	—	—	76,654	—	119	—	119
Exercise of common stock warrants	—	—	746,475	—	2,707	—	2,707
Issuance of common stock for extinguishment of debt	—	—	6,502,679	1	42,763	—	42,764
Common stock issued in exchange for AHPAC shares	—	—	1,390,993	—	—	—	—
Stock-based compensation expense	—	—	—	—	1,075	—	1,075
Notification of exercise of put option of redeemable common stock	—	(6,762)	—	—	—	—	—
Net loss	—	—	—	—	—	(64,831)	(64,831)
Balance as of December 31, 2018	728,548	$ —	91,261,413	$ 9	$177,272	$ (130,240)	$ 47,041
Adoption of ASC 606	—	—	—	—	—	332	332
Exercise of common stock warrants	—	—	74,052	—	628	—	628
Exercise of stock options	—	—	152,133	—	269	—	269
Common stock issued in warrant exchange	—	—	3,315,232	—	645	(645)	—
Stock-based compensation expense	—	—	—	—	936	—	936
Redemption of redeemable common stock placed into treasury	(728,548)	—	—	—	—	—	—
Stock issued in the 2019 Underwritten Public Offering, net of issuance costs of $3,510			10,068,056	1	46,830	—	46,831
Net loss	—	—	—	—	—	(40,454)	(40,454)
Balance as of December 31, 2019	—	$ —	104,870,886	$ 10	$226,580	$ (171,007)	$ 55,583
Exercise of stock options	—	—	996,286	1	2,822	—	2,823
Issuance of common stock associated with business acquisition	—	—	1,947,953	—	7,986	—	7,986
Stock-based compensation expense	—	—	—	—	1,661	—	1,661
Stock issued in the 2020 Underwritten Public Offering, net of issuance costs of $4,647	—	—	19,916,708	$ 2	$ 60,080	—	60,082
Net income						17,949	17,949
Balance as of December 31, 2020	—	$ —	127,731,833	$ 13	$299,129	$ (153,058)	$ 146,084

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,		
	2020	2019	2018
Cash flows from operating activities:			
Net income (loss)	$ 17,949	$(40,454)	$(64,831)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation	3,723	3,388	3,309
Amortization of intangible assets	3,745	6,043	3,669
Non-cash interest expense	236	243	845
Deferred interest expense	2,133	1,446	249
Deferred rent expense and lease incentive obligation	1,273	882	56
Gain on settlement of deferred acquisition consideration	(2,246)	—	—
Recovery of certain notes receivable from related parties	(1,516)	—	—
Deferred tax expense	112	111	186
Loss on disposal of property and equipment	201	146	1,209
Write-off of deferred offering costs	—	—	3,494
Provision recorded for sales returns and doubtful accounts	2,441	239	1,157
Adjustment for excess and obsolete inventories	3,050	1,297	2,473
Stock-based compensation	1,661	936	1,075
Change in fair value of warrant liability	—	—	469
Loss of extinguishment of debt	—	1,862	2,095
Change in fair value of Earnout liability	203	—	—
Changes in fair value of forfeiture rights	—	—	589
Changes in operating assets and liabilities:			
Accounts receivable	(18,825)	(4,691)	(7,110)
Inventory	(6,700)	(11,063)	(1,524)
Prepaid expenses and other current assets	(971)	(625)	(1,414)
Accounts payable	(635)	4,700	(60)
Accrued expenses and other current liabilities	1,443	2,942	2,354
Accrued interest - affiliate debt	—	—	(9,241)
Other liabilities	(476)	(930)	316
Net cash provided by (used in) operating activities	6,801	(33,528)	(60,635)
Cash flows from investing activities:			
Purchases of property and equipment	(21,145)	(5,984)	(1,857)
Proceeds from the repayment of notes receivable from related parties	2,132	—	—
Cash paid for business acquisition	(5,820)	—	—
Acquisition of intangible asset	—	(250)	—
Proceeds from disposal of property and equipment	—	—	1
Net cash used in investing activities	(24,833)	(6,234)	(1,856)
Cash flows from financing activities:			
Line of credit borrowings (repayments), net	(23,484)	7,000	8,866
Proceeds from term loan	10,000	50,000	—
Proceeds from long-term debt - affiliates	—	—	15,000
Proceeds from equity financing	64,729	50,340	92,000
Payment of equity issuance costs	(5,656)	(2,973)	(270)
Payment of recapitalization costs	—	—	(11,206)
Repayment of debt and debt issuance cost on affiliate debt	—	—	(22,680)
Repayment of notes payable	—	(17,585)	(10)
Principal repayments of capital lease obligations	(2,427)	(1,266)	(104)
Redemption of redeemable common stock placed into treasury	—	(6,762)	—
Proceeds from the exercise of stock options	2,823	269	119
Proceeds from the exercise of common stock warrants	—	628	—
Payments of deferred acquisition consideration	(3,517)	—	—
Payment of debt issuance costs	—	(924)	(177)
Net cash provided by financing activities	42,468	78,727	81,538
Change in cash and restricted cash	24,436	38,965	19,047
Cash and restricted cash, beginning of year	60,370	21,405	2,358
Cash and restricted cash, end of year	$ 84,806	$ 60,370	$ 21,405
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 9,609	$ 8,148	$ 5,423
Cash paid for income taxes	$ 61	$ 49	$ 8
Supplemental disclosure of non-cash investing and financing activities:			
Reimbursement of offering expenses included in prepaid expenses and other current assets	$ 1,009	$ —	$ —
Fair value of shares issued for business acquisition	$ 7,986	$ —	$ —
Deferred acquisition consideration and earnout liability recorded for business acquisition	$ 5,218	$ —	$ —
Fair value of shares issued in connection with investor debt settlement	$ —	$ —	$ 42,764
Fair value of shares issued in connection with settlement of investor warrants	$ —	$ —	$ 2,707
Common stock issued in exchange for APHAC shares	$ —	$ —	$ 1

Notice of put option exercise of redeemable common shares	$ —	$ —	$ 6,762
Non-cash deemed dividend related to warrant exchange	$ —	$ 645	$ —
Equity issuance costs included in accounts payable	$ —	$ 537	$ —
Purchases of property and equipment in accounts payable and accrued expenses	$ 2,391	$ 4,014	$ 172
Acquisition of intangible assets included in accrued expenses and other liabilities	$ —	$ 500	$ —
Equipment acquired under capital lease	$ —	$ 1,099	$ —

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. (formerly Avista Healthcare Public Acquisition Corp.) ("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, Business License Applicant ("BLA") 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 service centers ("ASCs") and physician offices. The Company has one operating and reportable segment.

COVID-19 pandemic

The emergence of the coronavirus (COVID-19) around the world, and particularly in the United States, continues to present significant risks to the Company. While the COVID-19 pandemic has not materially adversely affected the Company's financial results and business operations through the year ended December 31, 2020, the Company is unable to predict the impact that COVID-19 will have on its financial position and operating results because of the numerous uncertainties created by the unprecedented nature of the pandemic. The public health actions being undertaken to reduce the spread of the virus, and that may have to be undertaken again in the event of a resurgence of the virus, may create significant disruptions to the Company with respect to: (i) the demand for its products, (ii) the ability of its sales representatives to reach healthcare customers, (iii) its ability to maintain staffing levels to support its operations, (iv) its ability to continue to manufacture certain of its products, (v) the reliability of its supply chain and (vi) its ability to achieve the financial covenants required under the 2019 Credit Agreement (see Note "13. Long-Term Debt Obligations"). The extent to which the COVID-19 pandemic may impact the Company's business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, travel restrictions and social distancing in the U.S. and other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and other countries to contain and treat the disease.

The Company is closely monitoring the evolving impact of the pandemic on all aspects of its business. The Company has implemented a number of measures designed to protect the health and safety of its employees, support its customers and promote business continuity. The Company is also actively reviewing and implementing cost-saving measures including discontinuing or delaying all non-essential services and programs and instituting controls on travel, events, marketing and clinical studies to adapt the business plan for the evolving COVID-19 challenges.

Merger with Avista Healthcare Public Acquisition Corp

On December 10, 2018, Avista Healthcare Public Acquisition Corp., our predecessor company ("AHPAC"), consummated the previously announced merger (the "Avista Merger") pursuant to an Agreement and Plan of Merger, dated as of August 17, 2018 (as amended, the "Avista Merger Agreement"), by and among AHPAC, Avista Healthcare Merger Sub, Inc., a direct wholly-owned subsidiary of AHPAC ("Avista Merger Sub") and Organogenesis Inc.. As a result of the Avista Merger and the other transactions contemplated by the Avista Merger Agreement, Avista Merger Sub merged with and into Organogenesis Inc., with Organogenesis Inc. surviving the Avista Merger and becoming a wholly-owned subsidiary of AHPAC and AHPAC changed its name to Organogenesis Holdings Inc. (ORGO).

The Avista Merger was accounted for as a reverse merger in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Under this method of accounting, AHPAC was treated as the "acquired" company for accounting purposes and the Avista Merger was treated as the equivalent of Organogenesis Inc. issuing stock for the net assets of AHPAC, accompanied by a recapitalization. The net assets of AHPAC were recorded at historical cost, with no goodwill or other intangible assets recorded. Operations prior to the Avista Merger are those of Organogenesis Inc.

In accordance with the terms of the Avista Merger Agreement, at the effective time of the Avista Merger, each share of Organogenesis Inc. common stock then issued and outstanding was automatically canceled and converted into the right to receive 2.03 shares of ORGO Class A common stock, par value $0.0001 per share. 75,073,548 shares of ORGO Class A common stock were issued to the equity holders of Organogenesis Inc. In addition, all outstanding options and warrants exercisable for common stock in Organogenesis Inc. were exchanged for options and warrants exercisable for ORGO Class A common stock with the same terms and conditions except adjusted by the aforementioned exchange ratio.

In connection with the execution of the Avista Merger Agreement and the consummation of the Avista Merger, founders and certain directors of AHPAC, surrendered to AHPAC an aggregate of 6,359,007 founder shares and 16,400,000 private placement warrants. All such founder shares and private placement warrants were canceled. In addition, an aggregate of 1,390,993 shares of ORGO Class A common stock was issued upon conversion of the remaining outstanding founder shares in accordance with the terms of the Company's charter in connection with the Avista Merger.

In connection with the execution of the Avista Merger Agreement on August 17, 2018, Avista Capital Partners IV, L.P. and Avista Capital Partners IV (Offshore), L.P. (collectively, the "PIPE Investors") purchased, 6,538,732 shares of ORGO Class A common stock for an aggregate purchase price of $46,000. Concurrently with the completion of the Avista Merger, the PIPE Investors also purchased 9,022,741 shares of ORGO Class A common stock and 4,100,000 warrants to purchase one-half of one share of ORGO Class A common stock for an aggregate purchase price of $46,000.

Concurrently with the completion of the Avista Merger, the affiliate debt was discharged and terminated (See Note "12. Long-Term Debt—Affiliates").

During the year ended December 31, 2018, the Company recorded $3,072 of transaction expenses related to third-party legal and accounting services to consummate the Avista Merger. These costs were incorporated into selling, general and administrative expenses in the Company's consolidated statement of operations. Additionally, AHPAC incurred $11,206 in transaction costs prior to the Avista Merger that were paid in full by the Company after the consummation of the Avista Merger.

Liquidity and Financial Conditions

In accordance with ASC 205-40, Going Concern ("ASC 205-40"), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. While the Company has reported net income for the year ended December 31, 2020, the Company has recurring losses from operations since its inception and has funded its operations primarily with cash flow from product sales and proceeds from loans from affiliates and entities controlled by its affiliates, sales of its Class A common stock and third-party debt. As of December 31, 2020, the Company had an accumulated deficit of $153,058 and working capital of $106,127. For the year ended December 31, 2020, the Company has generated net income of $17,949, provided $6,801 of cash from operations and raised $64,729 in gross proceeds in the 2020 Underwritten Public Offering (see Note "14. Stockholders' Equity"). The Company may incur operating losses and negative cash flows from operations in the future as the Company expends resources to grow the organization to support the planned expansion of the business. The Company expects that its cash of $84,394 and other components of working capital as of December 31, 2020, plus net cash flows from product sales, will be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments for at least 12 months beyond the filing date of this annual report. The Company is closely monitoring ongoing developments in connection with the COVID-19 pandemic, which may negatively impact its commercial prospects, projected cash position and access to capital in the future. The Company will continue to assess its cash position and, if circumstances warrant, make appropriate adjustments to its operating plan.

The Company expects to continue investing in product development, sales and marketing, and customer support for its products. The Company may seek to raise additional funding through public and/or private equity financings, debt financings or other strategic transactions. There can be no assurance that the Company will be able to obtain additional debt or equity financing on terms acceptable to the Company, on a timely basis or at all, particularly in light of the adverse impacts of the COVID-19 pandemic on the capital markets. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations, and financial condition. The Company's current borrowings under the 2019 Credit Agreement are subject to compliance with certain financial covenants that include maintaining Minimum Trailing Twelve Month Consolidated Revenue and Non-PuraPly Revenue. If the Company is not able to comply with these covenants, due to the impacts of COVID-19 or otherwise, the borrowings under the 2019 Credit Agreement may become due and payable immediately unless the Company obtains an amendment or waiver from its lenders. There can be no assurance that the Company's lenders would agree to any such amendment or waiver on acceptable terms, or at all.

2. Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported results of operations during the reporting periods. 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. For periods prior to the closing of the Avista Merger on December 10, 2018, the notes to the consolidated financial statements have been updated to give effect to the Avista Merger.

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 $412 and $196 as of December 31, 2020 and 2019, respectively. Restricted cash represents employee deposits in connection with the Company's health benefit plan.

Accounts Receivable

Accounts receivable are stated at invoice value less estimated allowances for sales returns and doubtful accounts. The Company estimates the allowance for sales returns based on a historical percentage of returns over a twelve-month trailing average of sales. The Company continually monitors customer payments and maintains a reserve for estimated losses resulting from its customers' inability to make required payments. The Company considers factors when estimating the allowance for doubtful accounts 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, thereby reducing 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.

Inventories

Inventories are stated at the lower of cost (determined under 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 recorded at cost and depreciated over the estimated useful lives of the respective assets on a straight-line basis. As of December 31, 2020 and 2019, the Company's property and equipment consisted of leasehold improvements, furniture and computers, and equipment. Property and equipment estimated useful lives are as follows:

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

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the consolidated statement of operations. 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. 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.

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 first assesses 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 needed. Alternatively, the Company can bypass the qualitative test 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, 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.

There was no impairment of goodwill recorded during the years ended December 31, 2020, 2019 or 2018.

Intangible Assets Subject to Amortization

Intangible assets include intellectual property either owned by the Company or for 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 and 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 method 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 consist primarily of property and equipment and intangible assets. 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 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 either on discounted cash flows or appraised value, depending on the nature of the asset. The Company did not record any impairment of long-lived assets during the years ended December 31, 2020, 2019, or 2018.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders’ equity (deficit) as a reduction of proceeds generated as a result of the offering. Should the planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statement of operations.

The Company did not record any deferred offering costs in the consolidated balance sheets as of December 31, 2020 and 2019. During the year ended December 31, 2020 and 2019, the Company recorded $4,647 and $3,510 of equity issuance costs to additional paid-in capital against proceeds received from the 2020 and 2019 Underwritten Public Offering, respectively (see Note “14. Stockholders’ Equity”). During the year ended December 31, 2018, the Company wrote off deferred offering costs of $3,494 in connection with an abandoned public offering which was replaced with the Avista Merger transaction.

Revenue Recognition

Adoption of ASC Topic 606, Revenue from Contracts with Customers (“ASC 606”)

The Company adopted ASC 606 on January 1, 2019, using the modified retrospective method for all contracts not completed as of the date of adoption. The reported results for the years ended December 31, 2020 and 2019 reflect the application of ASC 606 guidance while the reported results for the year ended December 31, 2018 were prepared under the guidance of ASC Topic 605, *Revenue Recognition* (“ASC 605”). The adoption of ASC 606 represents a change in accounting principle that more closely aligns revenue recognition with the transfer of control of the Company’s products and provides enhanced disclosures to understand the nature, amount, timing, and uncertainty of revenues and cash flows arising from contracts with customers. In accordance with ASC 606, revenue is recognized when a customer obtains control of promised products. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these products.

Historically, for certain customers, products were shipped in advance of the receipt of a purchase order and the Company recognized revenue on these products only upon receipt of the purchase order which is when the transaction price was deemed fixed and determinable. As control of these products has transferred upon use of the product in a procedure, the recognition of revenue is accelerated to the procedure date under ASC 606. The adoption of ASC 606 did not have a material impact on the Company’s consolidated financial position, results of operations, equity or cash flows as of the adoption date or for the year ended December 31, 2019 or 2020.

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 group purchasing organization (“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 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 change 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, 2020, 2019 and 2018, the Company recorded GPO fees of $3,572, $3,096, and $1,923, 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 good.

Disaggregation of Revenue

The following table sets forth revenue by product category:

	Year Ended December 31,		
	2020	2019	2018
Advanced Wound Care revenue	$294,624	$220,744	$164,332
Surgical and Sports Medicine revenue	43,674	40,237	29,117
Total revenue	$338,298	$260,981	$193,449

Stock-Based Compensation

The Company measures stock-based awards granted 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. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Generally, the Company issues stock-based 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.

The Company recognizes stock-based compensation expense within selling, general and administrative expenses in the consolidated statement of operations 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 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 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. Advertising costs were approximately $2,722, $1,059, and $773 for the years ended December 31, 2020, 2019 and 2018, respectively.

Research and Development Costs

Research and development expenses include personnel costs for the Company's research and development personnel, expenses related to improvements to 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.

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 as a component of other expense, net. The foreign currency amounts recorded for all periods presented were insignificant.

Valuation of Contingent Purchase Earnout

In connection with the acquisition of CPN Biosciences, LLC ("CPN"), the Company recognized a non-current liability of $3,782, for the fair value of the contingent consideration (the "Earnout"). The Earnout liability is classified as a Level 3 measurement for which fair value is derived from inputs that are unobservable and significant to the overall fair value measurement. The fair value of such Earnout liability is estimated using a Monte Carlo simulation model that utilizes key assumptions including forecasted revenues and volatilities of the underlying financial metrics during the Earnout period. The Company assesses the fair value of the Earnout liability at each reporting period. Any subsequent changes in the estimated fair value of the liability are reflected in selling, general and administrative expenses until the liability is settled.

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. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

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, inventory, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. The fair value of the Earnout liability was carried at fair value, determined according to Level 3 inputs in the fair value hierarchy described above (see Note “4. Fair Value Measurement of Financial Instruments”). The carrying values of outstanding borrowings under the Company’s debt arrangements (see Notes “12. Long-Term Debt—Affiliates” and “13. Long-Term Debt Obligations”) approximate their fair values as determined based on a discounted cash flow model, which represents a Level 3 measurement.

Net Income (Loss) per Share

The Company determines net income (loss) 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 net income (loss) per share calculation and therefore computes basic net income (loss) per share by dividing net income (loss) by the weighted average number of common shares outstanding for the applicable period. Diluted net income (loss) per share is computed in the same manner as basic net income (loss) per share, 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, warrants to purchase shares of Class A common stock and unvested restricted stock are considered potential dilutive common shares.

Emerging Growth Company

Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public and private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. For example, the Company adopted ASU 2016-02, *Leases (Topic 842) on January 1, 2021. As a result, the Company’s financial statements may not be comparable to other public companies. The Company may take advantage of these exemptions up until December 31, 2021, or such earlier time that it is no longer an emerging growth company. It would cease to be an emerging growth company if the Company has more than $1.07 billion in annual revenue, the Company has more than $700.0 million in market value of its stock held by non-affiliates or the Company issues more than $1.0 billion of non-convertible debt securities over a three-year period.*

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* (“ASU 2016-02”), which applies to all leases and will require lessees to record most leases on the balance sheet but recognize expenses in a manner similar to the current standard. In July 2018, the FASB issued ASU 2018-10, *Codification Improvements to Topic 842*, Leases, which provides narrow amendments to clarify how to apply certain aspects of ASU 2016-02, and ASU 2018-11, *Leases (Topic 842)*: *Targeted Improvements*, which provides adopters an additional transition method by allowing entities to initially apply ASU 2016-02, and subsequent related standards, at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Additionally, in March 2019, the FASB issued ASU 2019-01, *Leases (Topic 842): Codification Improvements*, which clarifies the transition guidance related to interim disclosures provided in the year of adoption. ASU 2016-02 and related amendments and improvements are effective for fiscal years beginning after December 15, 2018 for public business entities and interim periods within those years and for all other entities for years beginning after December 15, 2020. Entities are required to use a modified retrospective

approach of adoption for leases that exist or are entered into after the beginning of the transition date. A full retrospective application is prohibited. The Company is a public entity but took advantage of the relief provided for emerging growth companies to allow them to follow the private company adoption timelines. As such, the effective date of this standard and the related improvements for the Company is January 1, 2021. The Company will recognize all of its leases with terms over twelve months on the balance sheet by recording a right-of-use asset and a corresponding lease liability. The Company will elect the practical expedients upon transition that will retain the lease classification, and initial direct costs for any leases that exist prior to adoption of the standard. The adoption of this standard and the related improvements is not going to result in a material impact on the Company's consolidated results of operations or cash flows but is going to result in a significant increase in total assets and total liabilities on the Company's consolidated balance sheet, with no cumulative effect adjustment to its consolidated balance sheet as of the date of adoption. The Company has completed the analysis of its population of existing lease agreements for transition and is working on the incremental borrowing rate to finalize the impact on the consolidated balance sheet. The Company is also working to complete the implementation of new processes to assist in the ongoing lease data collection and analysis as well as updating the accounting policies and internal controls in connection with the adoption of the new standard.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). Subsequent to the issuance of ASU 2016-13, the FASB has issued the following updates: ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments- Credit Losses*, ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*, ASU 2019-05, *Financial Instruments—Credit Losses (Topic 326)—Targeted Transition Relief* and ASU 2019-11, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*. The objective of ASU 2016-13 and all the related updates is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. The amendments in this ASU replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU 2016-13 and the related updates are effective for fiscal years, and interim periods within those years, beginning after December 15, 2019 for public business entities excluding entities eligible to be smaller reporting companies and for fiscal years, and interim periods within those years, beginning after December 15, 2022 for all other entities. Early adoption is permitted. The Company is a smaller reporting company and follows the private company adoption timelines and the Company will adopt this standard and the related improvements on January 1, 2023 by recognizing a cumulative-effect adjustment to retained earnings for any impact. The adoption of ASU 2016-13 and related improvements is not expected to have a material impact on the Company's consolidated financial statements.

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 offers a physician office management solution and advanced wound care products.

The aggregate consideration amounted to $19,024 as of the Acquisition Date. Total consideration consisted 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 (the "Holdback") and will be paid or issued, as applicable, eighteen months after the Acquisition Date, subject to any offsetting indemnification claims against CPN.

The Company is obligated to pay an Earnout to CPN's former shareholders if CPN's legacy product revenue in a twelve-month period, starting on January 1, 2021 (the "Earnout Period"), exceeds CPN's 2019 revenue. The amount of the Earnout, if any, will be equal to 70% of the excess and will be payable in March 2022. The Company recorded a non-current liability of $3,782 at the Acquisition Date, for the fair value of the contingent consideration related to the expected Earnout. The Earnout liability is classified as a Level 3 measurement for which fair value is derived from inputs that are unobservable and significant to the overall fair value measurement. The fair value of such Earnout liability is estimated using a Monte Carlo simulation model that utilizes key assumptions including forecasted revenues and volatilities of the underlying financial metrics during the Earnout period. The Company assesses the fair value of the Earnout liability at each reporting period. As of December 31, 2020, the Earnout liability was estimated at $3,985. Subsequent changes in the estimated fair value of the liability are reflected in earnings until the liability is settled (see Note "4. Fair Value Measurement of Financial Instruments").

This transaction was accounted for as a business combination using the acquisition method of accounting in accordance with ASC Topic 805, *Business Combinations*. Assets acquired and liabilities assumed have been recorded at their estimated fair values as of the Acquisition Date. The fair values of intangible assets were based on valuations using various income approaches and methods, such as the multiperiod excess earnings method, relief from royalty method, etc., which require the use of significant estimates and assumptions, including estimating future cash flows and developing appropriate discount rates. The excess of the purchase price over the tangible assets, identifiable intangible assets and assumed liabilities was recorded as goodwill.

Based upon the valuation, the total purchase price allocation was as follows:

Assets acquired:	
Accounts receivable	$ 1,155
Inventory	1,230
Prepaid expenses and other current assets	5
Property and equipment	85
Intangible assets	13,570
Other assets	4
Total assets acquired	16,049
Liabilities assumed:	
Accounts payable	27
Accrued expenses and other current liabilities	231
Total liabilities assumed	258
Total identifiable assets acquired, net	15,791
Total purchase price	19,024
Goodwill	$ 3,233

The purchase price allocation resulted in goodwill of $3,233, which will be deductible for income tax purposes. The resulting amount of goodwill is primarily attributed to expected synergies from cross-sale opportunities and future growth. Intangible assets of $13,570 include customer relationships of $10,690, developed technologies of $2,050, non-competition agreements of $750, and trademarks of $80, which are being amortized on a straight-line basis, over weighted-average useful lives of 10 years, 6 years, 5 years and 1 year, respectively.

At the time of the acquisition, CPN had approximately 30 employees. The results of operations of CPN have been included in the Company's consolidated financial statements beginning on the Acquisition Date. Revenue and expenses of CPN since the Acquisition Date were not material. The acquisition of CPN does not result in any changes to the Company's operating or reportable segment structure.

4. Fair Value Measurement of Financial Instruments

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values as of December 31, 2020. There were no such assets or liabilities as of December 31, 2019.

	Fair Value Measurements as of December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Earnout liability	$ —	$ —	$3,985	$3,985
	$ —	$ —	$3,985	$3,985

Earnout Liability

In connection with accounting for the CPN acquisition on September 17, 2020, the Company recorded the 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 valued using the Monte Carlo simulation model based on inputs that are not observable in the market, which represents a level 3 measurement within the fair value hierarchy. The Company assesses the fair value of the Earnout liability at each reporting period. Any subsequent changes in the estimated fair value of the liability are reflected in selling, general and administrative expenses until the liability is settled. As of December 31, 2020, the Earnout liability increased to $3,985 due to changes in the market data assumptions as well as a shorter period to the Earnout payment date. The following table provides a roll-forward of the fair value of the Company's Earnout liability, for which fair value is determined using Level 3 inputs:

	Earnout liability
Balance as of December 31, 2019	—
Acquisition Date fair value	3,782
Change in fair value	203
Balance as of December 31, 2020	$3,985

The Company did not have any financial assets and liabilities measured at fair value on a non-recurring basis as of December 31, 2020 and 2019.

5. Accounts receivable, net

Accounts receivable consisted of the following:

	December 31,	
	2020	2019
Accounts receivable	$61,792	$42,408
Less—allowance for sales returns and doubtful accounts	(4,988)	(3,049)
	$56,804	$39,359

The Company's allowance for sales returns and doubtful accounts was comprised of the following:

Balance as of December 31, 2018	$3,420
Additions	239
Write-offs	(610)
Balance as of December 31, 2019	$3,049
Additions	2,441
Write-offs	(502)
Balance as of December 31, 2020	$4,988

6. Inventories

Inventories, net of related reserves, consisted of the following:

	December 31,	
	2020	2019
Raw materials	$10,075	$ 9,178
Work in process	1,305	781
Finished goods	16,419	12,959
	$27,799	$22,918

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, and working with operations to maximize recovery of excess inventory. During the years ended December 31, 2020, 2019 and 2018, the Company charged $3,050, $1,297, and $2,473, respectively, for inventory excess and obsolescence to cost of goods sold within the consolidated statements of operations.

7. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2020	2019
Prepaid subscriptions	$2,013	$1,041
Prepaid conferences and marketing expenses	63	925
Prepaid deposits	1,438	87
Reimbursement of offering expenses	1,009	—
Other	412	900
	$4,935	$2,953

Prepaid deposits are deposits held by vendors which are expected to be released within twelve months and therefore they are properly recorded as current assets.

8. Property and Equipment, Net

Property and equipment consisted of the following:

	December 31,	
	2020	2019
Leasehold improvements	$ 39,574	$ 36,344
Furniture, computers and equipment	48,236	46,430
	87,810	82,774
Accumulated depreciation and amortization	(69,521)	(65,812)
Construction in progress	41,779	30,222
	$ 60,068	$ 47,184

Depreciation expense was $3,723, $3,388, and $3,309 for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020 and 2019, the Company had $21,689 of buildings under capital leases recorded within leasehold improvements. As of December 31, 2020 and 2019, the Company had $14,974 and $13,777, recorded within accumulated depreciation and amortization related to buildings under capital leases, respectively. Construction in progress primarily represents unfinished construction work on a building under a capital lease and, more recently, improvements at the Company's leased facilities in Canton and Norwood, Massachusetts.

9. Goodwill and Intangible Assets

On September 17, 2020, the Company acquired certain assets and assumed certain liabilities of CPN. This transaction was accounted for as a business combination in accordance with ASC Topic 805 *Business Combinations.* The Company recorded $3,233 of goodwill and $13,570 of intangible assets associated with this acquisition. Refer to Note "3. Acquisition" for detail.

Goodwill was $28,772 and $25,539 as of December 31, 2020 and 2019, respectively. There were no impairments recorded against goodwill during the years ended December 31, 2020 and 2019.

In April 2019, the Company purchased $750 of intangible assets related to patent and know-how which were recorded within the developed technology category. The Company paid $250 at the time of the transaction with the remaining purchase price being paid over two years after the transaction closed. As of December 31, 2020, $250 was remaining and was recorded in accrued expenses and other current liabilities on the consolidated balance sheets.

Identifiable intangible assets consisted of the following as of December 31, 2020:

	Original Cost	Accumulated Amortization	Net Book Value
Developed technology	$32,620	$ (14,330)	$18,290
Trade names and trademarks	2,080	(906)	1,174
Customer relationship	10,690	(312)	10,378
Non-compete agreements	1,010	(230)	780
Total	$46,400	$ (15,778)	$30,622

Identifiable intangible assets consisted of the following as of December 31, 2019:

	Original Cost	Accumulated Amortization	Net Book Value
Developed technology	$30,570	$ (11,266)	$19,304
Trade names and trademarks	2,000	(650)	1,350
Non-compete agreements	260	(117)	143
Total	$32,830	$ (12,033)	$20,797

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 $3,745, $6,043, and $3,669 for the years ended December 31, 2020, 2019 and 2018, respectively. Estimated future annual amortization expense related to these intangible assets is as follows:

2021	4,949
2022	4,883
2023	4,918
2024	3,403
2025	3,323
Thereafter	9,146
Total	$30,622

10. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2020	2019
Accrued personnel costs	$18,943	$17,640
Accrued royalties	2,971	2,874
Other	2,059	2,936
	$23,973	$23,450

11. Restructuring

On October 21, 2020, the Company committed to a plan to restructure the workforce and consolidate its La Jolla facilities as part of the Company's long-term plan to consolidate manufacturing operations into Massachusetts in order to reduce the Company's cost structure. The restructuring is expected to be completed by the end of 2021 and result in a charge of approximately $5.5 million, of which approximately $4.5 million is attributable to the retention benefits associated with approximately 75 employees and the remaining $1.0 million is related to the facility closures. As employees are required to provide future services, employee retention and other benefit-related costs related to the Company's restructuring are expensed over the service period.

As a result of this restructuring activity, the Company incurred a pre-tax charge of $618 during the three months ended December 31, 2020. This charge was related exclusively to employee retention benefits and was included in selling, general and administrative expenses in the consolidated statements of operations.

The liability related to the restructuring activities during 2020 was $618 as of December 31, 2020 and was included in accrued expenses and other current liabilities in the consolidated balance sheets.

12. Long-Term Debt—Affiliates

Historically, the Company has taken loans from its affiliates and entities controlled by its affiliates. More recent loans include the 2018 Loans of $15,000 and the 2016 Loans of $17,000. The loans from the Company's affiliates bore an annualized interest rate between 1.6% to 15% and were collateralized by substantially all assets of the Company and were subordinated to the Company's external indebtedness (see Note "13. Long-Term Debt Obligations"). They were settled in conjunction with the Avista Merger in 2018 as described below.

Concurrently with the consummation of the Avista Merger, the outstanding principal of $45,746 related to the affiliate debt was converted into 6,502,679 shares of ORGO Class A common stock, and the Company made a cash payment to such creditors equal to $35,641, including $22,000 of principal and $13,641 of accrued interest and accrued affiliate loan fees as of and through the closing date of the Avista Merger. Following the consummation of these transactions, the affiliate debt was deemed fully paid and discharged and terminated. As a result of the full satisfaction of the affiliate debt, the Company recorded a $2,095 loss on the extinguishment of the affiliate debt in the consolidated statement of operations for the year ended December 31, 2018. The loss was comprised of the write-off of the unamortized debt discount of $5,078 offset by $2,983 which is the difference between the debt principal converted into Class A common stock less the fair value of the Class A common stock issued for the conversion at a per-share price of $6.58.

13. Long-Term Debt Obligations

	December 31,	
	2020	2019
Line of credit	$ 10,000	$33,484
Term loan	60,000	50,000
Less debt discount and debt issuance cost	(290)	(366)
Less current maturities	(16,666)	—
Term loan, net of debt discount and debt issuance cost	$ 43,044	$49,634

2019 Credit Agreement

In March 2019, the Company, its subsidiaries and Silicon Valley Bank (“SVB”), and the several other lenders thereto (collectively, the “Lenders”) entered into a credit agreement, as amended (the “2019 Credit Agreement”), providing for a term loan (the “Term Loan Facility”) and a revolving credit facility (the “Revolving Facility”) in an aggregate principal amount of $100,000. Capitalized terms used herein and not otherwise defined are defined as set forth in the 2019 Credit Agreement.

The Term Loan Facility is structured in three tranches, as follows: (i) the first tranche of $40,000 was made available to the Company and fully funded on March 14, 2019; (ii) the second tranche of $10,000 was made available to the Company and fully funded in September 2019; and (iii) the third tranche of $10,000 was made available to the Company and fully funded in March 2020. The interest rate for the Term Loan Facility is 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 as of December 31, 2020 was 9.25%. The 2019 Credit Agreement requires the Company to make monthly interest-only payments on outstanding balances under the Term Loan Facility through February 2021. Thereafter, each term loan advance will be repaid in thirty-six equal monthly installments of principal, plus accrued interest, with the Term Loan Facility maturing on March 1, 2024 (the “Term Loan Maturity Date”).

The Company’s final payment on the Term Loan Facility, due on the Term Loan Maturity Date, will include all outstanding principal and accrued and unpaid interest under the Term Loan Facility, plus a final payment (the “Final Payment”) equal to the original aggregate principal amount of the Term Loan Facility multiplied by 6.5%. The Company may prepay the Term Loan Facility, subject to paying the Prepayment Premium (described below) and the Final Payment. The Prepayment Premium is equal to 2.50% of the outstanding principal amount of the Term Loan Facility if the prepayment occurs after the first and prior to the second anniversary of the closing, and 1.50% of the outstanding principal amount of the Term Loan Facility if the prepayment occurs after the second but prior to the third anniversary of the closing, and 0.50% thereafter. Once repaid, amounts borrowed under the Term Loan Facility may not be re-borrowed.

The Revolving Facility is equal to the lesser of $40,000 and the amount determined by the Borrowing Base, which is defined as a percentage of the Company’s book value of qualifying finished goods inventory and eligible accounts receivable. The interest rate for advances under the Revolving Facility is a floating per annum interest rate equal to the greater of the Wall Street Journal Prime Rate and 5.50%. The interest rate as of December 31, 2020 was 5.50%. If the actual outstanding advances are less than 25% of the then-available Revolving Commitments, the Company must pay monthly interest equal to the interest that would have accrued if the average outstanding advances had been 25% of the then-available Revolving Commitments. The Company is also required to pay an unused line fee equal to 0.25% per annum, calculated based on the difference of $40,000 *minus* the greater of (i) the average balance outstanding under the Revolving Facility for such period and (ii) 25% of the then-available Revolving Commitments. The maturity date for advances made under the Revolving Facility is March 1, 2024.

The Company may elect to reduce or terminate the Revolving Facility in its entirety at any time by repaying all outstanding principal, unpaid accrued interest and a reduction or termination fee equal to 3.00% of the aggregate Revolving Commitments so reduced or terminated if the reduction or termination occurs after the first and prior to the second anniversary of the closing, and 2.00% of the aggregate Revolving Commitments so reduced or terminated if the reduction or termination occurs after the second but prior to the third anniversary of the closing, and $0 thereafter.

The Company is required to achieve certain financial covenants under the 2019 Credit Agreement, including Minimum Trailing Twelve Month Consolidated Revenue and Non-PuraPly Revenue, tested quarterly. In addition, the Company is required to maintain Minimum Liquidity equal to the greater of (i) 6 months Monthly Burn and (ii) $10,000.

As of December 31, 2020, the Company had outstanding borrowings of $60,000 under the Term Loan Facility and $10,000 under the Revolving Facility with up to $30,000 available (subject to Borrowing Base) for future revolving borrowings. The Company accrues for the Final Payment of $3,900 over the term of the Term Loan Facility through a charge to the interest expense. The related liability of $1,858 and $681 as of December 31, 2020 and 2019, respectively, was included in other liabilities on the consolidated balance sheets. The Company incurred costs of $554 in connection with 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 the Revolving Facility, the Company incurred costs of $370, which are recorded as other assets. Both of these costs are being amortized to interest expense through March 1, 2024.

Future payments of the 2019 Credit Agreement, as of December 31, 2020, are as follows for the calendar years ending December 31:

2021	$16,667
2022	20,000
2023	20,000
2024	13,333
Total	$70,000

2017 Credit Agreement

On March 21, 2017, the Company entered into a credit agreement (the "2017 Credit Agreement") with SVB whereby SVB agreed to extend to the Company a revolving credit facility in an aggregate amount not to exceed $30,000 with a letter of credit sub-facility and a swing line sub-facility as a sublimit of the revolving loan facility. In April 2018, the Company further amended its 2017 Credit Agreement in order to receive additional funding of $5,000 through a term loan. The amendment increased the commitment under the 2017 Credit Agreement to an aggregate amount not to exceed $35,000, consisting of a term loan not to exceed $5,000 and a revolving loan not to exceed $30,000. In December 2018, the Company fully repaid and canceled the term loan including the outstanding principal and accrued and unpaid interest.

On March 14, 2019, $26,541, representing all outstanding unpaid principal and accrued interest relating to the revolving borrowing due under the 2017 Credit Agreement, was rolled into the 2019 Credit Agreement.

Master Lease Agreement

On April 28, 2017, the Company entered into the Master Lease Agreement (the "ML Agreement") with Eastward Fund Management LLC that allowed the Company to borrow up to $20,000 on or prior to June 30, 2018. If the Company elected to prepay the loan or terminated the loan early within the first 24 months, the Company was required to pay an early termination fee. The ML Agreements also included a final payment fee when the outstanding principal was fully paid off. In March 2019, upon entering into the 2019 Credit Agreement, the Company paid an aggregate amount of $17,649 due under the ML Agreement, including unpaid principal, accrued interest, final payment, and early termination penalty, with proceeds from the 2019 Credit Agreement, and the ML Agreement was terminated. Upon termination of the ML Agreement, the Company recognized $1,862 as loss on the extinguishment of the loan.

In connection with the ML Agreement, the Company issued a warrant to purchase 473,011 shares of Class A common stock at $2.53 per share as a pre-condition for the agreement. Prior to the closing of the Avista Merger on December 10, 2018, the warrant was deemed net exercised for 302,434 shares of the Company's Class A common stock.

14. Stockholders' Equity

As of December 31, 2020, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 400,000,000 shares of $0.0001 par value Class A common stock; and 1,000,000 shares of $0.0001 par value preferred stock. 128,460,381 shares of Class A common stock were issued and 127,731,833 shares were outstanding as of December 31, 2020. No shares of preferred stock were outstanding as of December 31, 2020. 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. These redeemable shares were initially issued in connection with the acquisition of Nutech Medical, Inc. ("NuTech Medical") in 2017 and included a put right. The holders of the shares exercised the right to put the shares back to the Company at an agreed-upon exercise price of $9.28 per share on March 24, 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. Through December 31, 2020, no cash dividends have been declared or paid.

At December 31, 2020 and 2019, the Company has reserved the following shares of Class A common stock for future issuance:

	December 31, 2020	December 31, 2019
Shares reserved for issuance for outstanding options	6,425,040	6,503,646
Shares reserved for issuance for outstanding restricted stock units	806,048	—
Shares reserved for issuance for future grants	6,832,649	9,008,996
Total shares of authorized common stock reserved for future issuance	14,063,737	15,512,642

Avista Merger

In connection with the Avista Merger in 2018 (see Note "1. Nature of Business and Basis of Presentation"), founders and certain directors of AHPAC, surrendered to AHPAC an aggregate of 6,359,007 founder shares and 16,400,000 private placement warrants. All such founder shares and private placement warrants were canceled. The remaining outstanding founder shares were converted into 1,390,993 shares of Class A common stock pursuant to the Company's charter in connection with the Avista Merger. In addition, the Company issued to the PIPE Investors 15,561,473 shares of Class A common stock and 4,100,000 warrants to purchase one-half of one share of Class A common stock for an aggregate purchase price of $92,000.

In connection with the Avista Merger on December 10, 2018, the Company also converted a portion of the affiliate debt into 6,502,679 shares of Class A common stock.

Following the Avista Merger on December 10, 2018, 31,000,000 public warrants to purchase one half of one share of Class A common stock at an exercise price of $11.50 per share remained outstanding. The public warrants were classified as equity and recorded to additional paid-in-capital.

Warrant Exchange and Warrant Exercise

	December 31, 2018					
Date Exercisable	Number of Warrants	Number of Shares Issuable	Exercise Price	Exercisable for	Classification	Expiration
November 3, 2010	109,620	109,620	$ 3.95	Common Stock	Equity	Later of 8/31/2019 or upon repayment of the notes payable
August 31, 2013	36,540	36,540	$ 3.95	Common Stock	Equity	Later of 8/31/2019 or upon repayment of the notes payable
August 31, 2015	36,540	36,540	$ 3.95	Common Stock	Equity	Later of 8/31/2019 or upon repayment of the notes payable
December 10, 2018	4,100,000	2,050,000	$ 11.50	Common Stock	Equity	December 10, 2023
December 10, 2018	31,000,000	15,500,000	$ 11.50	Common Stock	Equity	December 10, 2023
	35,282,700	17,732,700				

The table above presented the warrants outstanding as of December 31, 2018.

In the first quarter of 2019, the Company issued 54,626 shares of Class A common stock in connection with some exercises of public warrants and received cash proceeds of $628.

In the third quarter of 2019, the Company executed a series of transactions related to its then outstanding 30,890,748 public warrants and 4,100,000 private placement warrants. The Company issued an aggregate of 2,845,280 shares of Class A common stock for 29,950,150 public warrants at an exchange rate of 0.095. The Company issued an aggregate of 80,451 shares of Class A common stock for the remaining public warrants at an exchange rate of 0.0855. The Company issued an aggregate of 389,501 shares of Class A common stock for the private placement warrants at an exchange rate of 0.095.

On August 13, 2019, Massachusetts Capital Resource Company and Life Insurance Community Investment Initiative, LLC net exercised outstanding warrants to purchase an aggregate of 182,700 shares of the Company's Class A common stock at an exercise price of $3.95 per share. The Company issued an aggregate of 19,426 shares of Class A common stock in connection with this transaction.

As a result of these transactions, the Company issued an aggregate of 3,334,658 shares of Class A common stock, representing approximately 3% of the total Class A common stock outstanding after such issuances. No warrants were outstanding after these transactions.

As the fair value of the warrants exchanged in the warrant exchange transactions immediately prior to the exchanges was less than the fair value of the Class A common stock issued, the Company recorded a non-cash deemed dividend of $645 for the incremental fair value provided to the warrant holders in the three months ended September 30, 2019.

2020 Underwritten Public Offering

On November 12, 2020, the Company entered into an underwriting agreement, with Morgan Stanley & Co. LLC and SVB Leerink LLC, as representatives of the underwriters, with respect to a public offering (the "2020 Underwritten Public Offering") of 17,500,000 shares of the Company's Class A common stock, par value $0.0001 per share, at a price per share to the public of $3.25, less underwriting discounts and commissions. The Company also granted the underwriters an option to purchase up to an additional 2,625,000 shares of Class A common stock within thirty days after November 12, 2020 at the public offering price, less underwriting discounts and commissions to cover any over-allotments made by the underwriters in the sale and distribution of the Company's Class A common stock.

In connection with the 2020 Underwritten Public Offering, the Company entered into a fee letter agreement (the "2020 Letter Agreement") with Avista Capital Partners IV, L.P. ("Avista IV"), Avista Capital Partners (Offshore) IV, L.P. ("Avista IV Offshore" and together with Avista IV, the "Avista Funds") and Avista Capital Holdings, L.P., an affiliate of the Avista Funds (the "Management Company"), pursuant to which the Company agreed to pay the Management Company a fee in consideration for certain services rendered in connection with the investments in the Company made by the Avista Funds in the 2020 Underwritten Public Offering. The fee paid to the Management Company was equal to the fee paid to the underwriters on a per-share basis for the third-party funds raised. In connection with this public offering, the Avista Funds purchased 4,272,657 shares of Class A common stock and the Company paid a fee equal to $833. Joshua Tamaroff, one of the Company's directors, is an employee of the Management Company to which the Company paid this fee.

The 2020 Underwritten Public Offering closed on November 17, 2020. On the same date, the underwriters partially exercised their option to purchase up to 2,625,000 additional shares of Class A common stock by purchasing an additional 2,416,708 shares of Class A common stock. In connection with this offering, the Company issued a total of 19,916,708 shares of Class A common stock with gross proceeds of $64,729 and net proceeds of $59,073 after deducting underwriter discounts, payment of the fee to the Management Company and other offering expenses in the aggregate amount of $5,656. $1,009 of the offering expenses which should have been reimbursed to the Company by the underwriters on November 17, 2020 was not received until January 2021 and was included in prepaid expenses and other current assets on the consolidated balance sheet as of December 31, 2020. $4,647, representing the offering expenses net of the reimbursement was recorded to additional paid-in capital against the proceeds received.

2019 Underwritten Public Offering

On November 21, 2019, the Company entered into an underwriting agreement, with Credit Suisse Securities (USA) LLC and SVB Leerink, as representatives of the underwriters, with respect to a public offering (the "2019 Underwritten Public Offering") of 9,000,000 shares of the Company's Class A common stock, par value $0.0001 per share, at a price per share to the public of $5.00, less underwriting discounts and commissions. The Company also granted the underwriters an option to purchase up to an additional 1,350,000 shares of Class A common stock within thirty days after November 21, 2019 at the public offering price, less underwriting discounts and commissions to cover any over-allotments made by the underwriters in the sale and distribution of the Company's Class A common stock.

In Connection with the 2019 Underwritten Public Offering, the Company entered into a fee letter agreement (the "2019 Letter Agreement") with Avista IV, Avista IV Offshore and the Management Company, pursuant to which the Company agreed to pay the Management Company a fee in consideration for certain services rendered in connection with the Avista Funds' purchase of the Company's Class A common stock in the 2019 Underwritten Public Offering. The fee paid to the Management Company was equal to the fee paid to the underwriters on a per-share basis for the third-party funds raised. The Avista Funds purchased 6,000,000 shares of Class A common stock and the Company paid the Management Company a fee equal to $1,725. Joshua Tamaroff, one of the Company's directors, is an employee of the Management Company to which the Company paid this fee.

The 2019 Underwritten Public Offering closed on November 26, 2019. On December 6, 2019, the underwriters partially exercised their option to purchase up to 1,350,000 additional shares of Class A common stock by purchasing an additional 1,068,056 shares of Class A common stock. In connection with this offering, the Company issued a total of 10,068,056 shares with gross proceeds of $50,340 and net proceeds of $46,830 after deducting underwriter discounts, payment of the fee to the Management Company and other offering expenses in the aggregate amount of $3,510 which were recorded to additional paid-in capital net against the proceeds received.

15. Equity Incentive Plan Share-Based Compensation

2018 Stock Incentive 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.

As of December 31, 2020, a total of 9,198,996 shares of Class A common stock have been authorized to be issued under the 2018 Plan (subject to adjustment in the case of any stock dividend, stock split, reverse stock split, or similar change in capitalization of the Company).

2003 Stock Incentive Plan

The Organogenesis 2003 Stock Incentive Plan (the "2003 Plan"), provides for the Company to issue restricted stock awards, or to grant incentive stock options or non-statutory stock options. Incentive stock options may be granted only to the Company's employees. Restricted stock awards and non-statutory stock options may be granted to employees, members of the Board of Directors, outside advisors and consultants of the Company.

Effective as of the closing of the Avista Merger on 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.

Following the closing of the Avista Merger, the 2003 Plan is administered by the Company's Board of Directors.

Stock-Based Compensation Expense

The Company measures the compensation cost of employee or consultant services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized over the period during which an employee or consultant is required to provide service in exchange for the award. During the years ended December 31, 2020, 2019 and 2018, the Company recorded stock-based compensation expense of $1,661, $936, and $1,075, respectively, within selling, general and administrative expenses on the consolidated statements of operations.

Stock options awarded under the 2018 Plan and the 2003 Plan expire 10 years after the grant date and typically vest over four or five years. Restricted stock units awarded typically vest over four years.

Restricted Stock Units (RSUs)

During the year ended December 31, 2020, the Company granted 873,595 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 was 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, 2019	—	$ —
Granted	873,595	3.81
Vested	—	—
Canceled/Forfeited	(67,547)	3.76
Unvested at December 31, 2020	806,048	$ 3.82

As of December 31, 2020, the total unrecognized compensation cost related to unvested restricted stock units expected to vest was $1,760 and the weighted average remaining recognition period for unvested awards was 3.01 years.

Stock Options

The stock options granted during the years ended December 31, 2020 and 2019 were 1,553,723 and 100,000, respectively. The assumptions that the Company used to determine the grant-date fair value of stock options granted during these periods were as follows, presented on a weighted-average basis:

	Year Ended December 31,	
	2020	2019
Risk-free interest rate	0.46%	2.24%
Expected term (in years)	6.22	6.50
Expected volatility	37.4%	42.7%
Expected dividend yield	0.0%	0.0%
Exercise price	$ 4.04	$ 7.08
Underlying stock price	$ 3.37	$ 7.08

These assumptions resulted in an estimated weighted-average grant-date fair value per share of stock options granted during the years ended December 31, 2020 and 2019 of $1.05 and $3.24, respectively.

The following table summarizes the Company's stock option activity since December 31, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2019	7,179,636	$ 1.98	5.06	$ 20,799
Granted	1,553,723	4.04		
Canceled / forfeited	(636,043)	3.63		
Exercised	(1,476,998)	1.91		4,749
Outstanding as of December 31, 2020	6,620,318	2.33	5.22	34,458
Options exercisable as of December 31, 2020	4,824,807	1.64	3.86	28,412
Options vested or expected to vest as of December 31, 2020	6,274,637	$ 2.22	5.01	$ 33,307

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, 2020 and 2019 was $678 and $1,079, respectively.

As of December 31, 2020, the total unrecognized stock compensation expense was $1,438 and was expected to be recognized over a weighted-average period of 2.73 years.

As of December 31, 2019, there were partial recourse notes outstanding totaling $635. These notes were taken by a former executive to exercise his 675,990 shares of stock options and the notes were secured with these shares held by the former executive. When the loans are still outstanding, the options are not considered exercised and are included within the options outstanding for accounting purposes. In the three months ended December 31, 2020, the former executive repaid $301 of the principal balance of the notes (see Note “19. Related Parties Transactions”). The repayments were treated as the exercise price for 480,712 shares of the options and were included in the consolidated statement of redeemable common stock and stockholders’ equity. As of December 31, 2020, $334 of the principal balance of the partial recourse notes was outstanding and 195,278 shares were still not considered outstanding for accounting purposes.

16. Income Taxes

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”) was enacted to provide economic relief to those impacted by the COVID-19 pandemic. The CARES Act made various tax law changes, including, among other things: (i) modifications to the federal net operating loss rules, including permitting federal net operating losses incurred in 2018, 2019, and 2020 to be carried back to the five preceding taxable years in order to generate a refund of previously paid income taxes and eliminating the 80% of taxable income limitations in years 2018-2020; (ii) enhanced recoverability of alternative minimum tax credit carryforwards; (iii) delayed payment of employer payroll taxes; (iv) increased the limitation on business interest expenses under Internal Revenue Code (“IRC”) Section 163(j) for the 2019 and 2020 tax years to permit additional expensing of interest up to 50% of adjusted taxable income instead of 30% for 2019 and 2020; and (v) enacted a technical correction so that qualified improvement property is classified as 15-year cost recovery and can be immediately expensed under IRC Section 168(k). On December 27, 2020 President Trump signed into law updates to the CARES Act which provides extended relief predominately to individuals and partnerships. The items that would affect the Company are temporary allowance of a full deduction for business meals paid or incurred between December 31, 2020 and January 1, 2023. The Company will continue to monitor for any updates and the impact, but currently, the only material impact to the Company’s tax provision is the ability to increase the limitation on business interest expenses under IRC Section 163(j).

The components of the income tax provision (benefit) consisted of the following for the years ended December 31, 2020, 2019 and 2018:

	Year Ended December 31,		
	2020	2019	2018
(Benefit from) provision for income taxes:			
Current tax expense (benefit)			
Federal	$(106)	$(105)	$(212)
State	505	116	101
Foreign	19	28	9
Total current tax expense (benefit)	418	39	(102)
Deferred tax expense (benefit)			
Federal	109	105	212
State	—	—	—
Foreign	3	6	(26)
Total deferred tax expense	112	111	186
Total income tax expense	$ 530	$ 150	$ 84

As of December 31, 2020, the Company had available for the reduction of future years’ federal taxable income, net operating loss carry-forwards of approximately $151,335. Of these carry-forwards, $92,617 will expire from the year ended December 31, 2020 through 2037 and $58,718 can be carried forward indefinitely. The Company had state net operating loss carry-forwards of approximately $58,437 expiring from the year ended December 31, 2021 through 2039. At December 31, 2019, the Company had available for the reduction of future years’ federal taxable income, research and development credits of approximately $1,003 expiring between December 31, 2020 and December 31, 2039.

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, 2020 and 2019 are as follows:

	December 31,	
	2020	2019
Net operating loss carryforwards		
Federal	$ 31,783	$ 36,511
State	3,342	4,075
Foreign	18	21
Other	5,829	4,828
163j interest	4,979	7,030
Stock-based compensation	357	633
Capital leases	2,991	3,391
Fixed assets	2,589	2,528
Net deferred tax assets before valuation allowance	51,888	59,017
Valuation allowance	(48,252)	(54,251)
Intangibles	(3,618)	(4,639)
Net deferred tax assets	$ 18	$ 127

As of December 31, 2020 and 2019, the Company recorded a valuation allowance of $48,252 and $54,251, respectively. In 2020, the valuation allowance decreased by $5,999 primarily due to the federal and state net operating losses utilization in 2020, which offset the valuation allowance. Realization of deferred tax assets is dependent upon sufficient future taxable income during the period that deductible temporary differences and carryforwards are expected to be available to reduce taxable income.

As of December 31, 2019, the Company recorded a net deferred tax asset of $106 relating to AMT credits which are refundable under the Tax Act beginning with the 2018 tax return. This deferred tax asset will be realized, regardless of future taxable income, and thus no valuation allowance was provided against this asset. As a result of the enactment of CARES Act in 2020, the remaining AMT credit as of December 31, 2019 was refunded on the 2019 tax return and thus there is no remaining net U.S. deferred tax asset as of December 31, 2020. The Company's subsidiary in Switzerland is carrying a deferred tax asset of approximately $18 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 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,		
	2020	2019	2018
U.S. federal statutory income tax rate	21.0%	21.0%	21.0%
Federal valuation allowance	(28.9)%	(17.6)%	(18.4)%
State valuation allowance	(4.8)%	(3.9)%	(3.9)%
State and local income taxes	6.2%	3.5%	3.5%
Nondeductible expenses	6.0%	(1.4)%	(2.3)%
Uncertain tax position reserves	0.4%	(0.1)%	(0.1)%
Research and development credits	3.0%	(1.9)%	— %
Effective income tax rate	2.9%	(0.4)%	(0.2)%

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 $2,870, $3,192 and $3,722 as of December 31, 2020, 2019 and 2018, respectively. The net decrease primarily relates to the expiration of the carryforward period for certain Federal and Massachusetts R&D credits previously included as an unrecognized tax benefit.

A tabular roll forward of the Company's uncertainties in its income tax provision liability is presented below:

	Year Ended December 31,		
	2020	2019	2018
Gross balance at beginning of year	$ 2,618	$ 3,286	$ 3,486
Additions based on tax positions related to the current period	111	133	157
Reductions for tax positions of prior years	(606)	(801)	(357)
Gross balance at end of year	$ 2,123	$ 2,618	$ 3,286

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, 2016. However, carryforward attributes that were generated prior to December 31, 2016 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. There was $317 and $269 of interest recorded for uncertain tax positions for the years ended December 31, 2020 and 2019, respectively, which was classified in accrued expenses in the consolidated balance sheets. These amounts are not reflected in the reconciliation above.

17. Net Income (Loss) Per Share (EPS)

Basic EPS is calculated by dividing net income (loss) by the weighted-average number of shares outstanding during the period. Diluted EPS is calculated by dividing net income (loss) 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 (loss) attributable to the Class A common stockholders is as follows:

	Year Ended December 31,		
	2020	2019	2018
Numerator:			
Net Income (loss)	$ 17,949	$ (40,454)	$ (64,831)
Less: Non-cash dividend to warrant holders	—	645	—
Net Income (loss) attributable to common shareholders	$ 17,949	$ (41,099)	$ (64,831)
Denominator:			
Weighted average common shares outstanding —basic	107,737,936	92,840,401	69,318,456
Dilutive effect of restricted stock units	135,932	—	—
Dilutive effect of options	3,486,963	—	—
Weighted-average common shares outstanding—diluted	111,360,831	92,840,401	69,318,456
Earnings (loss) per share—basic	$ 0.17	$ (0.44)	$ (0.94)
Earnings (loss) per share—diluted	$ 0.16	$ (0.44)	$ (0.94)

For the year ended December 31, 2020, outstanding stock-based awards of 1,792,085 were excluded from the diluted EPS calculation as they are anti-dilutive. The Company had a net loss in the other periods presented. As such, the potentially dilutive securities have been excluded from the computation of diluted net loss per share as these securities have anti-dilutive effect and including them would reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to Class A common stockholders is the same for these periods. For the years ended December 31, 2019 and 2018, the Company excluded 7,179,636 and 25,727,963 potential shares of Class A common stock, respectively, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to the Class A common stockholders for these periods.

18. Commitments and Contingencies

Capital Leases

On January 1, 2013, the Company entered into capital 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. 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 stockholders of the Company. The leases terminate on December 31, 2022 and each contains a renewal option for a five-year period with the rental rate at the greater of (i) rent for the last year of the prior term, or (ii) the then fair market value. Notice of the exercise of this renewal option is due one year prior to the expiration of the initial term. Aggregate annual lease payments are approximately $4,308 with future rent increases of 10% effective January 1, 2022.

The Company records the capital lease asset within property and equipment and the liability is recorded within the capital lease obligations on the consolidated balance sheets.

As of December 31, 2020 and 2019, the Company owed an aggregate of $10,336, of accrued but unpaid lease obligations, which are subordinated to the 2019 Credit Agreement. The lease obligations will not be paid until the debt under the 2019 Credit Agreement is paid off in 2024 even though the capital leases expire in December 2022. The accrued but unpaid lease obligations include rent in arrears and unpaid operating and common area maintenance costs under the aforementioned leases. The principal portion of rent in arrears on the capital leases totaled $6,946 and $6,321 as of December 31, 2020 and 2019, respectively, and is included in the long-term portion of capital lease obligations. The interest portion of rent in arrears totaled $2,865 and $3,512 as of December 31, 2020 and 2019, respectively, and is included in other liabilities on the consolidated balance sheets. The unpaid operating and common area maintenance costs totaled $525 and $503 as of December 31, 2020 and 2019, respectively, and are included in other liabilities on the consolidated balance sheets.

Effective April 1, 2019, the Company agreed to accrue interest on the accrued but unpaid lease obligations at an interest rate equal to the rate charged in the 2019 Credit Agreement (see Note “13. Long-Term Debt Obligations”). The accrued interest is also subordinated to the 2019 Credit Agreement and, as such, is included in other liabilities on the consolidated balance sheet. Interest accrued as of December 31, 2020 and 2019 totaled $1,673 and $717, respectively.

In addition to the capital leases with affiliates discussed above, the Company also has certain insignificant capital leases with non-affiliates. Future obligations under capital leases in the aggregate and for the next five years is as follows:

2021	$ 4,786
2022	4,945
2023	—
2024	9,810
	19,541
Less amount representing interest	(4,480)
Present value of minimum lease payments	15,061
Less current maturities	(3,619)
Long-term portion	$11,442

Operating Lease

The Company leases vehicles 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.

In March 2014, in conjunction with the acquisition of Dermagraft from Shire plc, the Company entered into a rental sublease agreement for certain operating and office space in California. The sublease agreement calls for escalating monthly rental payments and expires in December 2021.

In conjunction with the acquisition of NuTech Medical in March 2017, the Company entered into an operating lease with Oxmoor Holdings, LLC, an entity that is affiliated with the former sole shareholder of NuTech Medical, related to the facility at NuTech Medical’s headquarters in Birmingham, Alabama. Under the lease, the Company is required to make monthly rent payments of approximately $21 through the lease termination date on December 31, 2021. The lease was extended in the first quarter of 2021 with the revised termination date on December 31, 2022.

In March 2019, the Company entered into an agreement to lease approximately 43,850 square feet of office and laboratory space in Norwood, Massachusetts. Pursuant to the lease agreement, the rent commencement date was February 1, 2020. The initial lease term is ten years from the rent commencement date and includes an option for an early extension term of five years which is exercisable during the first two years after the rent commencement date. In addition to the early extension term, the lease provides the Company with an option to extend the lease term for a period of ten years, if exercised, at rental rates equal to the then fair market value. Annual lease payments during the first year are $1,052 with increases of $44 each year during the initial ten-year lease term, an increase of $44 during the first year of the early extension term and $33 during year two through five of the early extension term. Upon execution of the agreement, the Company delivered a security deposit in the form of a letter of credit of $526 to the landlord. Following 36 months from the rent commencement date, the security deposit may be reduced by $263.

In August 2020, the Company entered into a lease for approximately 23,000 square feet in San Diego, California for office and laboratory use. The lease commences on the date when certain landlord's work is substantially completed, which is expected to be at the beginning of April 2021. The initial lease term is ten years from the lease commencement date, with an option to extend the term for a period of five years. Annual lease payments during the first year are $1,419 with 3% increase each year during the lease term. A security deposit of $237 is required throughout the term of the lease.

Operating lease expenses were $6,509, $6,231, and $4,628 for the years ended December 31, 2020, 2019 and 2018.

Future minimum lease payments due under noncancellable operating lease agreements as of December 31, 2020 are as follows:

2021	$ 5,640
2022	4,036
2023	3,698
2024	3,029
2025	3,017
Thereafter	15,531
	$34,951

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, 2020 and 2019, respectively, and are classified as part of accrued expenses on the Company's consolidated balance sheets. There was no royalty expense incurred during the years ended December 31, 2020, 2019, or 2018 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 $4,370, $3,778, and $2,059 during the years ended December 31, 2020, 2019 and 2018, respectively, within selling, general and administrative expenses on the consolidated statements of operations.

As part of the NuTech Medical acquisition, the Company inherited certain product development and consulting agreements for ongoing consulting services and royalty payments based on a percentage of net sales on certain products over a period of 15 years from the execution of the agreements. These product development and consulting agreements were canceled in January 2020 for total consideration of $1,950 which was paid on February 14, 2020. The $1,950 cancellation fee was recorded within selling, general and administrative expenses on the consolidated statement of operations for the year ended December 31, 2020.

Ransomware Attack

In August 2020, the Company's information technology ("IT") systems were exposed to a ransomware attack, which partially impaired certain IT systems for a short period of time. The Company finished investigating the incident, together with legal counsel and other incident response professionals. The Company did not experience any material loss related to the incident, and substantially all costs incurred were reimbursed by insurance.

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. The Company accrued $150 and $542 as of December 31, 2020 and 2019 in relation to certain pending lawsuits.

The purchase price for NuTech Medical acquired in 2017 included $7,500 deferred acquisition consideration of which the Company paid $2,500 in 2017. The remaining $5,000 of deferred acquisition consideration plus accrued interest owed to the sellers of NuTech Medical was previously in dispute. The Company asserted certain claims for indemnification that would offset in whole or in part its payment obligation and the sellers of NuTech Medical filed a lawsuit alleging breach of contract and seeking specific performance of the alleged payment obligation and attorneys' fees. In February 2020, the Company entered into a settlement agreement with the sellers of NuTech Medical and settled the dispute for $4,000, of which, $2,000 was paid immediately on February 24, 2020 and the remaining $2,000 is being paid in four quarterly installments of $500 each. As of December 31, 2020, the remaining balance was included in deferred acquisition consideration on the consolidated balance sheet. In addition, the Company assumed from the sellers of NuTech Medical the payment responsibilities related to a legacy lawsuit existing at the acquisition date of NuTech Medical. The assumed legacy lawsuit was settled in October 2020. In connection with the settlement of the deferred acquisition consideration dispute and the legacy lawsuit, the Company recorded a gain of $2,246 for the year ended December 31, 2020. The gain was included as a component of other expense, net, on the consolidated statement of operations.

19. Related Parties Transactions

Capital lease obligations to affiliates, including unpaid lease obligations, and an operating lease with affiliates are further described in Note "18 Commitments and Contingencies". Affiliate debts are described in Note "12. Long-Term Debt—Affiliates". Fees paid to the Avista Funds in connection with the 2019 and 2020 Underwritten Public Offering are described in Note "14. Stockholders' Equity."

During 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 mature with all principal and accrued interest due on the tenth anniversary of the issuance date of each subject loan. The borrower may prepay all or any portion of his Employer Loan at any time without premium or penalty. Interest on the Employer Loans accrues at various rates ranging from 2.30%—3.86% per annum, compounded annually. The Employer Loans are secured by shares of the Company's Class A common stock held by the former executives. With respect to the Liquidity Loans, the Company has 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. As of December 31, 2019, Liquidity Loans to two former executives were outstanding with an aggregate principal balance of $2,350 and Option Loans to one former executive were outstanding with an aggregate principal balance of $635. The principal and part of the interest receivable under the Employer Loans were fully reserved with net interest receivable of $0 and $556 as of December 31, 2020, and 2019, respectively, included in the notes receivable from related parties balance in the consolidated balance sheets. During the year ended December 31, 2020, one of the former executives paid $1,000 of the outstanding principal balance of his Liquidity Loans and the related interest receivable. The Company forgave $1,000 of the remaining outstanding principal balance of his Liquidity Loans. The other former executive paid $250 and $301 of the outstanding principal balance of his Liquidity Loans and Option Loans, respectively, and $266 of the related accrued interest. As a result, the Company recorded $1,516 as a recovery of the previously reserved related party receivables within selling, general and administrative expenses on the consolidated statement of operations for the year ended December 31, 2020. The $301 of the repaid principal balance of the Option Loans was recorded to equity. See Note "15. Equity Incentive Plan 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, 2020, 2019 and 2018, the Company made employer contributions of $2,731, $2,290, and $1,883, 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.

In the first quarter of 2021, 1,037,099 shares of options and 173,127 shares of restricted stock units were granted to our Board of Directors, executives and key employees. The majority of these options and restricted stock units will vest over four years.

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 the Registration Statements on Forms S-3 (No. 333-229003 and 333-233621) and Form S-8 (No. 333-229601) of Organogenesis Holdings Inc. of our report dated March 16, 2021, relating to the consolidated financial statements of Organogenesis Holdings Inc. and its subsidiaries, appearing in this Annual Report on Form 10-K of Organogenesis Holdings Inc. for the year ended December 31, 2020.

/s/ RSM US LLP

Boston, Massachusetts
March 16, 2021

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)) 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: March 16, 2021

/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)) 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: March 16, 2021

/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, 2020 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: March 16, 2021

/s/ Gary S. Gillheeney, Sr.
Gary S. Gillheeney, Sr.
Chief Executive Officer

Dated: March 16, 2021

/s/ David Francisco
David Francisco
Chief Financial Officer