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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, 2018

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
(State or Other Jurisdiction of
Incorporation or Organization)

98-1329150
(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
Class A Common Stock, \$0.0001 par value

Name of exchange on which registered
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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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 ☐
Non-accelerated filer ☐

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 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 \$310.93 million, computed by reference to the closing sale price of the common stock as reported by The Nasdaq Capital Market on June 30, 2018, 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 common stock outstanding as of March 1, 2019 was 92,009,737.

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 2018 Annual Meeting of Stockholders (the “Proxy Statement”) to be filed with the Securities and Exchange Commission on or before April 30, 2019.

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ANNUAL REPORT ON FORM 10-K
FOR FISCAL YEAR ENDED DECEMBER 31, 2018**

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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, 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. The majority of the 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.

Historically we have concentrated our efforts in the Advanced Wound Care market. In 2017, we acquired NuTech Medical which further expanded our wound care portfolio and broadened our addressable market to include the Surgical & Sports Medicine market. We believe the expanded product portfolio facilitated by this acquisition is enhancing the ability of our sales representatives to reach and penetrate customer accounts, contributing to strong growth over time.

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, primarily in the outpatient setting. We have a comprehensive portfolio of regenerative medicine products, capable of supporting patients from early in the

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wound healing process through to wound closure regardless of wound type. Our Advanced Wound Care products include Apligraf for the treatment of VLU and 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 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 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.

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, and in accordance with Section 388 of the Delaware General Corporation Law and the Cayman Islands Companies Law (2018 Revision), 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, 2018, we had approximately 700 employees worldwide. For the year ended December 31, 2018, we generated revenue of \$193.4 million and we incurred operating expenses of \$176.2 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 for over 15 years 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 the 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

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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 customizable for various sizes and types of wounds. The breadth of our portfolio gives us 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. The majority of the 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 4,000 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 will 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.
- **Expand 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. We plan 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 expect there are 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, presents 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.
- **Expand Sales Force and Increase Sales Productivity and Geographic Reach.** We plan 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, Asia 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 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.

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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.

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 expense 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 are 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

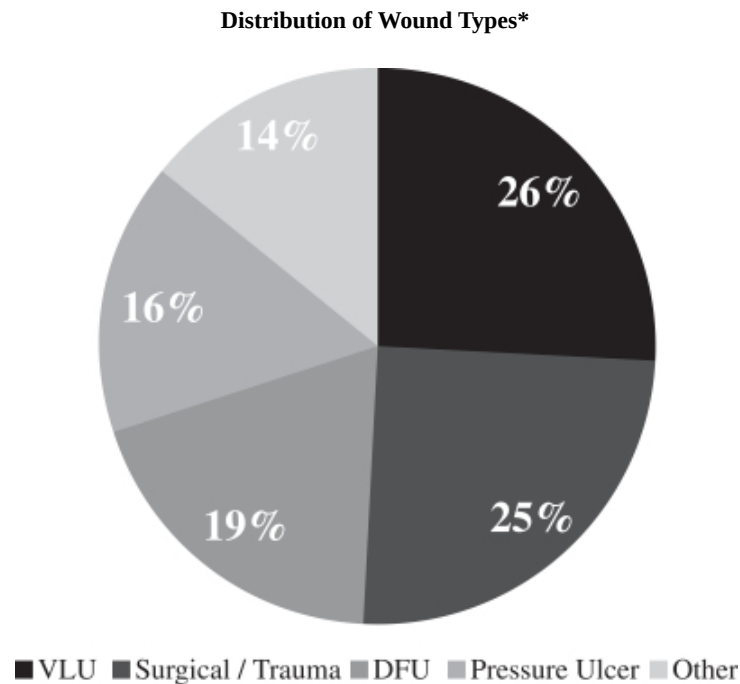
An acute wound is an injury that causes a rapid break in the skin and sometimes the underlying tissue. Acute wounds can be traumatic wounds, such as abrasions, lacerations, penetrating injuries and burns, or surgical

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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:



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

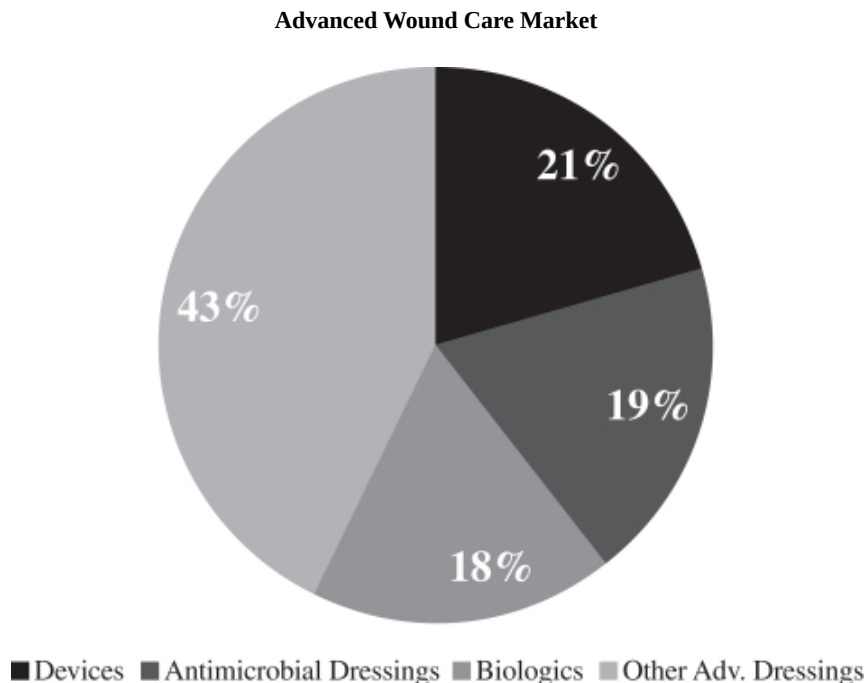
Due to the breadth of our wound care portfolio, our products are able to address both chronic and acute wounds across all of these wound types.

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.

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According to MedMarket Diligence, the global Advanced Wound Care market was estimated to be approximately \$7.3 billion in 2014 and consists of several product categories including advanced dressings, antimicrobial 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 2014 is set forth below.



According to MedMarket Diligence, the overall Advanced Wound Care market is expected to grow at a compound annual growth rate, or CAGR, of 7.7% through 2024.

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. The worldwide wound biologics market, which includes skin substitutes and growth factors, was estimated by Technavio to be approximately \$1.2 billion in 2016, of which skin substitute products are estimated to represent almost \$700 million.⁽⁹⁾ 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. This market grew from almost \$600 million in 2015 to almost \$700 million in 2016 at an annual growth rate of 14.3%. Going forward, the skin substitute market is projected to grow at a CAGR of more than 14.5% between 2016 and 2020, reaching \$1.15 billion by 2020, 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

⁽⁹⁾ Technavio (2016), Global Bioactive Wound Care Market Report, retrieved September 13, 2017, from EMIS Professional Database

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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.

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, an area in which NuTech Medical has an established presence. 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 \$4.7 billion and is expected to grow at a CAGR of 10% from 2016 to 2020. 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

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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 \$1.7 billion worldwide, excluding demineralized bone matrix, or DBM, and conventional allograft.⁽¹⁰⁾

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.⁽¹¹⁾

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 HA market exceeded \$2 billion in 2015.⁽¹²⁾

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

⁽¹⁰⁾ Technavio (2015), Global Orthobiologics Market Report, retrieved September 25, 2017, from EMIS Professional Database.

⁽¹¹⁾ Technavio (2015), Global Regenerative Medicine Market Report, retrieved September 26, 2017, from EMIS Professional Database.

⁽¹²⁾ Technavio (2015), Global Orthobiologics Market Report, retrieved September 25, 2017, from EMIS Professional Database.

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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 has 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 VLU, DFUs, and pressure ulcers and acute wounds such as traumatic wounds and burns.

The breadth and depth of our portfolio allows 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 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 tailored for a wide variety of wound sizes and types.

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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. Our products that are used to treat burns are used predominantly in the inpatient hospital setting. The table below summarizes our comprehensive advanced wound care product suite:

Product (Launch Year)	Description	Regulatory Pathway	Clinical Application
Affinity (2014)† 	Fresh amniotic membrane containing many types of viable cells, growth factors/cytokines, and ECM proteins	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 graft 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) 	Purified native collagen matrix with broad-spectrum polyhexamethylene biguanide, or PHMB, antimicrobial agent	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 the only available fresh, amniotic allograft 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 hypothermally 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

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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's native cellular properties support cell and tissue growth making it an excellent option to support wound and soft tissue healing. 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 850,000 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.

NuShield

NuShield is a dehydrated placental tissue graft that is topically or surgically applied to the target tissue to support healing. Regulated as a 361 HCT/P, NuShield is processed using our proprietary BioLoc process, which preserves the native structure of the amnion and chorion membranes, including the intermediate or spongy layer, and their reservoir of growth factors and other proteins. NuShield is available in multiple sizes, can be used to help support 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.

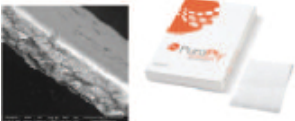
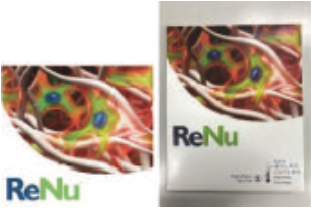
PuraPly Antimicrobial

PuraPly Antimicrobial, or PuraPly AM, was developed to address the challenges posed by bioburden and excessive inflammation in the wound. Functioning as a 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.

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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 containing many types of viable cells, growth factors/cytokines, and ECM proteins	361 HCT/P	Tendon, ligament and other soft tissue injuries
NuCel (2009)†* 	Cellular suspension, stem cell-containing allograft derived from human amnion tissue and amniotic fluid	361 HCT/P	Orthopedic surgical procedures including bony fusion
NuShield (2010)† 	Dehydrated placental tissue graft 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	Tendon, ligament and other soft tissue injuries
PuraPly AM (2016) 	Purified native collagen matrix with broad-spectrum PHMB antimicrobial agent	510(k)	Surgical treatment of open wounds
ReNu (2015)†* 	Cryopreserved suspension of amniotic fluid cells and morselized amnion tissue from the same donor	361 HCT/P	Chronic inflammatory and degenerative conditions; soft tissue injuries such as tendinosis and fasciitis

† 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.

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NuCel

NuCel is a surgically implanted allograft derived from human amniotic tissue and amniotic fluid. NuCel is used primarily in spinal and orthopedic surgical applications to support tissue healing, including bone growth and fusion. The amniotic tissue harvesting process protects key biologic characteristics of the tissue that support healing. Several published clinical studies have demonstrated the clinical efficacy of NuCel, particularly in patients with significant comorbidities such as diabetes and obesity. While NuCel is currently regulated as a 361 HCT/P, clinical efforts are ongoing 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 amniotic fluid, formulated for office use. It can be used to support healing of soft tissues, particularly in degenerative conditions such as OA and joint and tendon injuries such as tendinosis and fasciitis. 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, significantly longer than available alternatives. While ReNu is currently regulated as a 361 HCT/P, clinical efforts are ongoing to secure BLA-approval for the product. 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. Both products may be used as an adhesion barrier or as an on-lay or wrap in soft tissue repairs. The biological characteristics of these amniotic tissues 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 for the surgical treatment of open wounds.

Bone Allograft Products

Our bone allograft products, which are derived from donated human cadaveric bone, include OsteoIN, 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. OsteoIN is a demineralized bone matrix putty that can be molded and pressed into bone voids as a filler. 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. Both FiberOS and OCMP have osteoconductive and osteoinductive properties and are derived from the same donor. These products are typically sold as an ancillary product together with our amniotic product NuCel.

Trial and Study Results for FDA-Approved Products

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 accumulated a significant body of clinical evidence demonstrating the efficacy of 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 enhances 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 VLU 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.

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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 VLU and DLU. 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.

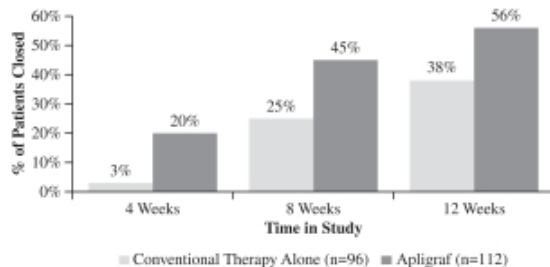
Pivotal FDA Registration Trials

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 cm² and 2.83 cm² 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.

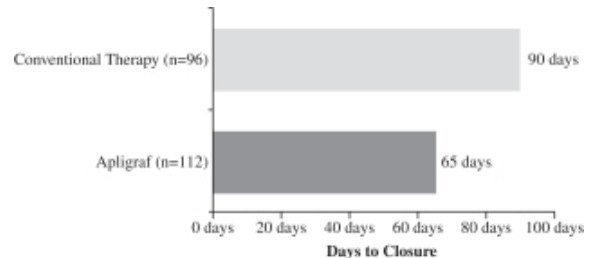
Apligraf was significantly more effective than conventional therapy for the incidence of complete wound closure over time. By 12 weeks of treatment, 56% (63 of 112 patients) of DFUs treated with Apligraf plus conventional therapy (debridement, saline dressings, total off-loading) were 100% closed, compared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

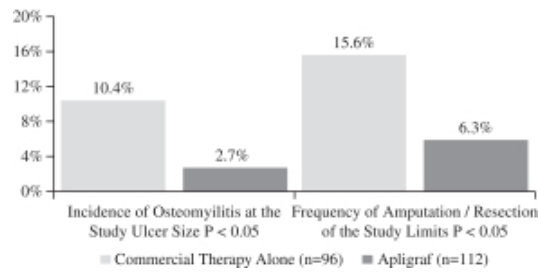
Incidence of 100% Wound Closure



Median Time to 100% Wound Closure

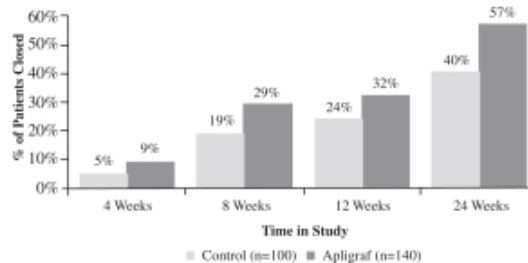


Reduction in Osteomyelitis and Amputation / Resection



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 Solsys Medical, LLC) 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

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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

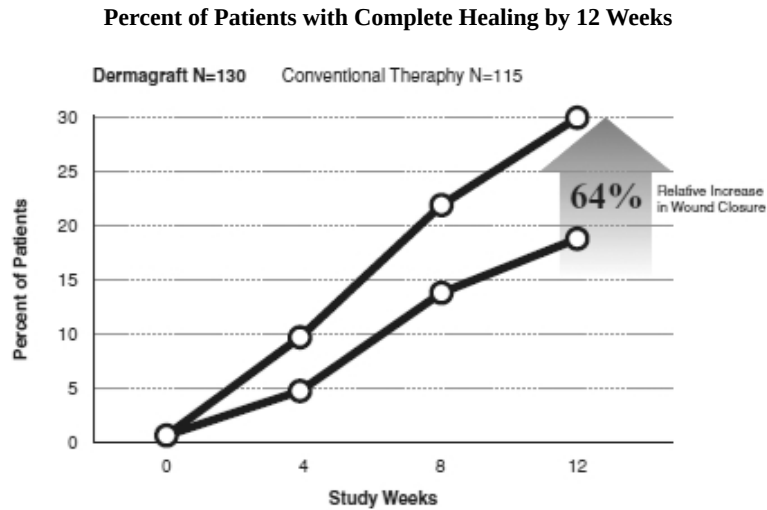
To elucidate the mechanisms through which Apligraf promotes healing of chronic VLUs, the University of Miami Miller School of Medicine Department of Dermatology & Cutaneous Surgery conducted an RCT in which 24 patients with non-healing VLUs were treated with either standard of care (compression therapy) 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

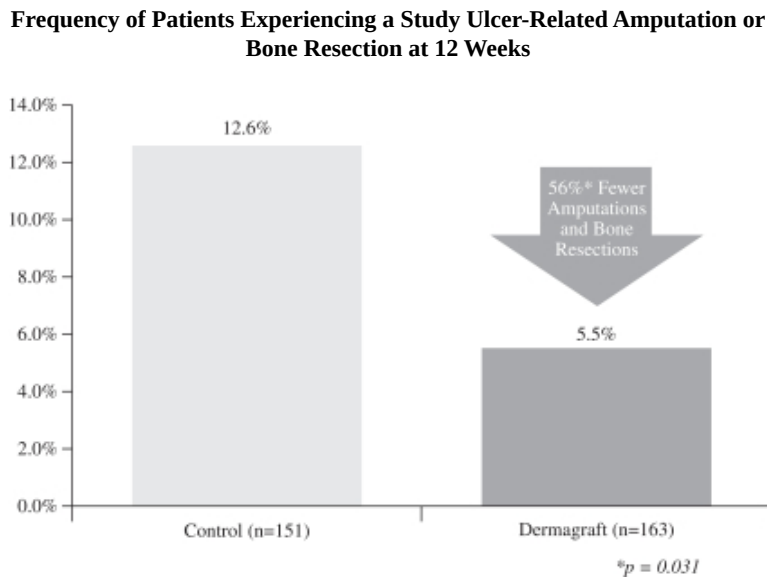
Dermagraft was approved as a Class III medical device for the treatment of DFUs based on the results of a large pivotal clinical trial. Three hundred fourteen patients were enrolled in a prospective RCT to evaluate the safety and efficacy of Dermagraft in conjunction with conventional therapy compared 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 1cm² and less than 20cm². 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 were 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.



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.



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.

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The economic study of Dermagraft in a Medicare population conducted by the Analysis Group is described under the heading “—Our Products—Clinical Trial Results—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. Several products in our pipeline have already received FDA approval or clearance, and we expect to commercialize them in the near term.

TransCyte

TransCyte is a bioengineered tissue scaffold that promotes burn healing, and has received PMA approval for the treatment of second- and third-degree burns. 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 commercially launch TransCyte, which was acquired from Shire and previously marketed by Smith & Nephew, 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 plan to commercially launch this product in the first half of 2019.

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 plan to commercially launch 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 510(k) indications for the treatment of chronic and acute wounds (other than 3rd degree burns) and the surgical treatment of open wounds. We plan to commercially launch this product in 2019.

Novachor

Novachor is a fresh chorionic membrane containing viable cells, growth factors/cytokines, and extracellular matrix (ECM) protein for the treatment of chronic and acute wounds that is currently regulated as a 361 HCT/P. We expect to commercially launch this product in the first quarter of 2020.

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

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the treatment of mucogingival conditions in adults. Gintuit consists of a cellular sheet comprised of human fibroblasts, keratinocytes, human ECM proteins, and bovine collagen that produce a wide array of cytokines and growth factors to support the regeneration of tissue. Gintuit is not currently marketed, but we plan to commercialize Gintuit in the future via a partnership in the oral surgery market.

Sponsors of products for which the FDA has approved a BLA are obligated by the 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, and 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 its PREA obligations. We responded and submitted a formal request for an extension for the pediatric study requirement for Gintuit; however, we were notified on October 5, 2017 that the request had been denied. Although we believe that, because Gintuit is not on the market and there is accordingly no foreseeable use of the product in pediatric populations, we are not currently subject to penalties for noncompliance. Should we decide to go to market with Gintuit, the product could be viewed as misbranded and subject to seizure or other enforcement action if marketing is resumed without completion of the required study.

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 has 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 patented 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 plan to commercially launch our PuraForce product from this platform in the second quarter of 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 BioLoc 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 BioLoc 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

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force, which focuses its efforts on outpatient wound care. We use a mix of direct sales representatives and independent agencies to service the Surgical & Sports Medicine market. As of December 31, 2018, we had approximately 215 direct sales representatives and approximately 130 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. We are evaluating independent agency relationships to sell the product in Mexico. Additionally, we are evaluating the regulatory pathways and market potential for our products in other major markets, including the European Union and Japan. 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 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 our 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

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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 will result in a disruption of our production capabilities. We have identified an alternate supplier and expect production from the new supplier to commence in the fourth quarter of 2019. As a result, the disruption in our production capabilities will continue until either our current supplier is able to take corrective action to satisfactorily remediate the deficiencies or our alternate supplier has commenced full-scale production.

Manufacture of our products is dependent on the availability of sufficient quantities of source tissue, which is the primary components 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.

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% (less the statutory sequestration rate of 2% of the government portion for a final payment rate of ASP+4.3%). In the outpatient hospital and ASC settings, Medicare payment for all our products (except PuraPly and PuraPly AM as described below) is bundled into the payment for the application procedure. During the period starting on January 1, 2018 and ending on September 30, 2018, payment for PuraPly AM and PuraPly is included in the bundled payment structure.

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 will have pass-through status effective on October 1, 2018 and Medicare will make a pass-through payment when PuraPly AM and PuraPly is used in outpatient hospital and ASC settings. PuraPly AM and PuraPly will retain pass-through status through September 30, 2020. The amount

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of the pass-through payment for PuraPly AM and PuraPly for the period from October 1, 2018 to March 31, 2019 will be equal to the pass-through amount that applied on December 31, 2017, which was ASP + 6%. After that, the pass-through amount will be ASP + 6% for the applicable calendar quarter. Additionally, from October 1, 2018 through September 30, 2020 (the period in which PuraPly AM and PuraPly have pass-through status), the Center for Medicare & Medicaid Services, or CMS, is directed to remove all amounts attributable to PuraPly AM and PuraPly from the bundled payment amount, which we expect will result in a decrease in the payment for skin substitute procedures that do not include a product with pass-through status. The Appropriations Act applies only to Medicare and does not apply to Medicaid or any commercial payers.

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

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. The bundled payment rates change every year as do the thresholds that determine which products are assigned to the high cost bundle. 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, Medicare 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

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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 approved for pass-through status from January 1, 2015 through December 31, 2017. Beginning on January 1, 2018, they have been included in the "bundled" payment structure. In response to this change in reimbursement, we added additional sizes of our PuraPly products and made adjustments to the pricing of existing sizes, which we believe will allow these products to compare favorably with other leading skin substitute brands included in the high cost bundle.

The Appropriations Act, which was enacted on March 23, 2018, restored the pass-through status of PuraPly AM and PuraPly effective October 1, 2018 and this status will continue through September 30, 2020. As a result, PuraPly AM and PuraPly will be included in the "bundled" payment structure from January 1, 2018 through September 30, 2018. Beginning on October 1, 2018, Medicare resumed pass-through payments when PuraPly AM and PuraPly are used in outpatient hospital and ASC settings. Under the Appropriations Act, all other skin substitute products, including all of our other products, will remain in the bundled payment structure. The amount of the pass-through payment for PuraPly AM and PuraPly for the period from October 1, 2018 through March 31, 2019 will be equal to the pass-through amount that applied on December 31, 2017, which was ASP +6%. After that, the pass-through amount will be ASP + 6% for the applicable calendar quarter. Additionally, from October 1, 2018 through September 30, 2020 (the period in which PuraPly AM and PuraPly have pass-through status), CMS is directed to remove all amounts attributable to PuraPly AM and PuraPly from the bundled payment amount, which we expect will result in a decrease in the payment for skin substitute procedures that do not include a product with pass-through status. The Appropriations Act applies only to Medicare, and does not apply to Medicaid or any commercial payers.

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 is adjusted for the statutorily mandated sequestration resulting in an actual payment of ASP plus 4.3%. This payment methodology applies only to physician offices.

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.

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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, BLA 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 Acelity Holdings, Inc., ACell, Incorporated, Amnio Medical, Inc., Angiodynamics, Inc., Arthrex, Inc., Integra LifeSciences Holdings Corporation, Medtronic plc, MiMedx Group, Inc., Osiris Therapeutics, Inc., Penumbra, Inc., Smith & Nephew plc, Solsys Medical, LLC 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 are 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

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ability to cure. In addition, we are 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 due by July 1, 2018. The license is assignable but not sub-licensable.

As of December 31, 2018, we owned 74 issued patents globally, of which 8 were U.S. patents. As of December 31, 2018, we owned 31 pending patent applications, of which 14 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 2018 and 2021. 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 our collagen biomaterial technology platform products, methods of using cultured connective tissue constructs, three-dimensional stromal tissue-based methods for vascularizing cardiac tissue, methods for treating recessed oral gingiva using cultured tissue constructs, bioreactor culture dish systems having an accessible sealing port, continuous extrusion methods of producing strands of biocompatible materials, hepatocyte growth factor- and hyaluronic acid-containing compositions and methods of using such compositions, methods of using osteoconductive implants, methods of using placental membrane preparations to generate tissue *in vivo*, and methods of harvesting or proliferating human prenatal stem cells. Our pending patent applications encompass additional areas, including bioengineered constructs comprising extracellular matrix produced by cultured cells and methods of making same, wound treating methods using amniotic-derived cells and placental membrane, hypothermic placental membrane storage methods, morselized amnion tissue-based wound treatment methods and adjustable debridement curette apparatuses. 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 13 U.S. trademark registrations and 8 foreign trademark registrations, as of December 31, 2018.

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 PHS Act 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.

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

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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 and PuraPly AM 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. If after receiving approval from the FDA, we make a material change in manufacturing equipment, location or process, additional regulatory review may be required. 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 by 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.

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

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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, although in light of the 361 HCT/P Guidance, it may be necessary to revise our labeling and marketing claims for Affinity and NuShield to clarify that they are intended as wound coverings, in order to ensure that they continue to qualify as Section 361 HCT/Ps. 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.

HCT/Ps that do not meet these criteria (which may, as noted above, include NuCel and ReNu), as well as certain tissue-engineered products, are regulated as biological products under Section 351 of the PHSA and also, in some respects, as drugs under the FDCA. Before a biologic product can be marketed in interstate commerce, it must receive approval of a BLA by the FDA. In addition to products regulated as medical devices, we also hold a BLA for Gintuit (125400/0), which is indicated for topical (non-submerged) application to a surgically created vascular wound bed in the treatment of mucogingival conditions in adults. Although we do not currently market Gintuit, should we resume its manufacture, the process must comply with the FDA's current cGMPs which are designed to ensure that finished products are not adulterated or misbranded or otherwise in violation of the requirements of the FDCA.

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. 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

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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 interactions in which we commonly engage, such as our 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 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.

Laws and regulations have also been enacted by the federal government and various states to regulate the sales and marketing practices of medical device and pharmaceutical manufacturers. The 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.

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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, 2018, we had approximately 700 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

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,

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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;
- whether our 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;
- 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;
- 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 we anticipate that we will incur substantial losses for the foreseeable future.

To date, we have financed our operations primarily through debt financings, and we have incurred losses from operations in many years since our inception. Our loss attributable to Organogenesis Holdings Inc. was

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\$(17.0) million, \$(8.4) million and \$(64.8) million for the years ended December 31, 2016, 2017 and 2018, respectively. As of December 31, 2018, we had an accumulated deficit of \$130.2 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 anticipated losses for the foreseeable future, have had, and may continue to have, an adverse effect on our business, results of operations and financial condition.

We have identified material weaknesses in our internal control over financial reporting, and our management has concluded that our disclosure controls and procedures are not effective. 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 material weaknesses 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. In connection with the audits of our financial statements for the years ended December 31, 2018, 2017 and 2016, our management team identified material weaknesses relating to (i) our lack of a sufficient complement of personnel with an appropriate level of knowledge and experience in the application of GAAP commensurate with our financial reporting requirements and (ii) our lack of resources necessary to implement an appropriate level of review controls to properly evaluate the completeness and accuracy of the transactions we enter into.

The material weaknesses are as follows:

- We did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including controls over the preparation and review of account reconciliations and journal entries.
- We did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose certain complex transactions, including the recapitalization and related debt extinguishment and conversion.

Although we took steps to remediate these material weakness and have made progress in remediating the aforementioned deficiencies, our management did not perform sufficient control testing to conclude that the material weaknesses were remediated and therefore some of the control deficiencies continued to exist as of December 31, 2018. We engaged external experts to complement internal resources and we began implementation of a new companywide enterprise resource planning system. We plan to continue to take additional steps to remediate the material weaknesses and improve our financial reporting systems and implement new policies, procedures and controls. If we do not successfully remediate the material weaknesses 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.

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

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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 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.

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.

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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 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.

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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.

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, including expenses associated with the relocation of our California based manufacturing facility; 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.

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

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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, but do not expect to this new supplier to commence production until the fourth quarter 2019 at the earliest. This disruption in supply will result in reduced Affinity revenue. Although we plan to increase production of our other products in order to meet the demand created by the shortage of our Affinity product, there can be no assurance that we will be able to replace, in whole or in part, lost Affinity revenue caused by this production suspension. This and any other unforeseen failure in the storage of our products or loss in supply could result in a loss of our market share and negatively affect our revenues and operations.

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Because we depend upon a limited group of suppliers and manufacturers for our Apligraf 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

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recovered through productivity gains, price increases or other methods could adversely affect 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.

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 acquisition of NuTech Medical. 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

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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 only recently acquired NuTech Medical which relied on independent sales agencies to market and sell its products and we have retained many of these relationships as we market and sell the same products. We have yet to bring fully the activities of these former NuTech Medical independent sales agencies under our oversight and compliance policies.

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 acquisition of NuTech Medical, 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 acquisition of NuTech Medical. 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;

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- 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 expanded our wound care portfolio and 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,

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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. 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 or the HITECH Act 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 behalfs. 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. Requirements applicable to business associates are complex and subject to varying interpretation. 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.

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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”) currently imposes, 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 predicts that the total cost to the medical device industry may be up to \$20 billion over the next decade. The Internal Revenue Service issued final regulations implementing the tax in December 2012, which require, 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. Thus, the medical device excise tax does not apply to the sale of a taxable medical device by the manufacturer, producer, or importer of the device during the period beginning on January 1, 2016, and ending on December 31, 2019. If this legislation is not repealed by December 31, 2019, we will be subject to this 2.3% excise tax on sales of certain of our products in the United States including Apligraf, Dermagraft and PuraPly, which 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 \$39.6 million and \$42.1 million as of December 31, 2018 and 2017, respectively. Approximately \$22 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, 2018, 2017 and 2016, 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.

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.

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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.

Risks Related to Regulation of Our Products and Other Government Regulations

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. There are also 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.

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

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and approval, which may require to 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, it may be necessary to revise our labeling and marketing claims for our amniotic membrane products, including our Affinity and NuShield products, to clarify that they are intended as wound coverings, to ensure that they meet the homologous use requirement and therefore continue to qualify as Section 361 HCT/Ps. To the extent that any 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, it may be 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. In the event NuCel and ReNu are deemed not to be Section 361 HCT/Ps, 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 indicates that the FDA is providing a 36-month enforcement grace period to allow sufficient time for distributors of HCT/Ps to make any regulatory submissions and obtain any premarket approvals necessary to comply with the guidance. Although we believe that the 36-month grace period provides adequate time to comply, if we are unable to obtain BLA approvals for NuCel and ReNu within the 36-month time 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 FDA will not take enforcement action during the 36-month 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

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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.

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.

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 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

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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 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. In connection with our acquisition of NuTech Medical in March 2017, we did not timely file a change of ownership notice for NuTech's tissue bank license with the Florida Agency for Health Care Administration for our cadaveric orthopedic products. Although a change of ownership application was submitted, we could be subject to fines or other penalties, including distribution restrictions on those two products, for failure to timely file. In June 2018, the change of ownership application was denied on the ground that it had not been timely filed. Accordingly, a new license application was submitted and a license was issued in October 2018.

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.

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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 involves 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

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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.

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.

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 and similar U.S. and foreign regulations governing product labeling and advertising, distribution, sale and marketing of our products.

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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 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

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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 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 creates 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), 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% less the sequestration amount (2% of the government's 80% portion). The ASP reimbursement methodology requires us to report, to the government, the ASP for each of our products every quarter. Government price reporting

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requirements are complex. If we do not report ASP at all or if we report ASP incorrectly 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.

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.

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 Healthcare Reform Act 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

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therapies are less effective than our products. Under the Trump Administration, there are ongoing efforts to modify or repeal all or part of PPACA or take executive action that affects its implementation. Tax reform legislation was recently passed that includes provisions that will impact healthcare insurance coverage and payment such as the elimination of the tax penalty for individuals who do not maintain health insurance coverage beginning in 2019 (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 will be additional reform proposals at federal and state levels. In addition, an appeal is currently pending from a district judge’s holding in December 2018 in *Texas v. Azar*, 4:18-cv-00167, that the entire Healthcare Reform Act is unconstitutional because the individual mandate is not severable from other provisions of the law. We cannot predict the 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 includes 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 will remain in effect through 2025 unless additional congressional action is taken. These or other similar reductions in government healthcare spending could result in reduced demand for our products or additional pricing pressure.

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.

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,

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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 has resulted in a reduction in our revenue as compared to prior periods.

On 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, 2017 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 will retain this “pass-through” reimbursement status through September 30, 2020. Other skin substitute products, including all of our other products, will remain in the bundled payment structure.

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

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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, other than the PuraPly AM and PuraPly products through 2017, 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. 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 has 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.

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.

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 will again lose this preferred status on October 1, 2020.

Under Medicare, our PuraPly AM and PuraPly products had pass-through reimbursement status through December 31, 2017 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.

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“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 will retain 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. Because CMS will remove from the bundled payment all amounts attributable to PuraPly AM and PuraPly while they have pass-through status (until September 30, 2020), the bundled payments that will be applicable to our other skin substitute products, such as Apligraf and Dermagraft, will likely decrease and this decrease could also have a material and adverse effect our revenue from these products. In addition, legislation could be enacted in the future to repeal the provisions of the Appropriations Act that relate to pass-through status and terminate or shorten the period during which pass-through will apply to PuraPly AM and PuraPly. Per the existing terms of the Appropriations Act, PuraPly AM and PuraPly will transition back into the bundled payment structure on October 1, 2020 and the loss of the pass-through payment status may 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.

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.

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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

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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

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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.

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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, 2018, we and our subsidiaries had approximately \$47.4 million of aggregate principal amount of indebtedness outstanding (including \$5.0 million of deferred acquisition expenses related to our acquisition of NuTech Medical). 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;

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- 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.

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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;
- 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 adjusted EBITDA covenant (measured as of the last day of each month) 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.

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Risks Related to Our Common Stock

There can be no assurance that the Company's common stock will continue to be listed on NASDAQ or 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 are required to demonstrate to the satisfaction of Staff and the Hearings Panel that we have a minimum of 300 round lot common 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 will become effective on March 22, 2019 (ten days after the Form 25 was filed). The public warrants currently trade "over-the-counter" under the trading symbol "ORGOW." Even if the Company is able to regain compliance with the Nasdaq listing standards prior to March 31, 2019, the Company can provide no assurance that it can maintain compliance with those standards.

If NASDAQ delists the Company's 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 common stock is a "penny stock" which will require brokers trading in the Company's 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

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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.

The Controlling Entities collectively beneficially own approximately 73% of the Company’s 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 common stock, which may reduce the value of an investment in its common stock. This voting control could also deprive stockholders of an opportunity to receive a premium for their shares of 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 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 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,

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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 bylaws inapplicable to, or unenforceable in respect of, one or more of the types of actions or proceedings listed above, 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.

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 taxes in the United States, 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;

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- 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 common stock adversely, then the price and trading volume of the Company common stock could decline.

The trading market for the Company 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 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.

The Company may amend the terms of the Company warrants in a manner that may be adverse to holders of such warrants with the approval by the holders of at least 65% of the then-outstanding warrants.

The Company's warrants were issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and AHPAC. The warrant agreement provides that the terms of the Company warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval by the holders of at least 65% of the then-outstanding public Company warrants to make any change that adversely affects the interests of the registered holders of such warrants. Accordingly, the Company may amend the terms of the warrants in a manner adverse to a holder if holders of at least 65% of the then-outstanding public Company warrants approve of such amendment. Although the Company's ability to amend the terms of the warrants with the consent of at least 65% of the then-outstanding public Company warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the Company warrants, shorten the exercise period or decrease the number of shares of the Company common stock purchasable upon exercise of a Company warrant.

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The Company may redeem your unexpired warrants prior to their exercise at a time that is disadvantageous to you, thereby making your warrants worthless.

The Company will have the ability to redeem outstanding public warrants at any time after they become exercisable and prior to their expiration, at a price of \$0.01 per warrant, provided that the closing price of the Company common stock equals or exceeds \$24.00 per share (as adjusted for share splits, share capitalizations, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading-day period ending on the third trading day prior to proper notice of such redemption provided that on the date we give notice of redemption. If and when the public warrants become redeemable, the Company may exercise its redemption right even if it is unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding public warrants could force you to (i) exercise your public warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so, (ii) sell your public warrants at the then-current market price when you might otherwise wish to hold your warrants or (iii) accept the nominal redemption price which, at the time the outstanding warrants are called for redemption, is likely to be substantially less than the market value of your warrants. None of the private placement warrants or the PIPE warrants will be redeemable by us so long as they are held by their initial purchasers, the PIPE Investors or their permitted transferees.

The exercise of outstanding warrants would increase the number of shares eligible for future resale in the public market and result in dilution to shareholders.

AHPAC issued warrants to purchase 15,500,000 AHPAC Class A ordinary shares as part of the IPO and prior to the IPO and in connection with the exercise of the over-allotment option, the Company issued PIPE warrants to the PIPE Investors to purchase 2,050,000 shares of the Company Class A common stock at \$11.50 per share in the equity financing. The shares of the Company common stock issued in the equity financing and additional shares of the Company common stock issued upon exercise of the Company's warrants will result in dilution to the then existing holders of shares of the Company Class A common stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could adversely affect the market price of the Company common stock.

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 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.

The JOBS Act permits "emerging growth companies" like us to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth 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

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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 common stock that are held by non-affiliates exceeds \$700 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. 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 cannot predict if investors will find the Company common stock less attractive because the Company will rely on these exemptions. If some investors find the Company common stock less attractive as a result, there may be a less active trading market for the Company common stock and the Company's stock price may be more volatile.

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 members of our board of directors.

We also lease facilities in La Jolla, California; San Diego, California; and Birmingham, Alabama. Our La Jolla facilities are leased through December 31, 2021 and include approximately 92,000 square feet devoted to operations, research and development, and manufacturing. Our 6,000 square foot warehouse facility in San Diego is leased through April 30, 2020. Our 25,000 square foot office in Birmingham supports the products we acquired as part of our acquisition of NuTech Medical, and is leased through December 31, 2020.

On March 13, 2019, Organogenesis Inc., our wholly owned subsidiary, entered into a lease for approximately 43,850 square feet in Norwood, Massachusetts for office and laboratory use. The lease commenced on March 13, 2019. The rent commencement date will be 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).

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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

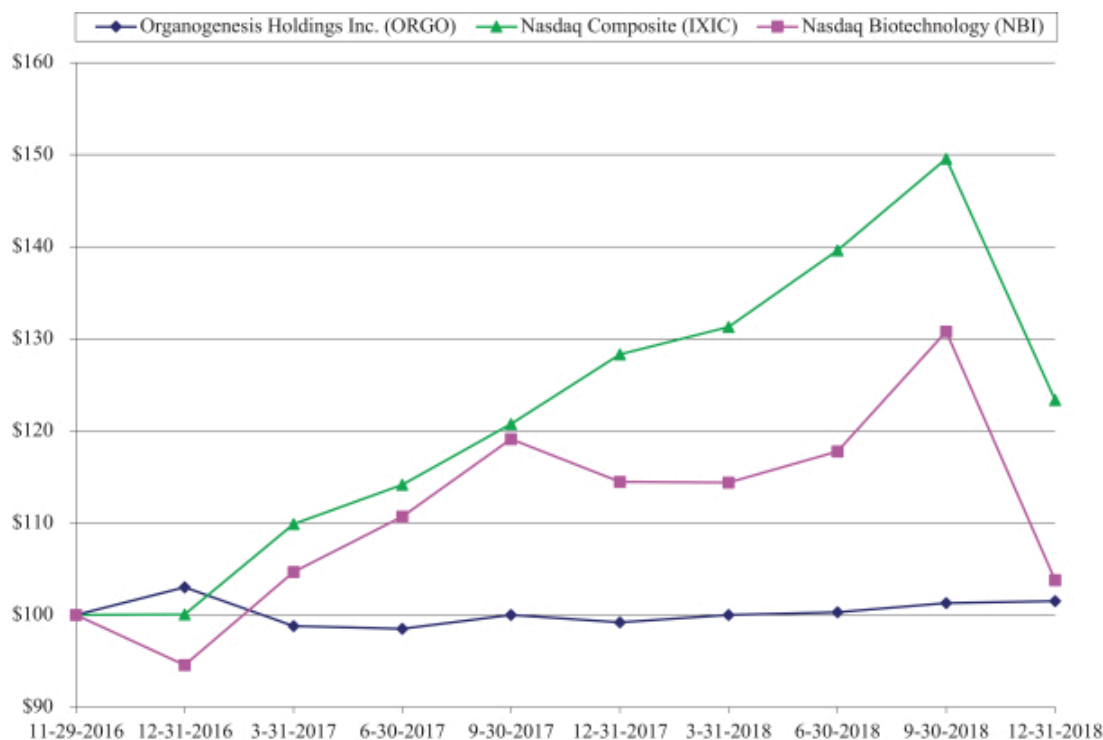
Market Information

Our Class A common stock is listed on the Nasdaq Capital Market under the symbol "ORGO". Prior to the closing of the business combination, our Units began trading on the Nasdaq Capital Market under the symbol "AHPAU" on October 11, 2016. On November 28, 2016, we announced that holders of our Units could elect to separately trade the Class A ordinary shares and public warrants included in the Units. On November 29, 2016, our Class A ordinary shares and public warrants began trading on the Nasdaq Capital Market under the symbols "AHPA" and "AHPAW," respectively. Trading of our Class A ordinary shares 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 are required to demonstrate to the satisfaction of Staff and the Hearings Panel that we have a minimum of 300 round lot common 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 will become effective on March 22, 2019 (ten days after the Form 25 was filed). The public warrants currently trade "over-the-counter" under the trading symbol "ORGOW." Each warrant entitles the holder to purchase one-half of one share of Class A common stock at a price of \$11.50 per share and the public warrants may only be exercised for a whole number of share of our Class A common stock. Our public warrants will expire on December 10, 2023. On December 14, 2018, Nasdaq filed a Form 25 Notification of Removal from Listing and/or Registration under Section 12(b) of the Securities Exchange Act of 1934 for the Units.

Comparative Stock Performance

The following stock performance graph compares the cumulative total return to stockholders for our Class A common stock for the period commencing November 29, 2016 (the date on which our Class A common stock commenced trading on The Nasdaq Capital Market) and ended December 31, 2018 against the cumulative total return of the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The calculation of total cumulative returns assumes a \$100 investment in our common stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Index, and assumes reinvestment of all dividends, if any. The historical information set forth below is not necessarily indicative of future performance.

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Recent Sales of Unregistered Securities

On December 14, 2015, prior to the closing of the business combination, Avista Acquisition Corp. (the “Sponsor”) purchased 8,625,000 Class B ordinary shares (the “Founder Shares”) for \$25,000, or approximately \$0.003 per share. In October 2016, the Sponsor transferred 471,250 Founder Shares to each of the Company’s then independent directors at a price per share of approximately \$0.003 per share.

Simultaneously with the consummation of our initial public offering, the Sponsor and certain other accredited investors (the “Initial Shareholders”) purchased from the Company an aggregate of 16,000,000 private placement warrants at a price of \$0.50 per private placement warrant (or an aggregate purchase price of \$8,000,000). On November 28, 2016, the Initial Shareholders purchased an additional 400,000 private placement warrants at a price of \$0.50 per warrant (or an aggregate purchase price of \$200,000) in conjunction with the exercise of the underwriters’ over-allotment option. Following the partial exercise of the over-allotment option, 875,000 Founder Shares were forfeited in order to maintain the Initial Shareholder’s ownership at 20% of the issued and outstanding ordinary shares. On November 28, 2016, the Sponsor sold 161,180 Founder Shares and 350,114 private placement warrants to one of our then independent directors at their original per share purchase price. On July 5, 2017, the Sponsor sold 186,320 Founder Shares and 404,723 private placement warrants to one of our independent directors at their original per share purchase price. Each private placement warrant entitles the holder to purchase one-half of one Class A ordinary share at \$5.75 per one-half share. The private placement warrants have terms and provisions that are identical to those of the Warrants sold as part of the Units in our initial public offering, except that the private placement warrants may be exercised on a cashless basis and are not redeemable by us so long as they are held by the Initial Shareholders or their permitted transferees.

On August 17, 2018, in connection with the signing of the Merger Agreement, the PIPE Investors entered into a purchase agreement for 9,022,741 shares of the Company’s common stock and 4,100,000 warrants to purchase one-half of one share of the Company’s common stock on substantially the same terms as the Private

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Placement Warrants for an aggregate purchase price of \$46,000,000. The acquisition of the Company's common stock and warrants closed on December 10, 2018.

On August 17, 2018, in connection with the signing of the Merger Agreement, certain creditors of the Company's now wholly owned subsidiary, Organogenesis Inc., entered into an exchange agreement with the Company pursuant to which a portion of the outstanding obligations of Organogenesis Inc. owed to creditors who were insiders of Organogenesis Inc. equal to \$45,746,347 ("Organogenesis Insider Debt") would be converted into 6,502,679 shares of the Company's common stock, and the Company would make a cash payment to such creditors in satisfaction of the remaining portion of the obligations under the Organogenesis Insider Debt, including the accrued and unpaid interest and any fees with respect to the Organogenesis Insider Debt. The acquisition of the Company's common stock closed on December 10, 2018 and the Organogenesis Insider Debt was deemed fully paid and satisfied in full and was discharged and terminated.

The sales of the above securities by the Company were deemed to be exempt from registration under the Securities Act, in reliance on Section 4(a)(2) of the Securities Act as transactions by an issuer not involving a public offering.

Use of Proceeds from the Offering

On October 14, 2016, we consummated our initial public offering of 30,000,000 units (the "Units") at a price of \$10.00 per Unit, each consisting of one Class A ordinary share of the Company and one warrant to purchase one-half of one Class A ordinary share of the Company. Our initial public offering did not terminate before all of the securities registered in our registration statement were sold. Credit Suisse Securities (USA) LLC and I-Bankers Securities, Inc. acted as underwriters for the offering. The securities sold in the offering were registered under the Securities Act on a registration statement on Form S-1 (File No. 333-213465). The SEC declared the registration statement effective on October 7, 2016. On November 28, 2016, the underwriters partially exercised the over-allotment option, and we sold an additional 1,000,000 Units at a price of \$10.00 per Unit.

Through December 31, 2018, we incurred \$833,589 for costs and expenses related to the initial public offering. Additionally, at the closing of the initial public offering and over-allotment option, we paid a total of \$6,200,000 in underwriting discounts and commissions. In addition, the underwriters agreed to defer the payment of \$10,850,000 in underwriting discounts and commissions, and further agreed to reduce such amount to \$5,218,205, which latter amount was paid upon consummation of the business combination on December 10, 2018. Prior to the closing of the initial public offering, the Sponsor loaned us \$300,000 to be used for a portion of the expenses of the initial public offering. These loans were repaid upon completion of the initial public offering out of the \$833,589 of initial public offering proceeds that were allocated for the payment of offering expenses other than underwriting discounts and commissions. Other than such loans, no payments were made by us to directors, officers or persons owning ten percent or more of our ordinary shares or to their associates, or to our affiliates. There has been no material change in the planned use of proceeds from the Public Offering as described in our final prospectus, dated October 10, 2016, filed with the SEC.

After deducting the underwriting discounts and commissions (excluding the amended deferred portion of \$4,128,205 in underwriting commissions, which amount was paid upon consummation of the business combination) and the estimated offering expenses, the total net proceeds from the initial public offering and the sale of the private placement warrants were \$311,166,411, of which \$310,000,000 (or \$10.00 per share sold in the initial public offering) was placed in the trust account. On October 30, 2018, the Company's redeemed all of the Company's remaining outstanding Class A ordinary shares and instructed the trustee to liquidate the trust account and to disburse the funds established in connection with the initial public offering, at which point all offering proceeds had been applied.

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ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data should be read in conjunction with our consolidated financial statements and related notes in Part II, Item 8 of this Annual Report on Form 10-K and with our “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Part II, Item 7 of this Annual Report on Form 10-K. Our selected statement of operations data for the fiscal years ended December 31, 2018, 2017 and 2016 and our selected balance sheet data as of December 31, 2018 and 2017 are derived from our audited consolidated financial statements included elsewhere in this report. The selected statements of operations data for the fiscal years ended December 31, 2015 and the balance sheet data as of December 31, 2016 and 2015 are derived from our audited consolidated financial statements not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of results to be expected for any future period. The selected financial data in this section are not intended to replace our consolidated financial statements and the related notes.

	Year Ended December 31			
	2018	2017	2016	2015
	(in thousands, except share and per share data)			
Consolidated Statement of Operations Data:				
Net revenue	\$ 193,449	\$ 198,508	\$ 138,732	\$ 98,975
Cost of goods sold	68,808	61,220	48,201	46,450
Gross profit	124,641	137,288	90,531	52,525
Operating expenses:				
Selling, general and administrative	161,961	133,717	93,029	68,174
Research and development	10,742	9,065	6,277	3,882
Write-off of deferred offering costs	3,494	—	—	—
Total operating expenses	176,197	142,782	99,306	72,056
Loss from operations	(51,556)	(5,494)	(8,775)	(19,531)
Other income (expense), net:				
Interest expense	(10,853)	(8,139)	(5,627)	(3,487)
Interest income	64	129	153	139
Change in fair value of warrants	(469)	(1,037)	(737)	—
Loss on the extinguishment of debt	(2,095)	—	—	—
Other income (expense), net	162	(9)	285	277
Total other income (expense), net	(13,191)	(9,056)	(5,926)	(3,071)
Net loss before income taxes	(64,747)	(14,550)	(14,701)	(22,602)
Income tax (expense) benefit	(84)	7,025	(65)	177
Net loss	(64,831)	(7,525)	(14,766)	(22,425)
Net income from non-controlling interest in affiliates	—	863	2,221	1,836
Net loss attributable to Organogenesis Holdings Inc.	\$ (64,831)	\$ (8,388)	\$ (16,987)	\$ (24,261)
Net loss per common share—basic and diluted	\$ (0.94)	\$ (0.14)	\$ (0.27)	\$ (0.38)
Weighted average common shares outstanding—basic and diluted	69,318,456	63,876,767	63,196,067	62,861,896
Other Financial Data:				
Adjusted EBITDA (1)	\$ (36,186)	\$ (25)	\$ (3,172)	\$ (19,229)

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- (1) To provide investors with additional information regarding our financial results, we monitor and have presented within this Annual Report on Form 10-K Adjusted EBITDA, which is a non-GAAP financial measure. This non-GAAP financial measure is not based on any standardized methodology prescribed by GAAP and is not necessarily comparable to similarly-titled measures presented by other companies.

We define EBITDA as net income (loss) attributable to Organogenesis Holdings Inc. before depreciation and amortization, interest expense and income taxes and 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, mark to market adjustments on our warrant liabilities, interest rate swaps and our contingent asset and liabilities, write-off of deferred offering costs, costs incurred with the Avista Merger and a loss on the extinguishment of debt. 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.

We use Adjusted EBITDA to evaluate our operating performance and trends and make planning decisions. We believe 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.

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) attributable to Organogenesis Holdings Inc., which is the most directly comparable GAAP equivalent. Some of these limitations are:

- Adjusted EBITDA excludes stock-based compensation expense, as stock-based compensation expense has recently been, and will continue to be for the foreseeable future, a significant recurring 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, contingent purchase earn-out and the fair value of interest rate swaps;
- Adjusted EBITDA excludes write-off of IPO costs, costs incurred in connection with the Avista Merger and a loss on the extinguishment of debt;
- 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. The following table presents a reconciliation of Adjusted EBITDA to net income (loss) attributable to Organogenesis Holdings Inc., the most directly comparable measure calculated in accordance with GAAP, for each of the periods presented.

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	Year Ended December 31,			
	2018	2017	2016	2015
	(in thousands)			
Net loss attributable to Organogenesis Holdings Inc.	\$(64,831)	\$(8,388)	\$(16,987)	\$(24,261)
Interest expense, net	10,789	8,010	5,474	3,348
Income tax expense (benefit)	84	(7,025)	65	(177)
Depreciation	3,309	3,591	5,702	6,063
Amortization	3,669	2,037	1,617	1,622
EBITDA	(46,980)	(1,775)	(4,129)	(13,405)
Stock-based compensation expense	1,075	919	473	459
Gain on settlement of litigation (1)	—	—	—	(2,988)
Change in contingent consideration forfeiture asset (2)	589	(212)	—	—
Change in contingent purchase earn out (3)	—	—	—	(3,300)
Change in fair value of interest rate swaps (4)	—	6	(253)	5
Change in fair value of warrant liability (5)	469	1,037	737	—
Write-off of deferred offering costs (6)	3,494	—	—	—
Avista merger transaction costs (7)	3,072	—	—	—
Loss on extinguishment of debt (8)	2,095	—	—	—
Adjusted EBITDA	<u>\$(36,186)</u>	<u>\$ (25)</u>	<u>\$ (3,172)</u>	<u>\$(19,229)</u>

- (1) Amount reflects the settlement received in 2015 in connection with a 2011 lawsuit filed against a former employee, alleging breach of an Invention, Non-Disclosure and Non-Competition Agreement.
- (2) Amount reflects the change in fair value of the common shares associated with the shares issued in connection with the acquisition of NuTech Medical that are forfeitable by the sole stockholder of NuTech Medical upon the occurrence of the FDA requiring approval of certain products acquired from NuTech Medical.
- (3) Amount reflects the change in fair value of a contingent purchase earn-out in connection with our acquisition of Dermagraft from Shire.
- (4) Amount reflects the change in fair value of our interest rate swaps that the Real Estate Entities entered into to manage the economic impact of fluctuations in interest rate. We do not use interest rate swaps for speculative or trading purposes and as such, the fair value of these instruments is recorded as an asset or liability on the consolidated balance sheet with change in the fair value of the instruments recognized as income or expense in the current period as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss.
- (5) In connection with our 2016 Loans (as defined below), we classified the warrants issued to purchase our common stock to the lenders, who are affiliates of ours as a liability on our consolidated balance sheet. Amounts reflect the change in fair value of the warrant liability.
- (6) Amount reflects a one-time write-off in the quarter ended June 30, 2018 of costs accumulated in connection with a proposed initial public offering of Organogenesis Inc. that was abandoned. The IPO process was abandoned and was replaced with the Avista Merger transaction.
- (7) 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 were expensed as incurred.

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(8) Amount reflects the write off of unamortized debt issuance costs upon repayment of affiliate debt in December 2018.

	As of December 31,			
	2018	2017	2016	2015
	(in thousands)			
Consolidated Balance Sheet Data:				
Cash and cash equivalents	\$ 21,291	\$ 2,309	\$ 1,778	\$ 1,139
Working capital (1)	4,743	(2,233)	(132)	(3,367)
Total assets	163,678	148,722	103,858	105,700
Total liabilities	116,637	157,277	119,837	102,186
Total Organogenesis Holdings Inc. stockholders' (deficit) equity	47,041	(15,317)	(15,979)	3,514

(1) We define working capital as current assets less current liabilities.

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 the section entitled "Selected Consolidated Financial Data" and 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, smoking, and cardiovascular and peripheral vascular disease. We offer our differentiated products and in-house customer support to a wide range of health care customers including hospitals, wound care centers, government facilities, ASCs, and physician offices. Our mission is to provide integrated healing solutions that substantially improve medical outcomes and the lives of patients while lowering the overall cost of care.

We offer a comprehensive portfolio of products in the markets we serve that address patient needs across the continuum of care. We have and intend to continue to generate data from clinical trials, real world outcomes and health economics research that validate the clinical efficacy and value proposition offered by our products. The majority of the 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.

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Historically we have concentrated our efforts in the Advanced Wound Care market. In 2017, we acquired NuTech Medical which further expanded our wound care portfolio and broadened our addressable market to include the Surgical & Sports Medicine market. We believe the expanded product portfolio facilitated by this acquisition is enhancing the ability of our sales representatives to reach and penetrate customer accounts, contributing to strong growth over time.

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, primarily in the outpatient setting. We have a comprehensive portfolio of regenerative medicine products, capable of supporting patients from early in the wound healing process through to wound closure regardless of wound type. Our Advanced Wound Care products include Apligraf for the treatment of VLU and 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 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 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.

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 Delaware corporation and a direct wholly owned subsidiary of AHPAC (“Avista Merger Sub”) and Organogenesis Inc., a Delaware corporation (“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, and in accordance with Section 388 of the Delaware General Corporation Law and the Cayman Islands Companies Law (2018 Revision), 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. 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.

For the year ended December 31, 2018, we generated \$193.4 million of revenue and had a net loss of \$64.8 million compared to revenue of \$198.5 million and a net loss of \$7.5 million for the year ended December 31, 2017. For the year ended December 31, 2016, we generated \$138.7 million of revenue and had a net loss of \$14.8 million. We expect to incur operating losses for the foreseeable 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, 2018, we had an accumulated deficit of \$130.2 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 common stock. We operate in one segment, regenerative medicine.

Items Affecting Comparability

NuTech Medical Acquisition. On March 18, 2017, we entered into an Agreement and Plan of Merger pursuant to which we acquired all of the outstanding shares of capital stock of Nutech Medical, Inc. (“NuTech Medical”) for aggregate consideration consisting of \$20.0 million in cash, \$12.0 million of which was paid at closing with the remainder to be paid on or before the fifteen-month anniversary of the closing (less a reduction

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of \$0.5 million resulting from an adjustment for working capital); and 3,642,746 shares of our Class A common stock, 2,185,647 of which were subject to forfeiture and 728,549 of which contain put and call features, and fully vested options to purchase 137,543 shares of our Class A common stock. In addition, a deferred tax liability of \$6.8 million recorded in connection with the acquisition allowed us to release a portion of the U.S. valuation allowance resulting in a tax benefit in the same amount. Upon the closing of the merger, NuTech Medical merged with and into Prime Merger Sub, LLC, with Prime Merger Sub, LLC surviving the merger as our wholly owned subsidiary. The results of operations for NuTech Medical are included in our consolidated financial statements as of March 24, 2017, which was the closing date of the merger.

Variable Interest Entity (VIE) Deconsolidation. We have historically consolidated the accounts of Dan Road Associates, LLC (“Dan Road Associates”), 85 Dan Road Associates, LLC (“85 Dan Road Associates”), and 65 Dan Road Associates, LLC (“65 Dan Road Associates”) as variable interest entities. We refer to these variable interest entities collectively as the “Real Estate Entities.” The Real Estate Entities, which are controlled by certain of our affiliates, are special purpose entities that hold real estate that is leased by us. We do not hold any capital stock of the Real Estate Entities. Based on the nature of the leases and the mortgages held by these affiliates, we determined that the Real Estate Entities were variable interest entities, which required consolidation. Following the removal of certain personal guarantees provided by these affiliates in respect of mortgage loans related to the property held by the Real Estate Entities, we determined that the Real Estate Entities no longer met the definition of variable interest entities and we deconsolidated them from our financial statements as of June 1, 2017.

Credit Agreement and ML Agreement. In March 2017, we entered into a credit agreement with Silicon Valley Bank, as amended, the Credit Agreement. The Credit Agreement provides for a revolving credit facility of up to \$30 million and a term loan of up to \$5.0 million. The term loan was repaid in full in December 2018. As of December 31, 2018, we had outstanding borrowings under the revolving credit facility portion of the Credit Agreement of \$26.5 million. In April 2017, we entered into a master lease agreement, or the ML Agreement, with Eastward Fund Management LLC. As of December 31, 2018, we had outstanding borrowings of \$15.9 million under the ML Agreement.

Avista Merger. In December 2018, we completed the Avista Merger pursuant to which Avista Merger Sub merged with and into Organogenesis Inc., with Organogenesis Inc. surviving as a wholly owned subsidiary of AHPAC. AHPAC was a publicly held special purpose acquisition company, which was formed in 2016 for the sole purpose of completing a business acquisition. In addition, in connection with the Avista Merger, AHPAC completed the Domestication and changed its name to Organogenesis Holdings Inc. (ORGO). Under the terms of the Avista Merger Agreement, all of the outstanding common stock of Organogenesis Inc. was exchanged for ORGO Class A common stock, and all outstanding options and warrants (other than warrants that expired, were exercised or were deemed automatically net exercised immediately prior to the Avista Merger) 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.

Concurrently with the signing of the Avista Merger Agreement, AHPAC entered into a subscription agreement with Avista Capital Partners IV, L.P. and Avista Capital Partners IV (Offshore), L.P. (the “PIPE Investors”) for the purchase and sale of 9,022,741 shares of ORGO Class A common stock and 4,100,000 warrants to purchase one-half of one share of ORGO’s Class A common stock for an aggregate purchase price of \$46.0 million to occur at the consummation of the Avista Merger (the “Additional Avista Investment”). The proceeds from the Additional Avista Investment were received in December 2018. The PIPE Investors also purchased, concurrently with the execution and delivery of the Avista Merger Agreement, 6,538,732 shares of ORGO Class A common stock for an aggregate purchase price of \$46.0 million (the “Initial Avista Investment”). Organogenesis Inc. received the proceeds from the Initial Avista Investment in August 2018.

Concurrently with the signing of the Avista Merger Agreement, our lenders agreed to release the subordination on the affiliate debt and the affiliate guarantee on the term debt, and the holders of the affiliate debt

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executed and delivered to the Company an exchange agreement (the “Exchange Agreement”) whereby we agreed that, concurrently with the consummation of the Avista Merger, outstanding principal of \$45.7 million related to the affiliate debt was exchanged for 6,502,679 shares of ORGO Class A common stock and a cash payment of \$35.6 million, representing \$22.0 million of principal and \$13.6 million of accrued interest related to all aforementioned affiliate debt 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 satisfied in full and was discharged and terminated. We incurred a loss of \$2.1 million on the extinguishment of the affiliate debt related to the write-off of the unamortized debt discount 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.

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 principally as a measure of our operating performance and 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) attributable to Organogenesis Holdings Inc. before depreciation and amortization, interest expense and income taxes and 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, mark to market adjustments on our warrant liabilities, interest rate swaps and our contingent asset and liabilities, write-off of IPO costs, costs incurred with the Avista Merger and a loss on the extinguishment of debt. 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.

We use Adjusted EBITDA to evaluate our operating performance and trends and make planning decisions. We believe 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.

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) attributable to Organogenesis Holdings Inc., which is the most directly comparable GAAP equivalent. Some of these limitations are:

- Adjusted EBITDA excludes stock-based compensation expense, as stock-based compensation expense has recently been, and will continue to be for the foreseeable future, a significant recurring 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;

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- 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, contingent purchase earn-out and the fair value of interest rate swaps;
- Adjusted EBITDA excludes the write-off of IPO costs, costs incurred in connection with the Avista Merger and a loss on the extinguishment of debt;
- 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 to net income (loss) attributable to Organogenesis Holdings Inc., the most directly comparable 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 products upon receipt of a purchase order from our customers and delivery of our products to our customers. For certain customers, products may be shipped in advance of the receipt of the purchase order but we recognize revenue on these products only upon receipt of a purchase order. We record revenue net of a reserve for returns, early payment discounts and GPO rebates, which represent a direct reduction to the revenue we recognize. We consign our Surgical & Sports Medicine products to hospitals, ASCs and clinics, which allows physicians to use them in surgical procedures. We recognize revenue upon the receipt of a purchase order.

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

The increase in revenue from 2016 to 2018 was primarily attributable to increased Advanced Wound Care sales volume due to additional sales headcount, increased efforts by our sales staff to expand the geographic locations in which we do business and the facilities that offer our products, as well as sales related to the products acquired in our acquisition of NuTech Medical in March of 2017.

Included within our Advanced Wound Care 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, Medicare can grant new products an additional “pass through payment” in addition to the bundled payment amount for a limited period of no more

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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 the reported periods. During the same periods, we saw decreases in the revenue generated from our other Advanced Wound Care products. 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, 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. 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, PuraPly and PuraPly AM remained in the bundled payment structure from January 1, 2018 through September 30, 2018. On 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 will retain pass-through reimbursement status until September 30, 2020. Other skin substitute products, including all of our other products, will remain in the bundled payment structure.

Cost of goods sold, gross profit and gross profit margin

Cost of goods sold includes product testing costs, quality assurance costs, personnel costs, manufacturing costs, raw materials and product costs, and facility 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, expanded product portfolio offerings, and the number of 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 revenue. Our gross profit and gross profit margin is affected by product and geographic sales mix, realized pricing of our products, the efficiency of our manufacturing operations and the costs of materials used to make our products. Regulatory actions, including healthcare reimbursement scenarios, which may require costly expenditures or result in pricing pressure, may decrease our gross profit and gross profit margin.

Selling, general and administrative expenses

Selling, general and administrative expenses generally include personnel costs, commissions, incentive compensation, customer support, administrative and labor costs, insurance, professional fees, depreciation, bad debt expense and information systems costs. We expect our selling, general and administrative expenses to continue to increase due to continued revenue growth, increased investments in market development, geographic expansion and expansion of our sales and marketing forces.

Research and development expenses

Research and development expenses relate to our investments in improvements to our manufacturing processes, product enhancements to our currently available products, and additional investments in our product pipeline and platforms. Our research and development costs also include expenses such as clinical trial and regulatory costs. We expense research and development costs as incurred. Our research and development expenses fluctuate from period to period based on the ongoing improvement to our manufacturing processes and

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product enhancements. We generally expect that these costs will increase over time as we continue to enhance our manufacturing process and products and add related personnel to support these enhancements and bring new products to market.

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 income (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 in connection with loans made to employees.

Change in fair value of warrant liability. In connection with the 2016 Loans (as defined below), we issued warrants to purchase our common stock to the lenders, who are affiliates of ours. We classify the warrants as a liability on our consolidated balance sheets because each warrant provides for down-round protection, which provides that the exercise price of the warrants be adjusted if we issue equity at a price that is below the current exercise price of the warrants. The price of the warrant will also be adjusted any time the price of another equity-linked instrument changes. The warrant liability was initially recorded at fair value and is subsequently remeasured to fair value at each reporting date. 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. Changes in the fair value of the warrant liability were recognized until the warrants were exercised immediately prior to the closing of the Avista Merger on December 10, 2018.

Loss on the extinguishment of debt. In connection with the consummation of the Avista Merger in December 2018 and the transactions contemplated by the Exchange Agreement, outstanding principal of \$45.7 million related to the affiliate debt was exchanged for 6,502,679 shares of ORGO Class A common stock and a cash payment of \$35.6 million, representing \$22.0 million of principal and \$13.6 million of accrued interest related to all aforementioned affiliate debt 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 satisfied in full 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.

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, management analyzes both positive and negative evidence related to the realization of deferred tax assets and inherent in that, assesses the likelihood of sufficient future taxable income. Management also considers the expected reversal of deferred tax liabilities and analyzes the period in which these would be expected to reverse to determine whether the taxable temporary difference amounts serve as an adequate source of future taxable income to support realizability of the deferred tax assets. In addition, management considers whether it is more likely than not that the tax position will be sustained on examination by taxing authorities based on the technical merits of the

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position. Based on a consideration of the factors discussed above, including the fact that through the year-ended December 31, 2018, our results reflected a three-year cumulative loss position, management has determined that a valuation allowance is necessary against the full amount of our net deferred tax assets, excluding alternative minimum tax credits. On December 22, 2017, the United States enacted new tax reform (“Tax Act”) and as a result alternative minimum tax credits will be refundable beginning with the 2018 tax return. The alternative minimum tax credits will be realized, regardless of future taxable income, and thus no valuation allowance has been provided against this asset.

Results of Operations

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

	Year Ended December 31		
	2018	2017 (in thousands)	2016
Net revenue	\$193,449	\$198,508	\$138,732
Cost of goods sold	68,808	61,220	48,201
Gross profit	124,641	137,288	90,531
Operating expenses:			
Selling, general and administrative	161,961	133,717	93,029
Research and development	10,742	9,065	6,277
Write-off of deferred offering costs	3,494	—	—
Total operating expenses	176,197	142,782	99,306
Loss from operations	(51,556)	(5,494)	(8,775)
Other income (expense), net:			
Interest expense, net	(10,789)	(8,010)	(5,474)
Change in fair value of warrants	(469)	(1,037)	(737)
Loss on the extinguishment of debt	(2,095)	—	—
Other income (expense), net	162	(9)	285
Total other income (expense), net	(13,191)	(9,056)	(5,926)
Net loss before income taxes	(64,747)	(14,550)	(14,701)
Income tax (expense) benefit	(84)	7,025	(65)
Net loss	(64,831)	(7,525)	(14,766)
Net income from non-controlling interest in affiliates	—	863	2,221
Net loss attributable to Organogenesis Holdings Inc.	<u>\$ (64,831)</u>	<u>\$ (8,388)</u>	<u>\$ (16,987)</u>

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EBITDA and Adjusted EBITDA

The following table presents a reconciliation of Adjusted EBITDA to net loss attributable to Organogenesis Holdings Inc., the most directly comparable GAAP measure, for each of the periods presented:

	Year Ended December 31,		
	2018	2017	2016
	(in thousands)		
Net loss attributable to Organogenesis Holdings Inc.	\$(64,831)	\$(8,388)	\$(16,987)
Interest expense, net	10,789	8,010	5,474
Income tax expense (benefit)	84	(7,025)	65
Depreciation	3,309	3,591	5,702
Amortization	3,669	2,037	1,617
EBITDA	(46,980)	(1,775)	(4,129)
Stock-based compensation expense	1,075	919	473
Change in contingent consideration forfeiture asset (1)	589	(212)	—
Change in fair value of interest rate swaps (2)	—	6	(253)
Change in fair value of warrant liability (3)	469	1,037	737
Write-off of deferred offering costs (4)	3,494	—	—
Avista merger transaction costs (5)	3,072	—	—
Loss on extinguishment of debt (6)	2,095	—	—
Adjusted EBITDA	<u>\$(36,186)</u>	<u>\$ (25)</u>	<u>\$ (3,172)</u>

- (1) Amount reflects the change in fair value of the common shares associated with the shares issued in connection with the acquisition of NuTech Medical that are forfeitable by the sole stockholder of NuTech Medical upon the occurrence of the FDA requiring approval of certain products acquired from NuTech Medical.
- (2) Amount reflects the change in fair value of our interest rate swaps that the Real Estate Entities entered into to manage the economic impact of fluctuations in interest rate. We do not use interest rate swaps for speculative or trading purposes and as such, the fair value of these instruments is recorded as an asset or liability on the consolidated balance sheet with change in the fair value of the instruments recognized as income or expense in the current period as a component of other income (expense), net in the consolidated statement of operations.
- (3) In connection with our 2016 Loans (as defined below), we classified the warrants issued to purchase our common stock to the lenders, who are affiliates of ours as a liability on our consolidated balance sheet. Amounts reflect the change in fair value of the warrant liability.
- (4) Amount reflects a one-time write-off in the quarter ended June 30, 2018 of costs accumulated in connection with a proposed initial public offering of Organogenesis Inc. that was abandoned. The IPO process was abandoned and was replaced with the Avista Merger transaction.
- (5) 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 were expensed as incurred.
- (6) Amount reflects the write off of unamortized debt issuance costs upon repayment of affiliate debt in December 2018 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.

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Comparison of the Year Ended December 31, 2018 and 2017

Revenue

	Year Ended December 31,		Change	
	2018	2017	\$	%
	(in thousands, except for percentages)			
Advanced Wound Care	\$164,332	\$178,896	\$(14,564)	(8)%
Surgical & Sports Medicine	29,117	19,612	9,505	48%
Net revenue	<u>\$193,449</u>	<u>\$198,508</u>	<u>\$ (5,059)</u>	<u>(3)%</u>

Net revenue from our Advanced Wound Care products decreased by \$14.6 million, or 8%, to \$164.3 million in the year ended December 31, 2018 from \$178.9 million in the year ended December 31, 2017. Our decrease in Advanced Wound Care net revenue was primarily attributable to the loss of pass-through reimbursement status for PuraPly during the first nine months of 2018. This decrease was partially offset by the introduction of amniotic products acquired from NuTech Medical. Net revenue from our Surgical & Sports Medicine products increased \$9.5 million, to \$29.1 million in the year ended December 31, 2018 from \$19.6 million in the year ended December 31, 2017. The increase in Surgical & Sports Medicine revenue was primarily due to the acquisition of NuTech Medical on March 24, 2017 as the Company recorded a full year of revenue related to NuTech Medical in the year ended December 31, 2018. Included within net revenue is PuraPly revenue of \$69.8 million and \$109.1 million for the years ended December 31, 2018 and 2017, respectively.

Cost of Goods Sold, Gross Profit and Gross Margin

	Year Ended December 31,		Change	
	2018	2017	\$	%
	(in thousands, except for percentages)			
Cost of goods sold	<u>\$ 68,808</u>	<u>\$ 61,220</u>	<u>\$ 7,588</u>	<u>12%</u>
Gross profit	<u>\$124,641</u>	<u>\$137,288</u>	<u>\$(12,647)</u>	<u>(9)%</u>
Gross margin %	64%	69%		

Cost of goods sold increased by \$7.6 million, or 12%, to \$68.8 million in the year ended December 31, 2018 from \$61.2 million in the year ended December 31, 2017. The increase in cost of goods sold was primarily due to increased unit volumes and additional manufacturing and quality control headcount related to a full year of NuTech Medical product sales. Gross profit decreased by \$12.6 million, or 9%, to \$124.6 million in the year ended December 31, 2018 from \$137.3 million in the year ended December 31, 2017. Our decrease in gross profit resulted primarily from the decrease in our Advanced Wound Care revenue driven by the loss of pass-through reimbursement status for PuraPly during the first nine months of 2018, partially offset by our increase in revenue from our Surgical & Sports Medicine products.

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Selling, General and Administrative Expenses

The following table presents selling, general and administrative expenses and the percentage relationship to total revenue for the periods indicated:

	Year Ended December 31,		Change	
	2018	2017	\$	%
	(in thousands, except for percentages)			
Selling, general and administrative	\$161,961	\$133,717	\$28,244	21%
<i>Selling, general and administrative as a percentage of revenue</i>	84%	67%		

Selling, general and administrative expenses increased by \$28.2 million, or 21%, to \$162.0 million in the year ended December 31, 2018 from \$133.7 million in the year ended December 31, 2017. The increase in selling, general and administrative expenses is primarily due to a \$25.2 million increase related to additional headcount, primarily in our direct sales force, an increase of \$1.6 million in amortization as a result of the NuTech Medical acquisition, an increase of \$1.7 million associated with marketing and promotional materials for our products, an increase of \$1.5 million associated with transaction advisory fees, and an increase of \$0.7 million related to the expiration of the forfeiture right asset. These increases are partially offset by a decrease of \$1.4 million in legal and consulting fees and costs associated with other strategic alternatives and the ongoing operations of our business and a decrease of \$0.8 million in royalties attributable to certain product sales. We expect our selling, general and administrative expenses to continue to increase throughout 2019.

Research and Development Expenses

The following table presents research and development expenses and the percentage relationship to total revenue for the periods indicated:

	Year Ended December 31,		Change	
	2018	2017	\$	%
	(in thousands, except for percentages)			
Research and development	\$10,742	\$9,065	\$1,677	18%
<i>Research and development as a percentage of revenue</i>	6%	5%		

Research and development expenses increased by \$1.7 million, or 18%, to \$10.7 million in the year ended December 31, 2018 from \$9.1 million in the year ended December 31, 2017. The increase in research and development expenses is primarily due to a \$1.6 million increase in clinical research costs associated with our Advanced World Care and Surgical & Sports Medicine products and increased headcount. We expect our research and development costs to continue to increase throughout 2019.

Write-off of Deferred Offering Costs

The following table presents the write-off of deferred offering costs and the percentage relationship to total revenue for the periods indicated:

	Year Ended December 31,		Change	
	2018	2017	\$	%
	(in thousands, except for percentages)			
Write-off of deferred offering costs	\$ 3,494	\$ —	\$ 3,494	**
<i>Write-off of deferred offering costs as a percentage of revenue</i>	2%	0%		

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** 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. The IPO process was abandoned and was replaced with the Avista Merger.

Other Expense, Net

	Year Ended December 31,		Change	
	2018	2017	\$	%
	(in thousands, except for percentages)			
Interest expense, net	\$(10,789)	\$(8,010)	\$(2,779)	35%
Change in fair value of warrant liability	(469)	(1,037)	568	(55)%
Loss on extinguishment of debt	(2,095)	—	(2,095)	**
Other expense, net	162	(9)	171	**
Total other expense, net	<u>\$(13,191)</u>	<u>\$(9,056)</u>	<u>\$(4,135)</u>	<u>46%</u>

** not meaningful

Other expense, net increased by \$4.1 million, or 46%, to \$13.2 million in the year ended December 31, 2018 from \$9.1 million in the year ended December 31, 2017. Interest expense, net increased to \$10.8 million in the year ended December 31, 2018 from \$8.0 million in the year ended December 31, 2017 primarily due increased borrowings of \$15.0 million in connection with the 2018 Loans (as defined below), and additional borrowings during 2018 under the Credit Agreement. The increase in the change in fair value of warrant liability is primarily due to the increase in the fair value of the shares underlying the warrants. 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 Benefit (Expense)

	Year Ended December 31,		Change	
	2018	2017	\$	%
	(in thousands, except for percentages)			
Income tax (expense) benefit	<u>\$(84)</u>	<u>\$7,025</u>	<u>\$(7,109)</u>	<u>(101)%</u>

Income tax expense increased by \$7.1 million to \$0.1 million in the year ended December 31, 2018 from a tax benefit of \$7.0 million in the year ended December 31, 2017. The increase in income tax expense is primarily the result of the prior period including the partial release of our valuation allowance which resulted from a deferred tax liability recorded through purchase accounting related to the NuTech Medical acquisition. There was no release of our valuation allowance in the year ended December 31, 2018.

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Comparison of the Year Ended December 31, 2017 and 2016

Revenue

	Year Ended December 31,		Change	
	2017	2016	\$	%
	(in thousands, except for percentages)			
Advanced Wound Care	\$178,896	\$138,732	\$40,164	29%
Surgical & Sports Medicine	19,612	—	\$19,612	**
Net revenue	<u>\$198,508</u>	<u>\$138,732</u>	<u>\$59,776</u>	<u>43%</u>

** not meaningful

Net revenue from our Advanced Wound Care products increased \$40.2 million, or 29%, to \$178.9 million in the year ended December 31, 2017 from \$138.7 million in the year ended December 31, 2016. Our growth in net revenue resulted from continued increases in sales volume resulting from the strength in our Advanced Wound Care products, primarily attributable to sales of our PuraPly products that qualified for “pass-through” status during the periods presented, driven by the addition of sales representatives and increased penetration in the Advanced Wound Care market, as well as a shift in our product mix. For the year ended December 31, 2017, we recorded incremental revenue from our Surgical & Sports Medicine products of \$19.6 million, which revenue consisted solely of revenue attributable to products that we acquired from NuTech Medical. Included within net revenue is PuraPly revenue of \$109.1 million and \$62.3 million for the years ended December 31, 2017 and 2016, respectively.

Cost of Goods Sold, Gross Profit and Gross Margin

	Year Ended December 31,		Change	
	2017	2016	\$	%
	(in thousands, except for percentages)			
Cost of goods sold	\$ 61,220	\$48,201	\$13,019	27%
Gross profit	<u>\$137,288</u>	<u>\$90,531</u>	<u>\$46,757</u>	<u>52%</u>
Gross margin %	69%	65%		

Cost of goods sold increased \$13.0 million, or 27%, to \$61.2 million in the year ended December 31, 2017 from \$48.2 million in the year ended December 31, 2016. The increase in cost of goods sold was primarily due to an \$11.2 million increase due to growth in sales volume and \$1.8 million in additional support costs.

Gross profit increased \$46.8 million, or 52%, to \$137.3 million in the year ended December 31, 2017 from \$90.5 million in the year ended December 31, 2016. Our growth in gross profit resulted primarily from increased sales volume due to the strength in our Advanced Wound Care products and incremental revenue from our Surgical & Sports Medicine products as a result of our NuTech Medical acquisition and the resulting higher margins realized as a result of manufacturing efficiencies associated with our Advanced Wound Care products.

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Selling, General and Administrative Expenses

The following table presents selling, general and administrative expenses and the percentage relationship to total revenue for the periods indicated:

	Year Ended December 31,		Change	
	2017	2016	\$	%
	(in thousands, except for percentages)			
Selling, general and administrative	\$133,717	\$93,029	\$40,688	44%
<i>Selling, general and administrative as a percentage of revenue</i>	67%	67%		

Selling, general and administrative expenses increased \$40.7 million, or 44%, to \$133.7 million in the year ended December 31, 2017 from \$93.0 million in the year ended December 31, 2016. The increase in selling, general and administrative expenses is primarily due to a \$16.1 million increase as a result of our acquisition of NuTech Medical and \$15.2 million related to increased headcount, primarily in our direct sales force. In addition, we experienced a \$5.4 million increase in legal and consulting fees and costs associated with other strategic alternatives and the ongoing operations of our business and an increase of \$4.0 million associated with Advanced Wound Care marketing and promotional materials and costs.

Research and Development Expenses

The following table presents research and development expenses and the percentage relationship to total revenue for the periods indicated:

	Year Ended December 31,		Change	
	2017	2016	\$	%
	(in thousands, except for percentages)			
Research and development	\$9,065	\$6,277	\$2,788	44%
<i>Research and development as a percentage of revenue</i>	5%	5%		

Research and development expenses increased \$2.8 million, or 44%, to \$9.1 million in the year ended December 31, 2017 from \$6.3 million in the year ended December 31, 2016. The increase in research and development expenses is primarily due to incremental costs of \$2.9 million resulting from our acquisition of NuTech Medical and a \$1.4 million increase in clinical research costs associated with our Advanced Wound Care products. These increases are partially offset by a decrease of \$1.5 million due to the completion of an ongoing shelf life study on our Advanced Wound Care products.

Other Expense, Net

	Year Ended December 31,		Change	
	2017	2016	\$	%
	(in thousands, except for percentages)			
Interest expense, net	\$(8,010)	\$(5,474)	\$(2,536)	46%
Change in fair value of warrant liability	(1,037)	(737)	(300)	41%
Other expense, net	(9)	285	(294)	(103)%
Total other expense, net	\$(9,056)	\$(5,926)	\$(3,130)	53%

Other expense, net increased \$3.1 million, or 53%, to \$9.1 million in the year ended December 31, 2017 from \$5.9 million in the year ended December 31, 2016. Interest expense, net increased to \$8.0 million in the

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year ended December 31, 2017 from \$5.5 million in the year ended December 31, 2016 primarily due to the \$17.0 million outstanding principal balance of the 2016 Loans (as defined below), which were outstanding for the full year 2017 versus the partial year 2016, and additional borrowings of \$17.6 million and \$16.0 million made in 2017 under the Credit Agreement and the ML Agreement, respectively. The increase in the change in fair value of warrant liability is primarily due to the increase in the fair value of the shares underlying the warrants.

Income Tax Benefit (Expense)

	Year Ended December 31,		Change	
	2017	2016	\$	%
	(in thousands, except for percentages)			
Income tax (expense) benefit	\$ 7,025	\$ (65)	\$ 7,090	**%

** not meaningful

Income tax expense decreased to an income tax benefit of \$7.0 million in the year ended December 31, 2017 from a \$0.1 million income tax expense in the year ended December 31, 2016, primarily due to a partial release of our valuation allowance, which resulted from a deferred tax liability recorded through purchase accounting.

Liquidity and Capital Resources

Since our inception, we have funded our operations and capital spending 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, 2018, we had \$21.3 million in cash. We expect that our cash on hand of \$21.3 million as of December 31, 2018, plus availability under our New Credit Agreement with Silicon Valley Bank, which we entered into in March 2019, and cash flows from product sales, will be sufficient to fund our operating expenses, capital expenditure requirements and debt service payments through at least March 31, 2020.

Our primary uses of cash are working capital requirements, capital expenditure requirements and debt service requirements. Additionally, from time to time, we may use capital for acquisitions and other investing and financing activities. Working capital is required principally to finance personnel and 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 and improvements, manufacturing equipment, computer hardware and software.

Our primary source of liquidity has been cash flow from operations and financing activities, including borrowings on promissory notes, lines of credit, loans from affiliates and entities controlled by certain of our affiliates and equity offerings. 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 the incurrence of additional indebtedness, additional equity financings or a combination of these potential sources of funds. In the event that we need access to additional cash, we may not be able to access the credit or equity markets on commercially acceptable terms or at all. Our ability to fund future operating expenses and capital expenditures and our ability to meet future debt service obligations or refinance our indebtedness will depend on our future operating performance which will be affected by general economic, financial and other factors beyond our control.

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

	2018	December 31, 2017 (in thousands)	2016
Cash	\$21,291	\$ 2,309	\$ 1,778
Line of credit	\$26,484	\$ 17,618	\$ 4,869
Due to affiliates	—	4,500	400
Notes payable	15,123	14,816	26,048
Capital lease obligations	17,655	17,759	3,600
Long-term debt—affiliates, including accrued interest	—	52,142	53,076
Total debt (1)	59,262	106,835	87,993
Net debt (2)	\$37,971	\$104,526	\$86,215

(1) Total debt equals current and long-term debt and capitalized lease obligations, net of discounts and issuance costs.

(2) Net debt is defined as total debt less total cash.

Cash Flows

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

	2018	Year Ended December 31, 2017 (in thousands)	2016
Net cash used in operating activities	\$(60,739)	\$ (3,574)	\$(4,871)
Net cash used in investing activities	(1,856)	(14,874)	(1,246)
Net cash provided by financing activities	81,642	18,948	6,776
Net increase in cash and restricted cash	\$ 19,047	\$ 500	\$ 659

Operating Activities

During the year ended December 31, 2018, net cash used in operating activities was \$60.7 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 \$22.4 million, partially offset by non-cash charges of \$26.5 million. Net cash used in connection with changes in our operating assets and liabilities include 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 \$5.0 million, an increase in prepaid expenses and other current assets of \$1.4 million, an increase in accrued expenses of \$0.4 million, an increase in other liabilities of \$0.1 million, all of which were offset by a decrease in accounts payable of \$0.1 million.

During the year ended December 31, 2017, net cash used in operating activities was \$3.6 million, resulting from our net loss of \$7.5 million and net cash provided by changes in our operating assets and liabilities of \$5.2 million, partially offset by non-cash charges of \$9.2 million. Net cash used in connection with changes in our operating assets and liabilities include an increase in accounts receivable of \$7.0 million, an increase in inventory of \$3.8 million due to an improvement in inventory management processes and an increase in prepaid expense and other current assets of \$2.7 million. The increases were partially offset by an increase in accounts payable of \$3.9 million, an increase in accrued interest on affiliate debt of \$3.2 million and an increase in accrued expenses of \$1.0 million.

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During the year ended December 31, 2016, net cash used by operating activities was \$4.9 million, resulting from our net loss of \$14.8 million and net cash provided by changes in our operating assets and liabilities of \$7.4 million partially offset by non-cash charges of \$17.3 million. Net cash provided by changes in our operating assets and liabilities includes a decrease in prepaid expense and other current assets of \$1.0 million, an increase in accrued expenses of \$1.1 million and an increase in accrued interest on affiliate debt of \$2.3 million, all partially offset by an increase in accounts receivable of \$6.6 million and an increase in inventory of \$5.4 million.

Investing Activities

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

During the year ended December 31, 2017, we used \$14.9 million of cash in investing activities that consisted primarily of \$11.8 million used in connection with our NuTech Medical acquisition, \$2.4 million of capital expenditures and a \$0.7 million decrease as a result of our VIE deconsolidation.

During the year ended December 31, 2016, net cash used by investing activities was \$1.2 million, primarily consisting of capital expenditures of \$1.4 million, partially offset by \$0.1 million in proceeds from disposals of our property and equipment.

Financing Activities

During the year ended December 31, 2018, net cash provided by financing activities was \$81.6 million that consisted primarily of \$91.7 million in net proceeds from the issuance of Class A common stock, proceeds from affiliate debt of \$15 million, \$8.9 million in net borrowings under our 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 \$22.0 million, repayment of fees in connection with affiliate debt of \$0.7 million and the payment of \$0.2 million of debt issuance costs.

During the year ended December 31, 2017, net cash provided by financing activities was \$18.9 million. The increase was primarily due to \$16.0 million in borrowings under the ML Agreement, net borrowings under our Credit Agreement of \$12.7 million, proceeds of \$1.0 million attributable to the Real Estate Entities in connection with cash contributions from member affiliates and proceeds of \$0.2 million from the exercise of stock options. The net cash provided by financing activities was partially offset by notes payable repayments of \$6.3 million, \$0.9 million of debt issuance costs related to the ML Agreement, repayment of \$1.3 million of our related party notes payable and \$2.5 million of deferred acquisition consideration related to our NuTech Medical acquisition.

During the year ended December 31, 2016, net cash provided by financing activities was \$6.8 million. The increase was primarily due to \$17.2 million in borrowings pursuant to the 2016 Loans (as defined below) and \$2.4 million in net borrowings under our 2010 Loans (as defined below) and 2015 Loans (as defined below). The net cash provided by financing activities was partially offset by 2010 Loans and 2015 Loans payable repayments of \$5.3 million, distributions to affiliates of \$5.2 million and repayments under the Credit Agreement of \$2.4 million.

Indebtedness

Long-Term Debt—Loans from the Controlling Entities

2010 Loans and 2015 Loans.

In October 2010, we entered into the 2010 Loan Agreement with certain of our affiliates, and entities controlled by certain of our affiliates pursuant to which we borrowed an aggregate principal amount of

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\$19.9 million, referred to as the 2010 Loans. The 2010 Loans were subordinated to the Credit Agreement, ML Agreement and certain obligations to the sellers of NuTech Medical. In December 2018, in connection with consummation of the transactions contemplated by the Exchange Agreement, the 2010 Loans were deemed fully paid and satisfied in full and were discharged and terminated. In November 2015, we entered into the 2015 Loan Agreement with certain of our affiliates and entities controlled by certain of our affiliates pursuant to which we borrowed an aggregate principal amount of \$11.4 million, referred to as the 2015 Loans. The 2015 Loans were subordinated to the Credit Agreement, ML Agreement and certain obligations to the sellers of NuTech Medical. In December 2018, in connection with consummation of the transactions contemplated by the Exchange Agreement, the 2015 Loans were deemed fully paid and satisfied in full and were discharged and terminated.

Real Estate Loans.

In June 2013, the Company entered into a secured financing arrangement with 65 Dan Road SPE, LLC, 85 Dan Road Associates and 275 Dan Road SPE, LLC pursuant to which we borrowed an aggregate principal amount of \$4.5 million, referred to as the Real Estate Loans. In December 2018, in connection with consummation of the transactions contemplated by the Exchange Agreement, the Real Estate Loans were deemed fully paid and satisfied in full and were discharged and terminated.

2016 Loans.

In April 2016, we entered into a Securities Purchase Agreement with certain of our affiliates and issued subordinated notes and warrants pursuant to which we borrowed an aggregate principal amount of \$17.0 million, referred to as the 2016 Loans. In December 2018, in connection with consummation of the transactions contemplated by the Exchange Agreement, the 2016 Loans were deemed fully paid and satisfied in full and were discharged and terminated. In connection with the 2016 Loans, we issued warrants to purchase 905,774 shares of common stock at an exercise price of \$3.58 per share. The warrants contained a down round protection provision whereby the exercise price and number of shares exercisable reset upon either the issuance of shares or other equity linked instruments at a price less than \$3.58 per share or upon the contractual price reset of other equity linked instruments post issuance. The warrants were net exercised immediately prior to the closing of the Avista Merger on December 10, 2018 and we issued 444,041 shares of Class A common stock.

2018 Loans.

In April 2018, we entered into the 2018 Loan Agreement with certain of our affiliates pursuant to which we borrowed an aggregate principal amount of \$15.0 million, referred to as the 2018 Loans. The 2018 Loans were subordinated to the Credit Agreement, ML Agreement and the sellers of NuTech Medical. In December 2018, in connection with consummation of the transactions contemplated by the Exchange Agreement, the 2018 Loans were deemed fully paid and satisfied in full and were discharged and terminated.

2017 Credit Agreement

In March 2017, we entered into a credit agreement with SVB, which we refer to as the Credit Agreement. The Credit Agreement, as amended, provides 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. As of December 31, 2018, we had outstanding borrowing under the revolving credit facility portion of the Credit Agreement of \$26.5 million.

2019 New Credit Agreement

On March 14, 2019, we and our subsidiaries, Organogenesis Inc. and Prime Merger Sub, LLC entered into a credit agreement with SVB and the several other lenders from time to time party thereto, which we refer to as the New Credit Agreement. The New Credit Agreement provides for a revolving credit facility of up to the lesser of \$40.0 million and the amount determined by the Borrowing Base (as defined in the New Credit Agreement) and a

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term loan 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 shall be made available to us until September 30, 2019 upon: (a) the lenders' receipt of financial statements for the quarter ended June 30, 2019, (b) our demonstrated compliance with the financial covenants in the New Credit Agreement and (c) our achievement of trailing twelve month revenue of at least \$221.25 million and a trailing three month EBITDA (as defined in the New Credit Agreement) loss not in excess of \$5.0 million; and (iii) the third tranche of \$10.0 million shall be made available to us until March 31, 2020 upon the lenders' confirmation of our compliance with the financial covenants in the New Credit Agreement through December 31, 2019; provided, however, that if we do not achieve the milestones required for the second tranche, the amount that may become available under the third tranche shall be increased from \$10.0 million to \$20.0 million.

We are required to comply with certain covenants and restrictions under the New Credit Agreement facilities. 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 credit facility or the term loan facility. Under the New Credit Agreement, we are required to achieve Minimum Trailing Twelve Month Consolidated Revenue (as defined in the New Credit Agreement), tested quarterly, at the following levels: \$200.0 million for the trailing twelve months ending March 31, 2019; \$213.5 million for the trailing twelve months ending June 30, 2019; \$221.25 million for the trailing twelve months ending September 30, 2019; and \$231.5 million for the trailing twelve months ending December 31, 2019, with minimum revenue covenant levels for 2020 to be agreed between the lenders and us no later than February 15, 2020. In addition, we are required to maintain Minimum Liquidity (as defined in the New Credit Agreement) equal to the greater of (i) 6 months Monthly Burn (as defined in the New Credit Agreement) and (ii) \$10.0 million. Finally, on or prior to December 31, 2019, we are obligated to enter into amended lease agreements with the owners of our facilities on Dan Road in Canton, Massachusetts providing for a lease term ending on a date that is later than March 14, 2024 and including arm's length terms with respect to assignability, bankruptcy, early termination and other provisions as the lenders under the New Credit Agreement deem reasonably necessary.

ML Agreement

In April 2017, we entered into the ML Agreement with Eastward Fund Management LLC. As of December 31, 2018, we had outstanding borrowings of \$15.9 million under the ML Agreement. In conjunction with the ML Agreement, we issued warrants to purchase 473,011 shares of common stock at an exercise price of \$2.53 per share. The warrants were net exercised immediately prior to the closing of the Avista Merger on December 10, 2018 and we issued 302,443 shares of Class A common stock.

Notes Payable—Real Estate Entities

Dan Road Associates has a mortgage note payable to a bank owed in monthly installments and bearing interest at LIBOR rate plus 220 basis points. The note matures in August 2021. The note is secured by a mortgage on the real estate occupied by the Company and owned by Dan Road Associates and, until the deconsolidation on June 1, 2017, limited personal guarantees from certain affiliates.

85 Dan Road Associates has a mortgage note payable to a bank owed in monthly installments and bearing interest at the LIBOR rate plus 185 basis points. The note matures in October 2022. The note is secured by a mortgage on the real estate occupied by the Company and owned by 85 Dan Road Associates and, until the deconsolidation on June 1, 2017, limited personal guarantees from certain affiliates.

65 Dan Road Associates has a mortgage note payable to a bank owed in monthly installments and bearing interest at the LIBOR rate plus 185 basis points. The note matures in October 2022. The note is secured by a mortgage on the real estate occupied by the Company and owned by 65 Dan Road Associates and, until the deconsolidation on June 1, 2017, limited personal guarantees from certain affiliates.

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On June 1, 2017, the Real Estate Entities entered into amendments to their respective mortgage notes payable that resulted in the removal of limited personal guarantees that had been provided by certain of our affiliates in respect of these mortgagees. As a result, we determined that the Real Estate Entities no longer met the definition of a variable interest entity, and accordingly, we determined that the Real Estate Entities were no longer required to be consolidated under the variable interest entity model in our consolidated financial statements. In connection with the deconsolidation of the Real Estate Entities, the notes payable associated with these entities were derecognized from our condensed consolidated balance sheet.

NuTech Medical

As part of the consideration for the acquisition of NuTech Medical on March 24, 2017, we agreed to make four quarterly payments of \$1.0 million during the first year following the closing, less a \$0.5 million adjustment for working capital, and a payment of \$4.0 million on the fifteen-month anniversary of the closing. As of December 31, 2018, \$5.0 million remains payable and is accruing interest at a rate of 6% per annum.

Interest Rate Protection

During 2016, 85 Dan Road Associates entered into an interest rate swap agreement with a notional amount of \$8.4 million and a fixed interest rate of 5.04% in connection with its mortgage note payable.

During 2016, 65 Dan Road Associates entered into an interest rate swap agreement with a notional amount of \$6.7 million and fixed interest rate of 5.04% in relation to its mortgage note payable.

During 2016, Dan Road Associates entered into an interest rate swap agreement with a notional amount of \$8.3 million and fixed interest rate of 3.39% in relation to its mortgage note payable.

The interest rate swaps have not been designated as hedging instruments, and as such, the fair value of these instruments was recorded as an asset or liability on the consolidated balance sheet with change in the fair value of the instruments recognized as income or expense in the current period as a component of other income (expense), net in the consolidated statement of operations and comprehensive income (loss).

On June 1, 2017, the Real Estate Entities entered into amendments to their respective mortgage notes, which resulted in the removal of the requirement that certain of our affiliates provide certain personal guarantees in respect of the mortgage loans. As a result, we determined that the Real Estate Entities no longer met the definition of a variable interest entity, and accordingly, we determined that the Real Estate Entities were no longer required to be consolidated under the variable interest entity model. Upon deconsolidation of the Real Estate Entities, the assets and liabilities associated with the interest rate swaps were derecognized.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2018 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
		(in thousands)		
Operating lease obligations (1)	\$ 12,123	\$ 4,530	\$ 7,147	\$ 446
Capital lease obligations (2)	27,100	13,747	8,615	4,738
Debt obligations (3)	48,649	5,641	39,190	3,818
Purchase commitments (4)	6,360	6,360	—	—
Deferred acquisition consideration (5)	5,618	5,618	—	—
Royalty maintenance obligation (6)	150	150	—	—
Total	<u>\$100,000</u>	<u>\$36,046</u>	<u>\$54,952</u>	<u>\$9,002</u>

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- (1) Amounts in the table reflect minimum payments due for our lease of office space and vehicles under operating leases that expire between 2019 and 2023.
- (2) Amounts in the table reflect the total cash payments on our capital lease obligations associated with the Real Estate Entities, including accrued interest of \$4,174. The leases have a ten-year term and expire in December 2022.
- (3) Amounts in the table reflect the contractually required principal and interest payable as of December 31, 2018 pursuant to outstanding borrowings under the Credit Agreement and the ML Agreement. The table reflects principal and interest payments due under the ML Agreement with interest only payments through April 2019 at an interest rate of 10.5%, as well as a final payment of \$1.2 million due upon repayment of all outstanding amounts. The table also reflects interest payments due under the Credit Agreement calculated using an interest rate of 7.25%, which was the applicable interest rate as of December 31, 2018 as well as the outstanding principal due in March 2020 in relation to the line of credit. In March 2019, in connection with entering into the New Credit Agreement, all amounts due under the Credit Agreement, including unpaid principal and accrued interest, and all amounts due under the ML Agreement, including unpaid principal, accrued interest and early termination penalty were repaid with proceeds from the New Credit Agreement and the Credit Agreement and ML Agreement were terminated.
- (4) Amounts in the table reflect purchase commitments to suppliers for raw materials and consumables to be utilized in the manufacturing process.
- (5) Amounts in the table reflect deferred acquisition consideration payable to the sellers of NuTech Medical including interest accruing at a rate of 6% per annum.
- (6) Amounts in the table reflect a royalty maintenance obligation. We are required to make a final payment of \$0.2 million in April 2019.

We are obligated, under certain license agreements, to pay royalties, based on a percentage of net sales of certain licensed products.

Critical Accounting Policies 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, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. Management bases its estimates, assumptions and judgments on historical experience and on various other factors that it believes to be reasonable under the circumstances. Different assumptions and judgments would change the estimates used in the preparation of our consolidated financial statements, which, in turn, could materially change our results from those reported. Management evaluates its estimates, assumptions and judgments on an ongoing basis. Historically, our critical accounting estimates have not differed materially from actual results. However, if our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may also have a material adverse effect on our consolidated statements of operations, liquidity and financial condition.

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

Revenue Recognition

We recognize revenue from product sales upon delivery, after risk of ownership passes to the customer in accordance with a purchase order which includes a fixed price, collection is probable, and no performance obligations exist. Product shipped to customers in advance of the receipt of a purchase order is not recognized as revenue or cost of goods sold until the purchase order is received. We record revenue net of a provision for estimated sales returns, early payment discounts and GPO rebates, which are accrued at the time revenue is recognized, based upon historical experience and specific circumstances.

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Consolidated Variable Interest Entities

We consolidate all entities where there exists a controlling financial interest. We have considered our relationships with certain entities to determine whether we have a variable interest in these entities and, if so, whether we are the primary beneficiary of the relationship.

In determining whether we are the primary beneficiary, we consider, among other things, if we have the authority to direct the activities of the variable interest entity, or VIE, that most significantly impact the entity's economic performance, including determining or limiting the scope or purpose of the VIE, selling or transferring property owned or controlled by the VIE, or arranging financing for the VIE. We also consider whether we have the obligation to absorb losses of or the right to receive benefits from the VIE. We also review all contractual relationships the entities have with other parties to determine if the entities meet the definition of a variable interest entity. We assess our determination of the primary beneficiary on an ongoing basis.

We are the sole tenant in each of the facilities owned by the Real Estate Entities under long-term capital leases. Furthermore, we have made substantial improvements to each of the leased buildings, all of which transfer residual value to us. As a result, the accounts and transactions of the Real Estate Entities are consolidated for financial reporting purposes as VIEs. Although we consolidated all of the assets and liabilities of the Real Estate Entities, the assets of the Real Estate Entities were not available to settle our obligations and the creditors of the Real Estate Entities do not have recourse against our assets, except as provided for contractually. We deconsolidated the Real Estate Entities as of June 1, 2017 due to the removal of certain personal guarantees made by members of our board of directors in respect of mortgages held on the leased properties.

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 returns. 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, geographic 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.

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Goodwill and Other Intangible Assets

Business combinations are accounted for under the acquisition method. The total cost of an acquisition is allocated to the underlying identifiable net assets, based on their respective estimated fair values as of the acquisition date. Determining the fair value of assets acquired and liabilities assumed requires management's judgment and 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. The excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

Goodwill is tested for impairment by reporting unit annually as of December 31 or more frequently when events or changes in circumstances indicate that the asset might be impaired. Examples of such events or circumstances include, but are not limited to, a significant adverse change in legal or business climate, an adverse regulatory action or unanticipated competition.

Management first assesses qualitative factors to determine whether the existence of events or circumstances would indicate that it is more likely than not that our fair value is less than its carrying amount. If after assessing the totality of events or circumstances, we were to determine that it is more likely than not that our fair value is less than its carrying amount, then we would perform a quantitative impairment test.

Impairment is tested by comparing the fair value of the reporting unit to our carrying value. If the fair value 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.

Identifiable intangible assets include developed technology and patents, trade names, trademarks, independent sales agency networks and non-compete agreements obtained through business acquisitions. We amortize our identifiable definite lived intangible assets over the estimated useful lives of each asset. When we determine that the carrying value of identifiable intangible assets may not be recoverable based upon the existence of one or more of the above indicators of impairment, the measurement of any impairment is determined by the excess of the carrying value over the fair value of the asset or asset group and the carrying value is reduced as appropriate.

There were no impairments of goodwill during 2018, 2017 or 2016.

Our estimates of discounted cash flows may differ from actual cash flows due to, among other things, economic conditions, changes to our business model or changes in operating performance. Significant differences between these estimates and actual cash flows could materially affect our future financial results. These factors increase the risk of differences between projected and actual performance that could impact our future estimates of the Company's fair value.

Impairment of Long-Lived Assets

We review other 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. When such an event occurs, management 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.

There were no impairments of long-lived assets during 2018, 2017 or 2016.

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Income Taxes

We provide for income taxes using the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the effect of all temporary differences between financial statement carrying amounts and the tax bases of assets and liabilities. 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 if based upon the weight of available evidence, it is more likely than not that some of all of the deferred tax assets will not be realized. Annually, management evaluates the recoverability of deferred taxes and the level of adequacy of the valuation allowance.

We recognize 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 had a greater than 50% likelihood of being realized upon ultimate settlement.

Valuation of Interest Rate Swaps

The Real Estate Entities utilize interest rate swaps to manage the economic impact of fluctuations in interest rates and do not use interest rate swaps for speculative or trading purposes. Periodically, the Real Estate Entities enter into interest rate swap agreements to modify the interest characteristics of the outstanding debt. The interest rate swaps have not been designated as hedging instruments, and as such, the fair value of these instruments is recorded as an asset or liability on the consolidated balance sheet with change in the fair value of the instruments recognized as income or expense in the current period as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss. The interest rate swaps are valued based on the prevailing market yield curve on the date of measurement.

On June 1, 2017, the Real Estate Entities entered into amendments to their respective mortgage notes that resulted in the removal of the requirement that members of our board of directors provide personal guarantees for the loans. As a result, we determined that the Real Estate Entities no longer met the definition of a variable interest entity, and accordingly, we determined that the Real Estate Entities were no longer required to be consolidated under the variable interest entity model. Upon deconsolidation of the Real Estate Entities, the assets and liabilities associated with the interest rate swaps were derecognized.

Valuation of Warrant Liability

In connection with the 2016 Loans, we issued warrants to purchase our common stock to the lenders, who are affiliates of ours. We classified the warrants as a liability on our consolidated balance sheets because each warrant provides for down round protection, which provides that the exercise price of the warrants be adjusted if we issue equity at a price that is below the current exercise price of the warrants. The warrant liability was initially recorded at fair value and was subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability were recognized as a component of other income (expense), net in the consolidated statement of operations. Changes in the fair value of the warrant liability were recognized until the warrants were exercised immediately prior to the closing of the Avista Merger on December 10, 2018.

We utilized a Binomial Lattice pricing model with five steps of the binomial tree to estimate the fair value of the warrant liability. We assess these assumptions and estimates on a quarterly basis as additional information impacting the assumptions is obtained. Estimates and assumptions impacting the fair value measurement included the estimated probability of adjusting the exercise price of the warrants, the number of shares for which the warrants will be exercisable, the fair value per share of the underlying common shares issuable upon exercise of the warrants, the remaining contractual term of the warrants, the risk free interest rate, the expected dividend yield, and the expected volatility of the price of the underlying shares of Class A common stock. We determined the fair value per share of our Class A common stock by completing a third party valuation (see

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“—Determination of the Fair Value of Common Stock” below). We have historically been a private company and lack company specific historical and implied volatility information of our shares. Therefore, we estimated the expected share volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrants. The risk free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. We estimated a 0% expected dividend yield based on the fact that we have never paid or declared dividends and do not intend to do so in the foreseeable future.

Valuation of Forfeiture Rights

In connection with the acquisition of NuTech Medical, we issued shares of common stock that are forfeitable by the sole stockholder of NuTech Medical upon the occurrence of the FDA requiring approval of certain products acquired from NuTech Medical. The fair value of the forfeiture rights was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the forfeiture right asset was determined by considering as inputs the type and probability of occurrence of FDA requiring approval, the number of shares of common stock to be forfeited and the fair value per share of the Class A common stock by completing a third party valuation of the Class A common stock. The fair value of our Class A common stock was determined using the probability weighted expected return method (“PWERM”), which considered the equity holders return under various liquidity event scenarios.

Valuation of Contingent Purchase Earn out

In connection with our acquisition of Dermagraft from Shire, we recognized a contingent purchase earn out that was valued by management with input from an independent third party valuation firm based on future probability weighted expected pay outs as of the date of acquisition and each subsequent reporting date.

Valuation of Redeemable Common Stock

In connection with our acquisition of NuTech Medical, we issued shares of Class A common stock which was recorded at fair value at the time of acquisition. The shares included a put right allowing the holder to put the shares back to Organogenesis Holdings Inc. at an agreed-upon exercise price on the second anniversary of the acquisition. The shares were classified as temporary equity and had been accreted to the full redemption amount. The shares have the same rights and preferences as common stock. In December 2018, we received notification that the put option will be exercised and therefore, we reclassified the carrying value from temporary equity to a current liability which is expected to be paid in March 2019.

Stock-Based Compensation

We measure stock-based awards granted to employees and directors based on the fair value on the date of the 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 the consolidated financial statements 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 stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. Historically there has been no public market for Organogenesis Inc. common stock, and as such we lack company-specific historical and implied volatility information for its common stock prior to the Avista

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Merger. 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 common stock and do not expect to pay any cash dividends in the foreseeable future.

Determination of the Fair Value of Common Stock

Prior to the closing of the Avista Merger in December 2018, there was no public market for the shares of Organogenesis Inc. common stock. The estimated fair value of its common stock had been determined by its board of directors as of the date of each option grant, with input from management, considering third-party valuations of its common stock as well as its board of directors’ assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent third-party valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants’ Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Following the closing of the Avista Merger, the fair value of our Class A common stock is determined based on the quoted market price of our Class A common stock.

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 and Adopted Accounting Pronouncements

We have reviewed all recently issued standards as disclosed in Note 2 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K. We are currently evaluating the impact that adoption of the standards will have on our financial position, results of operations and cash flows.

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 and the use of financial instruments to manage our exposure to such risk.

Interest Rate Risk

As of December 31, 2018, we had \$26.5 million of borrowings outstanding under our line of credit. Borrowings under the line of credit bears interest at variable rates. Based on the principal amount outstanding as of December 31, 2018, an immediate 10% change in the interest rate would not have a material impact on our debt related obligations, financial position or results of operations. All of our other outstanding indebtedness bear interest at fixed rates and, therefore, do not expose us to interest rate risk.

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,

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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-54 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, 2018. 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.

Management identified material weaknesses in our internal control over financial reporting, which is an integral component of our disclosure controls and procedures. 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 annual or interim financial statements will not be prevented or detected on a timely basis. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, our stock price.

During the periods presented in the consolidated financial statements and continuing at December 31, 2018, our management team identified material weaknesses in our internal control over financial reporting relating to (i) our lack of a sufficient complement of personnel with an appropriate level of knowledge and experience in the application of GAAP commensurate with our financial reporting requirements and (ii) our lack of resources necessary to implement an appropriate level of review controls to properly evaluate the completeness and accuracy of the transactions we enter into.

The material weaknesses are as follows:

- We did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including controls over the preparation and review of account reconciliations and journal entries.

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- We did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose certain complex transactions, including the recapitalization and related debt extinguishment and conversion.

Although the Company has made significant progress in remediating the aforementioned deficiencies, management did not perform sufficient control testing to conclude that the material weaknesses were remediated and therefore some of the control deficiencies continued to exist as of December 31, 2018.

The Company is currently taking actions to remediate the deficiencies in its internal controls over financial reporting and is implementing additional processes and controls designed to address the underlying causes associated with the above-mentioned deficiencies. The Company is committed to remediating the deficiencies described above and commenced remediation efforts during 2018 that will continue into fiscal year 2019. The Company's internal control remediation efforts include the following:

- We added additional accounting resources, including a Corporate Controller, who have the requisite background and knowledge in the application of GAAP.
- We engaged external experts to complement internal resources and to provide support related to more complex applications of GAAP. We will continue to utilize outside resources, as necessary, in fiscal year 2019 to supplement our internal team.
- We began the implementation of a new company-wide enterprise resource planning system and are in the process of designing effective financial and information technology general controls (ITGCs) over the system.
- We formalized documentation of certain policies throughout the year.
- We enhanced our process in accounting for, and documenting our positions related to, our accounting topics throughout the year.

In addition to implementing and refining the above activities, we expect to engage in additional activities in fiscal year 2019, including:

- We have engaged an outside firm to assist management with:
 - Enhancing the execution of our 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;
 - Reviewing our current processes, procedures and systems to identify opportunities to enhance the design of each process and to include additional control activities that will ensure all transactions are properly recorded;
 - Developing a monitoring protocol that will allow 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 assess whether the company is sufficiently staffed to meet its design objectives for internal control over financial reporting and whether the appropriate resources are performing the control activities.
- We will continue to report regularly to the audit committee on the progress and results of the remediation plan, including the identification, status and resolution of internal control deficiencies.

The Company believes these actions will be effective in remediating the deficiencies described above. As the Company continues to evaluate and work to improve its internal control over financial reporting, management may determine to take additional measures to address the deficiencies or determine to modify the remediation plan described above. Until the remediation steps set forth above are fully implemented and operating for a sufficient period of time, the material weaknesses described above will continue to exist.

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Based on the evaluation of our disclosure controls and procedures as of December 31, 2018, and due to the material weaknesses described above, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were not effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

Other than in connection with executing upon the implementation of the remediation plan outlined above, there were no changes in our internal control over financial reporting during the year-ended December 31, 2018 that have materially affected, or are reasonably likely to 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 2018 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

<u>Exhibit No.</u>	<u>Exhibit</u>
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)
2.4	Transaction Agreement, dated August 21, 2017, by and among Avista Healthcare Public Acquisition Corp., Avista Healthcare Merger Sub, Inc., Avista Healthcare NewCo, LLC and Envigo International Holdings, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed on August 22, 2017)
2.5	Amendment No. 1 to the Transaction Agreement, dated as of November 22, 2017, by and among Avista Healthcare Public Acquisition Corp., Envigo International Holdings, Inc., Avista Healthcare Merger Sub, Inc. and Avista Healthcare NewCo, LLC (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 November 22, 2017)
2.6	Amendment No. 2 to the Transaction Agreement, dated as of December 22, 2017, by and among Avista Healthcare Public Acquisition Corp., Envigo International Holdings, Inc., Avista Healthcare Merger Sub, Inc. and Avista Healthcare NewCo, LLC (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 26, 2017)
2.7	Amendment No. 3 to the Transaction Agreement, dated as of January 21, 2018, by and among Avista Healthcare Public Acquisition Corp., Envigo International Holdings, Inc., Avista Healthcare Merger Sub, Inc. and Avista Healthcare NewCo, LLC (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 January 22, 2018)

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<u>Exhibit No.</u>	<u>Exhibit</u>
2.8	<u>Amendment No. 4 to the Transaction Agreement, dated as of February 9, 2018, by and among Avista Healthcare Public Acquisition Corp., Envigo International Holdings, Inc., Avista Healthcare Merger Sub, Inc. and Avista Healthcare NewCo, LLC (incorporated by reference to Exhibit 2.5 to the Company's Registration Statement on Form S-4/A (File No. 333-221734) filed with the SEC on February 9, 2018).</u>
2.9	<u>Mutual Termination Agreement, dated February 14, 2018, by and among Avista Healthcare Public Acquisition Corp., Avista Healthcare Merger Sub, Inc., Avista Healthcare NewCo, LLC and Envigo International Holdings, Inc. (incorporated by reference to Exhibit 2.6 to the Company's Annual Report on Form 10-K (File No. 001-37906) filed with the SEC on March 14, 2018).</u>
3.1	<u>Certificate of Incorporation of ORGO (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018).</u>
3.2	<u>Bylaws of ORGO (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018).</u>
4.1	<u>Replacement Common Stock Purchase Warrant issued to Massachusetts Capital Resource Company on November 3, 2010 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018).</u>
4.2	<u>Replacement Common Stock Purchase Warrant issued to Life Insurance Community Investment Initiative, LLC on November 3, 2010 (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018).</u>
4.3	<u>Specimen Warrant Certificate (incorporated by reference to Exhibit 4.3 filed with the Form S-1 filed by the Company on September 2, 2016).</u>
4.4	<u>Specimen Warrant Certificate (incorporated by reference to Exhibit C of Exhibit 4.2 to the Company's Registration Statement on Form S-4/A (File No. 333-227090) filed with the SEC on August 29, 2018).</u>
10.1	<u>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).</u>
10.2	<u>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).</u>
10.3†	<u>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).</u>
10.4	<u>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).</u>
10.5	<u>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).</u>
10.6	<u>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).</u>

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<u>Exhibit No.</u>	<u>Exhibit</u>
10.7	<u>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)</u>
10.8	<u>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)</u>
10.9	<u>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)</u>
10.10	<u>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)</u>
10.11	<u>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)</u>
10.12	<u>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)</u>
10.13‡	<u>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)</u>
10.14‡	<u>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)</u>
10.15‡	<u>Employee Letter Agreement dated as of July 15, 2016 by and between Organogenesis Inc. and Timothy Cunningham (incorporated by reference to Exhibit 10.15 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)</u>
10.16‡	<u>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)</u>
10.17‡	<u>Employee Agreement dated as of March 18, 2017 by and between Organogenesis Inc. and Howard P. Walthall, Jr., as amended by that certain First Amendment dated as of October 10, 2017 (incorporated by reference to Exhibit 10.17 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)</u>
10.18‡	<u>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)</u>

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<u>Exhibit No.</u>	<u>Exhibit</u>
10.19‡	<u>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)</u>
10.20	<u>Separation Agreement dated as of March 4, 2015 by and between Organogenesis Inc. and Geoff MacKay (incorporated by reference to Exhibit 10.20 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)</u>
10.21	<u>Secured Promissory Note dated November 17, 2010 issued by Geoff MacKay and payable to Organogenesis Inc. (incorporated by reference to Exhibit 10.21 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)</u>
10.22	<u>Secured Promissory Note dated July 1, 2011 issued by Geoff MacKay and payable to Organogenesis Inc. (incorporated by reference to Exhibit 10.22 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)</u>
10.23	<u>Secured Promissory Note dated July 3, 2012 issued by Geoff MacKay and payable to Organogenesis Inc. (incorporated by reference to Exhibit 10.23 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)</u>
10.24	<u>Credit Agreement dated as of March 21, 2017 by and among Organogenesis Inc., the Lenders party thereto and Silicon Valley Bank, as Administrative Agent, Issuing Lender and Swingline Lender, as amended by that certain Joinder, Assumption and First Amendment to Credit Agreement dated as of March 24, 2017, as amended by that certain Second Amendment to Credit Agreement and Amendment to Guarantee and Collateral Agreement dated as of August 10, 2017, as amended by that certain Third Amendment to Credit Agreement dated as of November 7, 2017, as amended by that certain Waiver and Fourth Amendment to Credit Agreement dated as of February 9, 2018, as amended by that certain Fifth Amendment to Credit Agreement dated as of April 5, 2018, as amended by that certain Forbearance and Sixth Amendment to Credit Agreement dated as of May 23, 2018, as amended by that certain Consent dated August 17, 2018, as amended by that certain Seventh Amendment to Credit Agreement and Amendment to Consent Agreement dated as of October 31, 2018 (incorporated by reference to Exhibit 10.24 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)</u>
10.25	<u>Master Lease Agreement dated as of April 28, 2017 by and among Organogenesis Inc., Prime Merger Sub, LLC and Eastward Fund Management, LLC (incorporated by reference to Exhibit 10.25 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)</u>
10.26	<u>Consent Regarding Subordination Agreement dated as of December 15, 2017, by and between Silicon Valley Bank, Eastward Fund Management, LLC, Organogenesis Inc. and Prime Merger Sub, LLC (incorporated by reference to Exhibit 10.26 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)</u>
10.27‡	<u>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)</u>
10.28‡	<u>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)</u>
10.29‡	<u>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)</u>
10.30‡	<u>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)</u>

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<u>Exhibit No.</u>	<u>Exhibit</u>
10.31‡	<u>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)</u>
10.32‡	<u>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)</u>
10.33‡	<u>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)</u>
10.34††	<u>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)</u>
10.35	<u>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)</u>
10.36	<u>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)</u>
10.37*	<u>Exchange Agreement, dated August 17, 2018, by and among Avista Healthcare Public Acquisition Corp. and certain lenders listed on Schedule A therein.</u>
10.38	<u>Eighth Amendment to Credit Agreement and Amendment to Consent Agreement dated as of December 31, 2018 by and among Organogenesis Inc., Prime Merger Sub, LLC and Silicon Valley Bank (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 January 7, 2019)</u>
10.39	<u>Warrant Agreement, dated as of October 10, 2016, between the Company and Continental Stock Transfer & Trust Company, as warrant agent (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on October 14, 2016)</u>
10.40	<u>Form of Warrant Agreement to be entered into by Avista Healthcare Public Acquisition Corp. and Continental Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-4/A (File No. 333-227090) filed with the SEC on August 29, 2018)</u>
10.41	<u>Letter Agreement, dated October 10, 2016, among the Company, its officers and directors and Avista Acquisition Corp. (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 October 14, 2016)</u>
10.42	<u>Investment Management Trust Agreement, dated as of October 10, 2016, between the Company and Continental Stock Transfer & Trust Company, as trustee (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 October 14, 2016)</u>
10.43	<u>Administrative Services Agreement, dated October 10, 2016, between the Company and Avista Capital Holdings, L.P. (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 October 14, 2016)</u>
10.44	<u>Private Placement Warrants Purchase Agreement dated as of October 10, 2016, among the Company, Avista Acquisition Corp. and certain other purchasers named therein (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 October 14, 2016)</u>

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<u>Exhibit No.</u>	<u>Exhibit</u>
10.45	<u>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)</u>
10.46	<u>Promissory Note, dated September 1, 2016, issued to Avista Acquisition Corp. (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-213465) filed with the SEC on September 2, 2016)</u>
10.47	<u>Securities Subscription Agreement, dated December 14, 2015, between the Company and Avista Acquisition Corp. (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-213465) filed with the SEC on September 2, 2016)</u>
10.48	<u>Parent Sponsor Letter Agreement, dated August 21, 2017, by and among Avista Healthcare Public Acquisition Corp., Avista Acquisition Corp., and certain individuals (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 August 22, 2017)</u>
10.49	<u>Amendment No. 1, dated as of October 4, 2018, to the Investment Management Trust Agreement, dated as of October 10, 2016, between the Company and Continental Stock Transfer & Trust Company, as trustee (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 October 4, 2018)</u>
10.50	<u>Amended and Restated Letter Agreement, dated January 21, 2018, by and among Avista Healthcare Public Acquisition Corp., Avista Acquisition Corp., Håkan Björklund, Charles Harwood, Brian Markison and Robert O'Neil (incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on January 22, 2018)</u>
10.51	<u>Parent Sponsor Letter Agreement, dated August 17, 2018, by and among Avista Healthcare Public Acquisition Corp., Avista Acquisition Corp., and certain individuals. (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 17, 2018)</u>
10.52	<u>Subscription Agreement, dated August 17, 2018, by and between Avista Healthcare Public Acquisition Corp., Avista Capital Partners IV, L.P. and Avista Capital Partners IV (Offshore), L.P. (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 17, 2018)</u>
10.53	<u>Amended Letter Agreement, dated October 30, 2018, by and among Avista Healthcare Public Acquisition Corp., its officers and directors and Avista Acquisition Corp. (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 30, 2018)</u>
16.1	<u>Letter to Securities and Exchange Commission from Marcum LLP, dated December 10, 2018 (incorporated by reference to Exhibit 16.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)</u>
21.1*	<u>Subsidiaries of Organogenesis Holdings Inc.</u>
23.1*	<u>Consent of RSM US LLP</u>
31.1*	<u>Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934</u>
31.2*	<u>Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934</u>

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<u>Exhibit No.</u>	<u>Exhibit</u>
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, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2018 and December 31, 2017 of Organogenesis Holdings Inc., (ii) Consolidated Statements of Operations for the years ended December 31, 2018, 2017, and 2016 of Organogenesis Holdings Inc., (iii) Consolidated Statements of Redeemable Common Stock and Stockholders' Equity (Deficit) for the years ended December 31, 2018, 2017, and 2016 of Organogenesis Holdings Inc., (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017, and 2016 of Organogenesis Holdings Inc., and (v) Notes to Consolidated Financial Statements of Organogenesis Holdings Inc.

* Filed herewith.

† Confidential treatment requested as to certain portions, which portions have been omitted and filed separately with the SEC.

†† 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 18, 2019

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Gary S. Gillheeney, Sr.</u> Gary S. Gillheeney, Sr.	Chief Executive Officer, President and Director (Principal Executive Officer)	March 18, 2019
<u>/s/ Timothy M. Cunningham</u> Timothy M. Cunningham	Chief Financial Officer (Principal Financial and Accounting Officer)	March 18, 2019
<u>/s/ Alan A. Ades</u> Alan A. Ades	Director	March 18, 2019
<u>/s/ Maurice Ades</u> Maurice Ades	Director	March 18, 2019
<u>/s/ Albert Erani</u> Albert Erani	Director	March 18, 2019
<u>/s/ Arthur S. Leibowitz</u> Arthur S. Leibowitz	Director	March 18, 2019
<u>/s/ Wayne D. Mackie</u> Wayne D. Mackie	Director	March 18, 2019
<u>/s/ Glenn H. Nussdorf</u> Glenn H. Nussdorf	Director	March 18, 2019
<u>/s/ Joshua Tamaroff</u> Joshua Tamaroff	Director	March 18, 2019

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ORGANOGENESIS HOLDINGS INC.

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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. (formerly Avista Healthcare Public Acquisition Corp.) and its subsidiaries (the Company) as of December 31, 2018 and 2017, 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, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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 18, 2019

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ORGANOGENESIS HOLDINGS INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash	\$ 21,291	\$ 2,309
Restricted cash	114	49
Accounts receivable, net	34,077	28,124
Inventory	13,321	14,270
Prepaid expenses and other current assets	2,328	4,399
Contingent consideration forfeiture rights	—	589
Total current assets	71,131	49,740
Property and equipment, net	39,623	42,112
Notes receivable from related parties	477	413
Intangible assets, net	26,091	29,759
Goodwill	25,539	25,539
Deferred tax asset	238	424
Other assets	579	735
Total assets	<u>\$ 163,678</u>	<u>\$148,722</u>
Liabilities, Redeemable Common Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Deferred acquisition consideration	\$ 5,000	\$ 5,000
Redeemable common stock liability	6,762	—
Current portion of notes payable	2,545	—
Current portion of capital lease obligations	7,501	5,369
Accounts payable	19,165	19,053
Accrued expenses and other current liabilities	25,415	22,551
Total current liabilities	66,388	51,973
Line of credit	26,484	17,618
Notes payable, net of current portion	12,578	14,816
Long-term debt - affiliates	—	52,142
Due to affiliates	—	4,500
Warrant liability	—	2,238
Deferred rent, net of current portion	130	74
Capital lease obligations, net of current portion	10,154	12,390
Other liabilities	903	1,526
Total liabilities	116,637	157,277
Commitments and contingencies (Notes 20 and 24)		
Redeemable common stock, \$0.0001 par value; 728,549 shares issued and outstanding at December 31, 2018 and 2017.	—	6,762
Stockholders' equity (deficit):		
Common stock, \$0.0001 par value; 400,000,000 and 81,200,000 shares authorized at December 31, 2018 and 2017, respectively; 91,261,412 and 66,983,138 shares issued and outstanding at December 31, 2018 and 2017, respectively.	9	6
Additional paid-in capital	177,272	50,086
Accumulated deficit	(130,240)	(65,409)
Total stockholders' equity (deficit)	47,041	(15,317)
Total liabilities, redeemable common stock and stockholders' equity (deficit)	<u>\$ 163,678</u>	<u>\$148,722</u>

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,		
	2018	2017	2016
Net revenue	\$ 193,449	\$ 198,508	\$ 138,732
Cost of goods sold	68,808	61,220	48,201
Gross profit	124,641	137,288	90,531
Operating expenses:			
Selling, general and administrative	161,961	133,717	93,029
Research and development	10,742	9,065	6,277
Write-off of deferred offering costs	3,494	—	—
Total operating expenses	176,197	142,782	99,306
Loss from operations	(51,556)	(5,494)	(8,775)
Other income (expense), net:			
Interest expense	(10,853)	(8,139)	(5,627)
Interest income	64	129	153
Change in fair value of warrants	(469)	(1,037)	(737)
Loss on the extinguishment of debt	(2,095)	—	—
Other expense, net	162	(9)	285
Total other income (expense), net	(13,191)	(9,056)	(5,926)
Net loss before income taxes	(64,747)	(14,550)	(14,701)
Income tax (expense) benefit	(84)	7,025	(65)
Net loss	(64,831)	(7,525)	(14,766)
Net income attributable to non-controlling interest in affiliates	—	863	2,221
Net loss attributable to Organogenesis Holdings Inc.	\$ (64,831)	\$ (8,388)	\$ (16,987)
Net loss per share attributable to Organogenesis Holdings Inc.—basic and diluted	\$ (0.94)	\$ (0.14)	\$ (0.27)
Weighted average common shares outstanding—basic and diluted	69,318,456	63,876,767	63,196,067

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 Organogenesis Holdings Inc. Stockholders' Equity	Non- controlling Interest in Affiliates	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount					
Balances as of December 31, 2015	—	—	63,872,057	6	33,090	(38,660)	(5,564)	9,078	3,514
Stock-based compensation expense	—	—	—	—	473	—	473	—	473
Non-controlling interest distributions	—	—	—	—	—	—	—	(5,200)	(5,200)
Net income (loss)	—	—	—	—	—	(16,987)	(16,987)	2,221	(14,766)
Balances as of December 31, 2016	—	—	63,872,057	6	33,563	(55,647)	(22,078)	6,099	(15,979)
Shares issued in connection with NuTech Medical acquisition	728,549	6,339	2,914,197	—	10,270	—	10,270	—	10,270
VIE deconsolidation	—	—	—	—	—	(1,374)	(1,374)	(7,962)	(9,336)
Extinguishment of subordinated notes - affiliates	—	—	—	—	4,577	—	4,577	—	4,577
Exercise of stock options	—	—	196,884	—	221	—	221	—	221
Warrants issued in connection with notes payable	—	—	—	—	959	—	959	—	959
Cash contributions from members of affiliates	—	—	—	—	—	—	—	1,000	1,000
Stock-based compensation expense	—	—	—	—	919	—	919	—	919
Accretion of redeemable common shares	—	423	—	—	(423)	—	(423)	—	(423)
Net loss	—	—	—	—	—	(8,388)	(8,388)	863	(7,525)
Balance as of December 31, 2017	728,549	\$ 6,762	66,983,138	6	50,086	(65,409)	(15,317)	—	(15,317)
Proceeds from equity financing, net of issuance costs of \$270	—	—	15,561,473	2	91,728	—	91,730	—	91,730
Recapitalization costs	—	—	—	—	(11,206)	—	(11,206)	—	(11,206)
Exercise of stock options	—	—	76,654	—	119	—	119	—	119
Exercise of common stock warrants	—	—	746,475	—	2,707	—	2,707	—	2,707
Issuance of common stock for extinguishment of debt	—	—	6,502,679	1	42,763	—	42,764	—	42,764
Common stock issued in exchange for AHPAC shares	—	—	1,390,993	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	1,075	—	1,075	—	1,075
Notification of exercise of put option of redeemable common stock	—	(6,762)	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	(64,831)	(64,831)	—	(64,831)
Balance as of December 31, 2018	728,549	\$ —	91,261,412	\$ 9	\$ 177,272	\$ (130,240)	\$ 47,041	\$ —	\$ 47,041

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,		
	2018	2017	2016
Cash flows from operating activities:			
Net loss	\$(64,831)	\$ (7,525)	\$(14,766)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	3,309	3,591	5,702
Amortization of intangible assets	3,669	2,037	1,617
Non-cash interest expense	3,300	2,415	1,662
Non-cash interest income	(64)	(111)	(108)
Non-cash rent expense	56	70	(26)
Deferred tax (benefit) expense	186	(7,301)	—
Loss (gain) on disposal of property and equipment	1,209	(8)	(9)
Impairment of notes receivable	—	113	—
Write-off of deferred offering costs	3,494	—	—
Provision recorded for sales returns and doubtful accounts	1,157	1,166	25
Provision recorded for inventory reserve	5,949	5,497	7,472
Stock-based compensation	1,075	919	473
Change in fair value of warrant liability	469	1,037	737
Loss on extinguishment of debt	2,095	—	—
Change in fair value of interest rate swap	—	6	(253)
Changes in fair value of forfeiture rights	589	(212)	—
Changes in operating assets and liabilities:			
Accounts receivable	(7,110)	(7,010)	(6,556)
Inventory	(5,000)	(3,817)	(5,367)
Prepaid expenses and other current assets	(1,414)	(2,680)	1,009
Accounts payable	(60)	3,967	33
Accrued expenses and other current liabilities	368	982	1,110
Accrued interest—affiliate debt	(9,241)	3,190	2,339
Other liabilities	56	100	35
Net cash used in operating activities	(60,739)	(3,574)	(4,871)
Cash flows from investing activities:			
Purchases of property and equipment	(1,857)	(2,426)	(1,361)
Proceeds from disposal of property and equipment	1	8	115
Acquisition of NuTech Medical, net of cash acquired	—	(11,790)	—
VIE deconsolidation	—	(666)	—
Net cash used in investing activities	(1,856)	(14,874)	(1,246)
Cash flows from financing activities:			
Line of credit borrowings (repayment), net	8,866	12,749	(2,399)
Notes payables—related party borrowings (repayment), net	—	(1,335)	2,398
Repayment of debt and debt issuance cost on affiliate debt	(22,680)	—	—
Proceeds from long-term debt—affiliates	15,000	—	17,204
Proceeds from equity financing, net of issuance costs	92,000	—	—
Payment of equity issuance costs	(270)	—	—
Payment of recapitalization costs	(11,206)	—	—
Repayment of notes payable	(10)	(6,325)	(5,250)

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	Year Ended December 31,		
	2018	2017	2016
Distributions to non-controlling interest in affiliates	—	—	(5,200)
Borrowing from affiliates	—	—	23
Proceeds from the exercise of stock options	119	221	—
Cash contributions from members of affiliates	—	1,000	—
Proceeds from notes payable—master lease	—	16,000	—
Payments of deferred acquisition consideration	—	(2,500)	—
Payment of debt issuance costs	(177)	(862)	—
Net cash provided by financing activities	81,642	18,948	6,776
Change in cash and restricted cash	19,047	500	659
Cash and restricted cash, beginning of year	2,358	1,858	1,199
Cash and restricted cash, end of year	<u>\$21,405</u>	<u>\$ 2,358</u>	<u>\$ 1,858</u>
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 7,553	\$ 5,715	\$ 3,965
Cash paid for income taxes	\$ 8	\$ 96	\$ 29
Supplemental disclosure of non-cash investing and financing activities:			
Fair value of shares issued in connection with investor debt settlement	\$42,764	\$ —	\$ —
Fair value of shares issued in connection with settlement of warrants	\$ 2,707	\$ —	\$ —
Common stock issued in exchange for AHPAC shares	\$ 1	\$ —	\$ —
Notice of put option exercise of redeemable common shares	\$ 6,762	\$ —	\$ —
Fair value of warrant issued in connection with Subordinated Notes	\$ —	\$ —	\$ 464
Debt issuance costs included in accrued expenses	\$ —	\$ —	\$ 680
Purchases of property and equipment in accounts payable and accrued expenses	\$ 172	\$ 764	\$ 63
Fair value of warrant issued in connection with notes payable	\$ —	\$ 959	\$ —
Extinguishment of Subordinated Notes—affiliates	\$ —	\$ 4,577	\$ —
Accretion of redeemable common stock	\$ —	\$ 423	\$ —
Shares issued in connection with NuTech Medical acquisition	\$ —	\$16,609	\$ —
Deconsolidation of variable interest entities, net of cash	\$ —	\$ 9,052	\$ —
Issuance of deferred acquisition consideration	\$ —	\$ 7,500	\$ —
Issuance of contingent consideration forfeiture rights	\$ —	\$ 377	\$ —

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

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. The Company’s products have been shown through clinical and scientific studies to support and, in some cases, accelerate tissue healing and improve patient outcomes. The Company is advancing the standard of care in each phase of the healing process through multiple breakthroughs in tissue engineering and cell therapy. The Company’s 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. The Company offers 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. The Company’s mission is to provide integrated healing solutions that substantially improve medical outcomes and the lives of patients while lowering the overall cost of care.

The Company offers a comprehensive portfolio of products in the markets it serves that address patient needs across the continuum of care. The Company has and intends 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 the Company’s products. The majority of the existing and pipeline products in the Company’s portfolio have Premarket Application approval, Business License Applicant approval or Premarket Notification 510(k) clearance from the United States Food and Drug Administration (“FDA”). Given the extensive time and cost required to conduct clinical trials and receive FDA approvals, the Company believes its data and regulatory approvals provide us a strong competitive advantage. The Company’s product development expertise and multiple technology platforms provide a robust product pipeline which the Company believes will drive future growth.

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 Delaware corporation and a direct wholly owned subsidiary of AHPAC (“Avista Merger Sub”) and Organogenesis Inc., a Delaware corporation (“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. In addition, in connection with the Avista Merger, and in accordance with Section 388 of the Delaware General Corporation Law and the Cayman Islands Companies Law (2018 Revision), AHPAC redomesticated as a Delaware corporation (the “Domestication”). After the Domestication, AHPAC changed its name to Organogenesis Holdings Inc. (ORGO).

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 cancelled, extinguished and converted into the right to receive 2.03 shares of ORGO Class A common stock, par value \$0.0001 per share, (after giving effect to the Domestication). At the effective time of the Avista Merger, 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 (other than warrants that expired, were exercised or were deemed automatically net exercised immediately prior to the Avista Merger) 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.

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The Avista Merger was accounted for as a reverse merger in accordance with accounting principles generally accepted in the United States (“GAAP”). Under this method of accounting, AHPAC was treated as the “acquired” company for accounting purposes. This determination was primarily based on Organogenesis Inc.’s equity holders having a majority of the voting power of the combined company, Organogenesis Inc. comprising the ongoing operations of the combined entity, Organogenesis Inc. comprising a majority of the governing body of the combined company, and the Organogenesis Inc.’s senior management comprising the senior management of the combined company. Accordingly, for accounting purposes, 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.

Prior to the completion of the Avista Merger, on August 17, 2018, the PIPE investors also purchased, 6,538,732 shares of ORGO Class A common stock for an aggregate purchase price of \$46,000 (the “Initial Avista Investment”). The Company received the proceeds from the Initial Avista Investment in August 2018.

Concurrently with the completion of the Avista Merger, Avista Capital Partners IV, L.P. and Avista Capital Partners IV (Offshore), L.P. (the “PIPE Investors”) 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 (the “Additional Avista Investment”). The Company received the proceeds from the Additional Avista Investment in December 2018.

Concurrently with the signing of the Avista Merger Agreement, Organogenesis Inc.’s lenders agreed to release the subordination on the affiliate debt and the affiliate guarantee on the term debt, and the holders of the affiliate debt executed and delivered to the Company an exchange agreement whereby such creditors and the Company agreed that, concurrently with the consummation of the Avista Merger, outstanding principal of \$45,746, with a carrying value of \$40,669, related to the affiliate debt was exchanged for 6,502,679 shares of ORGO Class A common stock and a cash payment of \$35,641, representing \$22,000 of principal and \$13,641 of accrued interest related to all aforementioned affiliate debt 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 satisfied in full and was discharged and terminated.

Acquisition of Nutech Medical, Inc.

In March 2017, the Company purchased Nutech Medical, Inc. (“NuTech Medical”) pursuant to an Agreement of Plan of Merger (“NuTech Merger Agreement”) dated March 18, 2017. As a result of this transaction, NuTech Medical merged with and into Prime Merger Sub, LLC, with Prime Merger Sub, LLC surviving the merger as a wholly-owned subsidiary of the Company. Under the terms of the NuTech Merger Agreement, the Company transferred \$12,000 in cash, \$7,500 of deferred acquisition consideration, 137,543 fully vested common stock options and 3,642,746 shares of the Company’s common stock, of which 728,549 shares are redeemable. Results of operations for NuTech Medical are included in the Company’s consolidated financial statements from the date of acquisition (See Note 5).

Going Concern

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

Through December 31, 2018, the Company 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 common stock and third-party debt. The Company has incurred recurring losses since inception, including net losses of \$64,831, \$8,388, and \$16,987 for the years ended December 31, 2018, 2017 and 2016, respectively. In addition, as of

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December 31, 2018, the Company had an accumulated deficit of \$130,240 and working capital of \$4,743. The Company expects to continue to generate operating losses for the foreseeable future. As of March 18, 2019, the issuance date of the consolidated financial statements for the year ended December 31, 2018, the Company expects that its cash of \$21,291 as of December 31, 2018, plus cash flows from product sales, availability under the New Credit Agreement (see Note 28) with Silicon Valley Bank, which was entered into in March 2019, will be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments through at least March 31, 2020.

The Company may seek to raise additional funding through public and/or private equity financings, debt financings or other strategic transactions. The Company may not be able to obtain funding on acceptable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders.

The Company expects to continue investing in product development, sales and marketing and customer support for its products. The long-term continuation of the Company's business plan is dependent upon the generation of sufficient revenues from its products to offset expenses, capital expenditures, debt service payments, and contingent payment obligations. In the event that the Company does not generate sufficient revenues and is unable to obtain funding, the Company will be forced to delay, reduce, or eliminate some or all of its research and development programs, product portfolio expansion, commercialization efforts or capital expenditures, which could adversely affect the Company's business prospects, ability to meet long-term liquidity needs or the Company may be unable to continue operations.

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

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 and disclosure of contingent assets and liabilities at the date of the financial statements and the reported results of operations during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The consolidated financial statements include the accounts of Organogenesis Holdings Inc. (a Delaware corporation following the Domestication), and its wholly owned subsidiary, Organogenesis Inc. and the wholly owned subsidiaries of Organogenesis Inc., including Organogenesis GmbH (a Switzerland corporation) and Prime Merger Sub, LLC from the acquisition date of March 24, 2017. The accounts of Dan Road Associates, LLC ("Dan Road Associates"), 85 Dan Road Associates, LLC ("85 Dan Road Associates") and Canton 65 Dan Road Associates, LLC ("65 Dan Road Associates") were variable interest entities requiring consolidation (each a "Real Estate Entity," collectively the "Real Estate Entities") through the deconsolidation date of June 1, 2017, as discussed below. 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.

Dan Road Equity I, LLC, a wholly owned subsidiary of Dan Road Associates, and 65 Dan Road SPE, LLC, a wholly owned subsidiary of 65 Dan Road Associates, were each formed in 2011. Dan Road Equity I, LLC and 65 Dan Road, LLC were formed as special purpose entities ("SPEs") solely to own the real property of its

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respective parent. As such, in connection with the formation of the SPEs, Dan Road Associates and 65 Dan Road Associates transferred title to the real property held by them, along with the related mortgages and operations, to Dan Road Equity I and 65 Dan Road, LLC respectively.

On June 1, 2017, the Real Estate Entities entered into amendments to their respective mortgage notes which resulted in the removal of the requirement that the Company's affiliates provide personal guarantees for the mortgages. As a result, the Company determined that the Real Estate Entities no longer met the definition of a variable interest entity, and accordingly, the Company determined that the Real Estate Entities were no longer required to be consolidated under the variable interest entity model. The Real Estate Entities were deconsolidated and the financial statements as of June 1, 2017 derecognized all assets and liabilities of the Real Estate Entities (See Note 4). The results of operations for the years ended December 31, 2017 include the operations of the Real Estate Entities through the date of deconsolidation. The consolidated balance sheet as of December 31, 2018 and December 31, 2017 and the results of operations for the year ended December 31, 2018 do not include the accounts of the Real Estate Entities.

All intercompany balances and transactions have been eliminated in consolidation.

Consolidated Variable Interest Entities

The Company is required to evaluate its relationships with certain entities which meet the definition of a variable interest entity to determine whether consolidation is required under GAAP, as there exists a controlling financial interest. The Company has considered its relationships with certain entities, some of which are wholly-owned by affiliates of the Company, to determine whether it had a variable interest in these entities and, if so, whether the Company is the primary beneficiary of the relationship.

In making the determination that an entity meets the definition of a variable interest entity, the Company assesses various factors including voting rights, right to receive residual gain and losses as well as the ability of the entity's equity at risk to finance the future operations of the entity. Significant judgement is required when evaluating the sufficiency of the equity at risk and the Company considers all relevant relationships the entities have related to financing the operations including but not limited to equity investment, debt financing and personal guarantees of equity holders to secure debt financing.

In evaluating whether or not the Company has a controlling financial interest and would be considered the primary beneficiary of the entity, the Company must determine if it has the ability to control the activities that most significantly impact the economic performance of an entity determined to be a variable interest entity and also if the Company has the obligation to absorb losses or the right to receive residual returns which could be significant to a variable interest entity. The Company considers the following factors in determining if it has the right to control activities of the entity: the purpose and the design of the entity, all relationships the Company has with the entity, as well as relationships affiliates may have with each entity, to determine who has the power to direct the activities that most significantly impact the economic performance of the entity. This evaluation requires consideration of all facts and circumstances relevant to decision-making that affects the entity's future performance and the exercise of professional judgment in deciding which decision making rights are most important. This analysis takes into account power through related parties who also have the ability to assert significant influence on the Company's decision making ability. The Company evaluates all of its economic relationships with variable interest entities to determine the significance of its obligation to absorb losses or right to receive returns including leasing arrangements, residual value guarantees and amounts due to or from the variable interest entities. The Company assesses its determination as the primary beneficiary on an ongoing basis at each balance sheet date.

The Company was the primary tenant in each of the facilities owned by the Real Estate Entities under long-term leases which were determined to be capital leases which would effectively act as a residual guaranty on the value of the assets of the Real Estate Entities. Furthermore, the Company has made substantial improvements to each of the buildings, all of which transfer residual value to the Company.

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As a result, the accounts and transactions of the Real Estate Entities are consolidated, for financial reporting purposes, until derecognized. The non-controlling interest in earnings are reported as net income attributable to non-controlling interest in affiliates in the consolidated statements of operations. Losses generated by the Real Estate Entities prior to 2008, which occurred prior to the adoption of FIN 46 and subsequently ASC 810 were recorded in the Company's retained earnings and remained constant until the Real Estate Entities were deconsolidated on June 1, 2017.

Although the Company consolidated all of the assets and liabilities of the Real Estate Entities, the assets of the Real Estate Entities were not available to settle obligations of the Company and the creditors of the Real Estate Entities did not have recourse against the assets of the Company, except as provided for contractually.

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 decision maker is the Chief Executive Officer. The Company's chief 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 \$114 and \$49 as of December 31, 2018 and 2017, 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 12-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, geographic 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 receivable previously written off are recorded when received.

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Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is recorded on the first-in, first-out method. Work in process and finished goods include materials, labor and allocated overhead. Inventory also includes 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 asset on a straight-line basis. As of December 31, 2018 and 2017, 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 and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the consolidated statement of operations and comprehensive loss. 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 accounts, and depreciated over their respective useful lives.

Goodwill

Business combinations are accounted for under the acquisition method. The total cost of an acquisition is allocated to the underlying identifiable net assets, based on their respective estimated fair values as of the acquisition date. Determining the fair value of assets acquired and liabilities assumed requires management's judgment and 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. Assets acquired and liabilities assumed are recorded at their estimated fair values. The excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

Goodwill is tested for impairment annually as of December 31 or more frequently when events or changes in circumstances indicate that the asset might be impaired. Examples of such events or circumstances include, but are not limited to, a significant adverse change in legal or business climate, an adverse regulatory action or unanticipated competition.

The Company first assesses qualitative factors to determine whether the existence of events or circumstances would indicate that it is more likely than not that the fair value of the reporting unit was less than

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its carrying amount. If after assessing the totality of events or circumstances, the Company were to determine that it is more likely than not that the fair value of the reporting unit is less than its carrying amount, then the Company would perform a quantitative impairment test.

The Company compares the fair value of the reporting unit to 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.

There was no impairment of goodwill identified during the years ended December 31, 2018, 2017 or 2016.

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, independent sales agency networks and non-compete agreements obtained through business acquisitions. Amortization of intangible assets subject to amortization is calculated on the straight-line method based on the following estimated useful lives:

Trade names and trademarks	10-12 years
Developed technology	10-12 years
Independent sales agency network	3 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 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, management 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 on long-lived assets during the years ended December 31, 2018, 2017 or 2016.

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 and comprehensive loss.

The Company had \$0 and \$2,724 of deferred offering costs as of December 31, 2018 and 2017, respectively, in prepaid expenses and other current assets within the consolidated balance sheets. During the year ended December 31, 2018, the Company wrote off deferred offering costs of \$3,494 in connection with an expected

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initial public offering that has since been abandoned by the Company, of which \$770 were incurred during the year ended December 31, 2018. During the year ended December 31, 2018, \$270 of equity issuance costs were recorded to additional paid-in capital against proceeds received from the Initial Avista Investment equity financing transaction.

Warrant Liability

In connection with entering into the subordinated notes agreement (see Note 14), the Company agreed to issue warrants to purchase Class A common stock to the debtors under the agreement. The Company classifies the warrants as a liability on its consolidated balance sheet because each warrant provided for down-round protection which causes the exercise price of the warrants to be adjusted if future equity issuances are below the current exercise price of the warrants. The price of the warrant will also be adjusted any time the price of another equity-linked instrument changes. The warrant liability was initially recorded at fair value upon entering into the Subordinated Notes agreement and was subsequently remeasured to fair value at each reporting date until the warrants were net exercised in December 2018. Changes in the fair value of the warrant liability are recognized as a component of other income (expense), net in the consolidated statement of operations. The liability-classified warrants were exercised in connection with the Avista Merger and the Company has no warrant liability as of December 31, 2018.

Revenue Recognition

Revenue from product sales is recognized upon delivery, after risk of ownership passes to the customer in accordance with a purchase order which includes a fixed price, collection is probable, and no performance obligations exist. Product shipped to customers in advance of the receipt of a purchase order is not recognized as revenue or cost of goods sold until the purchase order is received. Revenue is recorded net of a provision for estimated sales returns and early payment discounts, which are accrued at the time revenue is recognized, based upon historical experience and specific circumstances.

Shipping and Handling

The Company records amounts incurred related to shipping and handling costs as a cost of goods sold.

Product Warranties

Each of the Company's products carry product warranties, which generally provide customers the right to return defective product during the specified warranty period for replacement at no cost to the customer. The Company did not record any reserves for product warranties as of December 31, 2018 or 2017.

Stock-Based Compensation

The Company measures stock-based awards granted to employees 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 recognizes stock-based compensation expense within the consolidated financial statements 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 stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. The Company historically has been a private company and lacks company-specific historical and

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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 expected term of stock options granted to non-employees is equal to the contractual term of the option award. 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.

From 2010 through 2013, the Company had a loan program that permitted certain officers of the Company to borrow funds secured by their individual equity holdings in Company stock and options (see Note 12).

Advertising

Advertising costs are expensed as incurred and are included in selling, general and administrative expense in the consolidated statements of operations. Advertising costs were approximately \$773, \$947, and \$1,196 for the years ended December 31, 2018, 2017 and 2016, respectively.

Research and Development Costs

Research and development expenses relate to the Company's investments in improvements to manufacturing processes, product enhancements to currently available products, and additional investments in the Company's product pipeline and platforms. Research and development costs also include expenses such as clinical trial and regulatory costs. The Company expenses research and development costs as incurred.

Interest Income

Interest income is primarily recognized by the Company for interest earned on Employee Loans (see Note 12) and interest earned by the Real Estate Entities on loans entered into by the entities through the date of deconsolidation on June 1, 2017.

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 income (expense), net. The foreign currency amounts recorded for all periods presented were insignificant.

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 annually 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.

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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 Company's warrant liability was carried at fair value, determined according to Level 3 inputs in the fair value hierarchy described above (see Note 6). The warrant liability was valued utilizing a Binomial Lattice pricing model, which includes both observable and unobservable inputs, which represents a Level 3 measurement (see Note 14). The Company's contingent consideration forfeiture rights asset was carried at fair value, determined according to Level 3 inputs in the fair value hierarchy described above (see Note 6). The fair value of the redeemable common stock liability is carried at fair value, determined according to Level 3 inputs in the fair value hierarchy described above (see Note 6). The fair value of the forfeiture right asset was determined by considering as inputs the type and probability of occurrence of a FDA Event, the number of common shares to be forfeited, which is subject to negotiation, and the fair value per share of its common shares, by completing a third-party valuation of its common shares. The carrying values of outstanding borrowings under the Company's debt arrangements (see Notes 14 and 15) approximate their fair values as determined based on a discounted cash flow model, which represents a Level 3 measurement.

The Company's estimate of the fair value of long-term debt—affiliates is based on the present value of future cash flows calculation. The discount rate applied considered the subordinate nature of this debt to the Company's senior and mezzanine debt and the return a third party would be expected to require for a similar instrument over the estimated time to liquidation. During the year ended December 31, 2018, the long-term debt—affiliates was fully satisfied through a combination of a cash payment and conversion to Class A common stock. As of December 31, 2018 and 2017, the carrying amount for the long-term debt—affiliates and due to affiliates was \$0 and \$57,322. As of December 31, 2018 and 2017, the fair value of the long-term debt—affiliates and due to affiliates was \$0 and \$35,161.

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Net Loss per Share

The Company follows the two-class method when computing net income (loss) per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) attributable to common stockholders is computed by adjusting net income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares. For purpose of this calculation, outstanding stock options, warrants to purchase shares of common stock and unvested restricted stock are considered potential dilutive common shares.

Medical Device Excise Tax

Effective January 1, 2013, the U.S. government implemented a medical device excise tax equal to 2.3% of product sales for companies selling medical device products, which it subsequently suspended for the period from January 1, 2016 to December 31, 2019. There was no medical device excise tax during the years ended December 31, 2018, 2017 or 2016.

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 or 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. As a result, our financial statements may not be comparable to other public companies.

Reclassification of Prior Period Balances

Reclassifications have been made to prior period amounts to conform to the current-year presentation of the reporting of deferred principal payments on outstanding capital lease obligations as a component of the current portion of capital lease obligations on the consolidated balance sheets. These amounts were previously reported as accrued expenses on the consolidated balance sheets. These reclassifications have no effect on the reported net loss or net equity for the years ended December 31, 2018, 2017 and 2016.

Recently Adopted Accounting Pronouncements

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"), which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting

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is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. The adoption of this standard in 2018 did not have a material impact on the consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share Based Payment Accounting* (“ASU 2016-09”), which changes the accounting for certain aspects of share based payments to employees. The new guidance requires excess tax benefits and tax deficiencies to be recorded in the statement of operations when the awards vest or are settled. In addition, cash flows related to excess tax benefits will no longer be separately classified as a financing activity apart from other income tax cash flows. The standard also clarifies that all cash payments made on an employee’s behalf for withheld shares should be presented as a financing activity on the statement of cash flows, and provides an accounting policy election to account for forfeitures as they occur. ASU No. 2016-09 is effective for public entities with annual periods beginning after December 15, 2016, and interim periods within those years. ASU No. 2016-09 is effective for private entities with annual periods beginning after December 15, 2017 and interim periods within fiscal years beginning after December 15, 2018. Early adoption is permitted, but all of the guidance must be adopted in the same period. The adoption of this standard in 2018 did not have a material impact on the Company’s consolidated financial statements.

In October 2016, the FASB issued ASU No. 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other than Inventory* (“ASU 2016-16”), which requires the recognition of the income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. The standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. The adoption of this standard in 2018 did not have a material impact on the consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Classification of Certain Cash Receipts and Cash Payments* (“ASU 2016-15”), which clarifies how entities should classify certain cash receipts and cash payments on the statement of cash flows to eliminate diversity in practice. Specifically relating to contingent consideration payments made after a business combination, an entity should classify cash payments that are not made within a relatively short period of time after a business combination to settle a contingent consideration liability as financing and operating activities. The portion of cash payment up to the acquisition date fair value of the contingent consideration liability (including measurement period adjustments) is classified as a financing activity and the portion paid in excess of the acquisition date fair value is classified as an operating activity. The new standard is effective for fiscal years beginning after December 15, 2017 and interim periods therein. Early adoption is permitted however all of the amendments must be adopted in the same period and interim period adoption requires adjustments to be reflected as of the beginning of the fiscal year. The guidance is to be applied on a retrospective basis with relevant disclosures under ASC 250. The adoption of this standard in 2018 did not have a material impact on the consolidated financial statements.

Recently Issued Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820), Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement* (“ASU 2018-13”). The amendments in this ASU require certain existing disclosure requirements in Topic 820 to be modified or removed, and certain new disclosure requirements to be added to the Topic. In addition, this ASU allows entities to exercise more discretion when considering fair value measurement disclosures. ASU 2018-13 will be effective for the Company beginning January 1, 2020 with early adoption permitted. The Company is in the process of evaluating the impact of ASU 2018-13 on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* (“ASU 2016-02”). The purpose of this amendment requires the recognition of lease assets and lease liabilities by lessees for those leases longer than twelve months. This update requires lessees to recognize at the lease commencement date a lease liability which

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is the lessee's obligation to make lease payments arising from a lease, measured on a discounted basis, and right-of-use assets, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. Lessees will no longer be provided with a source of off-balance sheet financing. ASU 2016 02 is effective for annual periods beginning after December 15, 2018 for public business entities, and for all other entities, for fiscal years beginning after December 15, 2019 and requires a modified retrospective adoption. Lessees and lessors must apply a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The modified retrospective approach would not require any transition accounting for leases that expired before the earliest comparative period presented. Applying a full retrospective transition approach is not allowed. The Company is currently evaluating the impact that the standard will have on its consolidated financial statements and related disclosures. The Company will established a cross-functional coordinated team to evaluate and implement the new lease standard. The Company is in the process of implementing changes to its processes and internal controls to meet the standard's reporting and disclosure requirements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"). This ASU amends the guidance for revenue recognition, creating the new ASC Topic 606 ("ASC 606"). The core principle of ASC 606 is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve that core principle, an entity should apply the following steps: identify the contract(s) with a customer; identify the performance obligations in the contract; determine the transaction price; allocate the transaction price to the performance obligations in the contract; and recognize revenue when (or as) the entity satisfies a performance obligation. ASC 606 supersedes the revenue recognition requirements in ASC 605, Revenue Recognition, most industry-specific guidance throughout the industry topics of the accounting standards codification, and some cost guidance related to construction-type and production-type contracts. This ASC is effective for private entities for annual periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2019. 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.

The Company has completed its assessment process of the effects of ASC 606 and its amendments on its consolidated financial statements and has implemented changes to its business processes, systems and controls to support revenue recognition and the related disclosures under this ASU. The Company plans to adopt ASC 606 on January 1, 2019, and will do so retrospectively with the cumulative effect of initially applying the guidance recognized at the date of initial application (the modified retrospective transition method) to all existing contracts that have remaining obligations as of January 1, 2019. The adoption of ASC 606 will require additional disclosure around the Company's revenue recognition in its financial statements. Historically, for certain customers, products were shipped in advance of the receipt of the purchase order but the Company recognized revenue on these products only upon receipt of a purchase order. As control of these products has transferred upon use of the product in a procedure, the recognition of revenue will be accelerated to the procedure date under ASC 606. ASC 606 is not expected to have a material impact on the Company's consolidated financial statements. The cumulative adjustment to opening retained earnings will be insignificant at January 1, 2019.

3. Reverse Acquisition with Avista and Organogenesis

On December 10, 2018 Organogenesis Inc. completed the Avista Merger, pursuant to which Avista Merger Sub merged with and into Organogenesis Inc., with Organogenesis Inc. surviving the merger and becoming a wholly owned subsidiary of AHPAC. Following the Domestication and the Avista Merger, AHPAC changed its name to Organogenesis Holdings Inc., also referred to as ORGO (see Note 1).

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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 cancelled, extinguished and converted into the right to receive 2.03 shares (the “Exchange Ratio”) of ORGO Class A common stock, par value \$0.0001 per share, (after giving effect to the Domestication). At the effective time of the Avista Merger, 75,073,548 shares of ORGO Class A common stock were issued to the equity holders of Organogenesis Inc. Each warrant to acquire shares of Organogenesis Inc. common stock outstanding and unexercised immediately prior to the Avista Merger (other than warrants that expired, were exercised or were deemed automatically net exercised immediately prior to the Avista Merger) was assumed and remains subject to substantially the same terms and conditions set forth in the warrant, except that: (i) the number of shares of ORGO Class A common stock which can be purchased pursuant to the warrant is equal to a number of shares equal to (as rounded down to the nearest whole number) (A) the number of shares of Organogenesis Inc. common stock that the warrant entitled the holder thereof to acquire immediately prior to the Avista Merger, multiplied by (B) the Exchange Ratio; and (ii) the exercise price for the warrant is equal to (as rounded up to the nearest whole cent) (A) the exercise price of the warrant immediately prior to the Avista Merger (in U.S. Dollars), divided by (B) the Exchange Ratio. Subject to the terms and conditions of the Avista Merger Agreement, each option to purchase shares of Organogenesis Inc. common stock was assumed and now: (i) represents the right to acquire a number of shares of ORGO Class A common stock equal to (as rounded down to the nearest whole number) the product of (A) the number of shares of Organogenesis Inc. common stock which the Organogenesis Inc. option had the right to acquire immediately prior to the Avista Merger, multiplied by (B) the Exchange Ratio; and (ii) has an exercise price equal to (as rounded up to the nearest whole cent) the quotient of (A) the exercise price of the Organogenesis Inc. option immediately prior the Avista Merger (in U.S. Dollars), divided by (B) the Exchange Ratio.

On the date of the Avista Merger, 31,000,000 AHPAC public warrants to purchase one half of one AHPAC Class A ordinary shares with an exercise price of \$11.50 per share were outstanding and remained outstanding following the Avista Merger. Following the Domestication, each public warrant is exercisable for one half of one share of ORGO Class A common stock, but may only be exercised for a whole share. The public warrants are exercisable for up to a maximum of 15,500,000 shares of ORGO Class A common stock.

In connection with the execution of the Avista Merger Agreement on August 17, 2018, founders of AHPAC and certain directors of AHPAC, who together owned all of AHPAC’s founder shares entered into a letter agreement pursuant to which, (i) such holders surrendered to AHPAC at the execution of the Avista Merger Agreement, an aggregate of 1,937,500 founder shares and (ii) such holders agreed to surrender an aggregate of 4,421,507 founder shares and 16,400,000 private placement warrants at the consummation of the Avista Merger. All such founder shares and private placement warrants were cancelled. Prior to the closing of the Avista Merger, 500,000 of the founder shares were converted into 500,000 AHPAC Class A ordinary shares and in connection with the Domestication those 500,000 Class A ordinary shares became 500,000 shares of ORGO Class A common stock pursuant to the Company’s charter. The remaining 890,993 founder shares that remained outstanding prior to the closing of the Avista Merger were converted to the same number of ORGO Class A common stock at the closing of the Avista Merger in accordance with the terms of the Company’s charter.

Concurrently with the closing of the Avista Merger, a portion of the affiliate debt was converted into 6,502,679 shares of ORGO Class A common stock based on a conversion price of \$7.035 per share, and the Company made a cash payment of \$35,641 to the holders of the affiliate debt in satisfaction of the remaining portion of the outstanding principal of \$22,000 and related accrued interest and fees of \$13,641. Following the consummation of these transactions, the affiliate debt was deemed fully paid and satisfied in full and was discharged and terminated.

Concurrently with the closing of the Avista Merger, the PIPE Investors 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.

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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 are incorporated into selling, general and administrative expenses in the Company's consolidated statement of operations. Additionally, AHPAC incurred \$11,205 in transaction costs prior to the Avista Merger that were paid in full by the Company after the consummation of the Avista Merger.

4. Real Estate Entities

On June 1, 2017, Dan Road Associates, 85 Dan Road Associates and 65 Dan Road Associates entered into amendments to their respective mortgage notes whereby the Company's affiliates contributed equity to the entities which was used to pay down the mortgage notes. This resulted in the removal of the requirement that the Company's affiliates provide personal guarantees for the loans and as a result, the Company determined that the Real Estate Entities no longer met the definition of a variable interest entity. Accordingly, the Company determined that the Real Estate Entities were no longer required to be consolidated under the variable interest entity model. Prior to the amendment, the Company was deemed to have had a variable interest in Dan Road Associates, 85 Dan Road Associates and 65 Dan Road Associates; and Dan Road Associates, 85 Dan Road Associates and 65 Dan Road Associates were deemed to be variable interest entities of which the Company was the primary beneficiary. As a result, the Company has consolidated the results of the Real Estate Entities since 2011 (lease inception), and, prior to the amendments to the mortgage notes, recognized a non-controlling interest in its consolidated balance sheet.

The following table shows the VIE deconsolidation as of June 1, 2017:

June 1, 2017	Dan Road Associates	85 Dan Road Associates	65 Dan Road Associates	Total
Cash	\$ 247	\$ 51	\$ 368	\$ 666
Due from affiliates	2,018	6,414	4,448	12,880
Prepaid expenses and other current assets	126	—	—	126
Total current assets	2,391	6,465	4,816	13,672
Property and equipment	3,149	3,982	2,801	9,932
Total assets	\$ 5,540	\$ 10,447	\$ 7,617	\$ 23,604
Accrued expenses and other current liabilities	\$ (8)	\$ (52)	\$ (43)	\$ (103)
Notes payable, net of current portion	(7,029)	(6,389)	(5,186)	(18,604)
Other liabilities	(232)	—	—	(232)
Total liabilities	(7,269)	(6,441)	(5,229)	(18,939)
Net assets	(1,729)	4,006	2,388	4,665
Accumulated deficit	3,297	—	—	3,297
Non-controlling interest in affiliates	1,568	4,006	2,388	7,962
Consideration transferred	—	—	—	—
Gain (loss) on deconsolidation	\$ —	\$ —	\$ —	\$ —

As of June 1, 2017, the Real Estate Entities were deconsolidated and the Company derecognized all assets and liabilities of the Real Estate Entities, which resulted in no gain or loss being recorded as no consideration was transferred and no non-controlling interests were retained by the Company. The Company will continue to assess its relationships with the Real Estate Entities in the future to determine if reconsolidation would be necessary as facts and circumstances change.

5. Acquisition of NuTech Medical

On March 18, 2017, the Company and Prime Merger Sub, LLC ("Merger Sub"), a wholly owned subsidiary organized for the purposes of this transaction, entered into the NuTech Merger Agreement to acquire all of the

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outstanding shares of capital stock in NuTech Medical, an Alabama-based market leader in surgical and biologics.

On March 24, 2017, upon consummation of this transaction, NuTech Medical was merged into Merger Sub, and Merger Sub was the surviving entity. The acquisition was completed as a strategic investment to enhance the Company's ability to offer a more dynamic and competitive line of complementary bio-active and regenerative products.

This acquisition qualified as a business combination under FASB ASC 805 and the Company has recorded all assets acquired and liabilities assumed at their acquisition-date fair values. The excess of the purchase price over the fair value of the tangible and identifiable intangible assets acquired less the liabilities assumed has been recorded as goodwill. The goodwill of \$19,446 arising from the acquisition consists largely of expected changes from improvements to the Company's competitive position due to technological research, trade synergies, and the assembled workforce.

The following table summarizes the estimated fair value of the consideration transferred, fair values of the assets acquired and liabilities assumed by the Company, and the resulting goodwill:

Consideration	
Cash	\$ 12,000
Common stock	2,515
Redeemable common stock	6,339
Restricted common stock	7,548
Stock options	207
Deferred acquisition consideration	8,000
Working capital adjustment	(500)
Contingent consideration forfeiture rights	(377)
Total consideration	<u>35,732</u>
Common stock transferred	(16,402)
Deferred acquisition consideration	(7,500)
Common stock options issued	(207)
Contingent consideration forfeiture rights	377
Cash received	<u>(210)</u>
	<u>\$ 11,790</u>
Allocated as follows:	
Cash	\$ 210
Accounts receivable	3,131
Inventory	2,730
Other current assets	51
Property and equipment	284
Goodwill	19,446
Identifiable intangible assets	20,410
Total assets acquired	<u>46,262</u>
Accounts payable	2,850
Accrued expenses and other current liabilities	803
Deferred tax liability	6,877
Total liabilities assumed	<u>10,530</u>
Net assets acquired	<u>\$ 35,732</u>

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The purchase price of \$35,732 consisted of cash consideration, the fair value of Class A common stock of the Company, options to purchase Class A common stock of the Company, a note payable to the sellers, and contingent consideration forfeiture rights as follows:

- \$12,000 cash consideration paid at closing;
- \$8,000 of future payments issued as deferred acquisition consideration that accrues interest at a rate of 6% per annum. The deferred acquisition consideration was paid \$1,000 quarterly for the first 12-months less a working capital adjustment of \$500, and \$4,000 plus accrued interest to be paid on the 15-month anniversary of the closing. As of December 31, 2018, \$2,500 was paid related to the deferred acquisition consideration (see Note 24);
- issuance of 728,549 non-restricted shares of Class A common stock at an acquisition date fair value of \$3.45 per share for a value of \$2,515;
- issuance of 728,549 redeemable shares of Class A common stock valued at an acquisition date fair value of \$8.70 per share for a total fair value of \$6,339; the put right associated with the shares of Class A common stock allows the holder to put the shares back to the Company at an agreed-upon exercise price of \$9.28 per share on the second anniversary of the closing. The Company also has the right to call the shares at an agreed-upon exercise price of \$9.28 per share on the second anniversary of the acquisition. The acquisition date fair value of the shares containing the put and call rights was determined by calculating the present value of \$9.28 at a discount rate of 2.91% over a two-year period;
- issuance of 2,185,647 restricted shares of Class A common stock which are subject to forfeiture in the event certain adverse FDA events occur during the one-year period following the acquisition. In accordance with business combination guidance, the Company contingently bifurcated the forfeiture right asset and recorded it at a fair value of \$377 on the date of the acquisition. The forfeiture right asset will be remeasured at each balance sheet date with the change in the fair value being recorded in the consolidated statement of operations. These shares were valued at \$7,548 which incorporated the fair value of the Company's Class A common stock at the acquisition date and the Company's estimate of the probability of the forfeiture provisions occurring and the ultimate amount of shares expected to be forfeited in the event a forfeiture event occurs. The forfeiture percentage was based on the Company's analysis of similar products and their history of these regulatory requirements; and
- issuance of 137,137 fully-vested options granted to certain key employees of NuTech Medical. The options were valued at \$207.

There was a \$500 reduction to the purchase price due to changes in the amount of working capital acquired. This \$500 was recovered by the Company through the reduction of the second quarterly payment of the deferred acquisition consideration.

The Company utilized an independent third-party valuation in determining the estimated fair value of the Company's common stock, which resulted in a valuation of Class A common stock of \$3.45 per share as of March 24, 2017. The Company estimated the fair value of each stock option vested using the Black-Scholes option-pricing model, which utilized an input of \$3.45 for the fair value of the Company's Class A common stock, an assumption of 47.91% for the peer companies' volatility of common stock price, an expected term of 5.0 years, a risk-free interest rate of 1.93% for a period that approximates the expected term of the stock options and an expected dividend yield of 0%.

The assets and liabilities of NuTech Medical are recorded in the Company's consolidated financial statements at their estimated fair values. Goodwill, which is not expected to be deductible for statutory tax purposes, is calculated as the excess value of consideration paid over the fair value of assets acquired and liabilities assumed. The purchase price resulted in goodwill of \$12,569 net of a discrete tax benefit of \$6,877.

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The historical carrying values of current assets and liabilities approximate their fair value on the date of acquisition due to their short-term nature. Gross accounts receivable of \$3,268 were acquired with a fair value of \$3,131. Property and equipment was recorded at its fair value on the date of acquisition as determined by the Company. The Company assessed the fair value of the lease agreements for the NuTech Medical office location using a market approach concluding that the terms were at-market value, therefore, no asset or liability was recorded. Valuation of the developed technology intangible asset was derived from the multi-period excess earnings method, which takes into account the return on the investment of the asset. Valuation of the trade name and trademark intangible asset was derived from the relief from royalty method. Valuation of the distributor network intangible asset was derived from a combination of the cost approach and the distributor income approach method. Valuation of the non-compete agreements intangible asset was derived from the lost profits approach method. The intangible assets will be amortized using accelerated methods, which reflect the pattern in which the economic benefits of the intangible assets are consumed, over a weighted average period of 9.6 years. The excess of the fair value of the assets acquired and liabilities assumed was recorded as goodwill.

The additional intangible assets recorded are not deductible for statutory tax purposes. As such, a deferred tax liability of \$6,877 associated with the non-deductible intangibles and other differences between the carry over basis of assets acquired and assets assumed and their fair value was recorded with purchase accounting.

The results of operations of NuTech Medical have been included in the Company's consolidated statements of operations from the acquisition date. Since the acquisition date through the year ended December 31, 2017, revenue was \$22,340, which is included in the Company's consolidated statements of operations.

During the year ended December 31, 2017, the Company recorded \$295 of transaction expenses related to third-party legal and accounting services to consummate the NuTech Merger. These costs are incorporated into selling, general and administrative expenses in the Company's consolidated statement of operations

The following table shows the unaudited pro forma statements of operations for the year ended December 31, 2017 as if the NuTech Medical Acquisition had occurred on January 1, 2017. This pro forma information does not purport to represent what the Company's actual results would have been if the acquisitions had occurred as of the date indicated or what such results would be for any future periods.

	For the Year Ended December 31, 2017
Net revenue	\$ 204,177
Net income	\$ (9,183)

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6. Fair Value Measurement of Financial Instruments

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

	Fair Value Measurements as of December 31, 2018 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Redeemable common stock liability	\$ —	\$ —	\$6,762	\$6,762
Contingent purchase earn-out liability	—	—	—	—
	<u>\$ —</u>	<u>\$ —</u>	<u>\$6,762</u>	<u>\$6,762</u>
	Fair Value Measurements as of December 31, 2017 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Contingent consideration forfeiture rights	\$ —	\$ —	\$ 589	\$ 589
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 589</u>	<u>\$ 589</u>
Liabilities:				
Warrant liability	\$ —	\$ —	\$2,238	\$2,238
Contingent purchase earn-out liability	—	—	—	—
	<u>\$ —</u>	<u>\$ —</u>	<u>\$2,238</u>	<u>\$2,238</u>

Redeemable Common Stock

On March 24, 2017, the Company issued 728,549 shares of Class A common stock in connection with the NuTech Medical acquisition which were recorded at their fair value of \$8.69 per share. These shares include a put right allowing the holder to put the shares back to the Company at an agreed-upon exercise price of \$9.28 per share on March 24, 2019. The Company also has the right to call the shares at an agreed-upon exercise price of \$9.28 per share prior to the second anniversary of the acquisition. These shares had been classified as temporary equity and had been accreted to the full redemption amount of \$9.28 per share as the holders have the right to exercise the put right on March 24, 2019. These shares have the same rights and preferences as common stock. During the year ended December 31, 2018 and 2017, the Company recorded \$0 and \$423 related to the accretion of these shares to their redemption amount, respectively. In December 2018, the Company received notification that the put option will be exercised. Accordingly, the Company reclassified the carrying value of the redeemable Class A common stock of \$6,762 to a current liability which is expected to be paid in March 2019.

Contingent Consideration Forfeiture Rights

In connection with the acquisition of NuTech Medical (see Note 5), the Company issued 2,185,647 shares of Class A common stock that were forfeitable upon the occurrence of an adverse FDA event related to certain products acquired from NuTech Medical ("FDA Event") through the one year anniversary of the acquisition date in March 2018. The forfeiture rights expired because there was no adverse FDA event. The fair value of the forfeiture right was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the forfeiture right asset was determined by considering as inputs the type and probability of occurrence of FDA Event, the number of common shares to be forfeited, which is subject to negotiation, and the fair value per share of its common shares, by completing a third-party valuation of its Class A common shares. The significant unobservable input used in the fair value measurement of the forfeiture right is the fair value per share of the underlying common shares that are subject to

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forfeit upon the occurrence of the FDA Event of certain products acquired from NuTech Medical. The Company believes that a 10% change in the fair value of the underlying shares would not have a material impact on our financial position or results of operations. The fair value of the Company's common stock was determined using the probability weighted expected return method ("PWERM") which considered the equity holders return under various liquidity event scenarios. The change in the fair value of the contingent consideration forfeiture rights is recorded within selling, general and administrative expenses on the consolidated statement of operations. The fair value of the contingent consideration forfeiture rights was determined to be \$0 and \$589 as of December 31, 2018 and 2017, respectively.

Contingent Purchase Earn-out

The contingent purchase earn-out liability associated with the Company's acquisition of Dermagraft from Shire plc was valued at \$3,300 by the Company, with input from an independent third-party valuation firm, based on future probability-weighted expected pay-outs as of the date of acquisition. The contingent purchase earn-out liability was payable by the Company upon the achievement of certain revenue targets for the Dermagraft product through December 31, 2018. The fair value of the contingent earn-out liability was determined to be \$0 at December 31, 2018 and 2017. The fair value of the contingent earn-out liability could change in future periods if the Company realizes a significant increase in sales related to the acquired Dermagraft assets and the Company will reassess the fair value at each balance sheet date.

Warrant Liability

The warrant liability is the fair value of warrants to purchase Class A common stock that the Company agreed to issue to the debt holders of its obligations under a Subordinated Notes agreement (see Note 15). The fair value of the warrant liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The Company utilized a Binomial Lattice pricing model with five steps of the binomial tree to estimate the fair value of the warrant liability. Estimates and assumptions impacting the fair value measurement included the estimated probability of adjusting the exercise price of the warrants, the number of shares of Class A common stock for which the warrants will be exercisable, the fair value per share of the underlying Class A common stock issuable upon exercise of the warrants, the remaining contractual term of the warrants, the risk-free interest rate, the expected dividend yield, and the expected volatility of the price of the underlying Class A common stock. The Company determined the fair value per share of its Class A common stock by completing a third-party valuation of its common stock. The Company historically has been a private company and lacks company-specific historical and implied volatility information of its shares. Therefore, it estimated its expected share volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrants. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company estimated a 0% expected dividend yield based on the fact that the Company has never paid or declared dividends and does not intend to do so in the foreseeable future. The significant unobservable inputs used in the fair value measurement of the warrant liability are the fair value per share of the underlying Class A common stock issuable upon exercise of the warrants and the expected volatility of the price of the underlying Class A common stock. The Company believes that a 10% change in the fair value of the underlying shares and expected volatility would not have a material impact on our financial position or results of operations.

On December 10, 2018, concurrent with the completion of the Avista Merger, the warrants were net exercised for 444,041 shares of ORGO Class A common stock. Immediately prior to the exercise of the warrants the Company remeasured the fair value of the warrants on December 10, 2018.

During the year ended December 31, 2018, 2017 and 2016, the Company recorded expense of \$469, \$1,037 and \$737, respectively, for the change in the fair value of the warrant liability on the consolidated statements of operations.

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The following table provides a roll forward of the aggregate fair values of the Company's warrant liability, redeemable common stock liability, contingent consideration forfeiture rights and contingent purchase earn-out liability, for which fair value is determined using Level 3 inputs:

	Contingent Consideration Forfeiture Rights	Warrant Liability	Redeemable Common Stock Liability	Contingent Purchase Earn-Out Liability
Balance as of December 31, 2016	—	(1,201)	—	—
Initial fair value of contingent consideration forfeiture rights	377	—	—	—
Change in fair value	212	(1,037)	—	—
Balance as of December 31, 2017	589	(2,238)	—	—
Change in fair value	(589)	(469)	—	—
Issuance of common stock for the exercise of warrant		2,707		
Reclassification of redeemable common stock		—	6,762	
Balance as of December 31, 2018	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 6,762</u>	<u>\$ —</u>

7. Accounts receivable, net

Accounts receivable consisted of the following:

	December 31,	
	2018	2017
Accounts receivable	\$37,497	\$31,349
Less — allowance for sales returns and doubtful accounts	(3,420)	(3,225)
	<u>\$34,077</u>	<u>\$28,124</u>

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

Balance as of December 31, 2016	\$2,109
Additions	1,166
Write-offs	(50)
Balance as of December 31, 2017	3,225
Additions	1,157
Write-offs	(962)
Balance as of December 31, 2018	<u>\$3,420</u>

8. Inventories

Inventories, net of related reserves for excess and obsolescence, consisted of the following:

	December 31,	
	2018	2017
Raw materials	\$ 4,711	\$ 6,537
Work in process	1,759	991
Finished goods	6,851	6,742
	<u>\$13,321</u>	<u>\$14,270</u>

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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, 2018, 2017 and 2016, the Company charged \$5,949, \$5,497, and \$7,472, respectively, to cost of goods sold within the consolidated statements of operations. As of December 31, 2018 and 2017, the Company recorded a reserve for excess and obsolete inventory of \$2,951 and \$2,954, respectively.

9. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2018	2017
Deferred offering costs	\$ —	\$2,724
Prepaid rent	—	29
Prepaid subscriptions	594	584
Prepaid inventory testing	116	36
Prepaid conferences and marketing expenses	392	588
Prepaid insurance	223	196
Prepaid deposits	764	—
Other	239	242
	<u>\$2,328</u>	<u>\$4,399</u>

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

10. Property and Equipment

Property and equipment consisted of the following:

	December 31,	
	2018	2017
Leasehold improvements	\$ 34,345	\$ 35,143
Furniture, computers and equipment	44,752	43,375
	79,097	78,518
Accumulated depreciation and amortization	(62,435)	(59,212)
Construction in progress	22,961	22,806
	<u>\$ 39,623</u>	<u>\$ 42,112</u>

On June 1, 2017, in connection with the deconsolidation of the Real Estate Entities, the property and equipment associated with the Real Estate Entities in the net aggregate amount of \$9,932, was derecognized from the Company's consolidated balance sheet (see Note 5).

Depreciation expense was \$3,309, \$3,591, and \$5,702 for the years ended December 31, 2018, 2017 and 2016, respectively. During the year ended December 31, 2018, the Company disposed of \$1,309 in equipment with accumulated depreciation of \$99. Cash proceeds of \$1 were received and a loss on disposal of \$1,209 was recorded. During the year ended December 31, 2017, the Company disposed of \$418 in equipment with accumulated depreciation of \$418. Cash proceeds of \$8 were received and a gain on the disposal of \$8 was recorded. As of December 31, 2018 and 2017, the Company had \$21,889 of buildings under capital leases recorded within leasehold improvements. As of December 31, 2018 and 2017, the Company had \$12,779 and

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\$5,989 recorded within accumulated depreciation and amortization related to buildings under capital leases, respectively. Construction in progress primarily represents ongoing construction work on the 275 Dan Road SPE, LLC property (see Note 17). Leasehold improvements at December 31, 2018 includes \$1,464 related to ongoing renovations at 85 Dan Road not yet placed in service. Leasehold improvements at December 31, 2017 includes \$618 related to ongoing renovations at 85 Dan Road not yet placed in service.

11. Notes Receivable—Related Parties

During 2010, the Company's board of directors approved a loan program that permitted the Company to make loans to three officers 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"). The Employer Loans mature with all principal and accrued interest due on the tenth anniversary of the issuance date of each subject loan, except that in certain circumstances the Employer Loans may mature earlier. The borrower may prepay all or any portion of his Employer Loan at any time without premium or penalty.)

The Company has not executed any new Employer Loans since the year ended December 31, 2012. However, certain Employer Loans made prior to 2013 remain outstanding as of December 31, 2018. Interest on the Liquidity Loans accrues at various rates ranging from 2.30%—3.86% per annum, compounded annually. The Liquidity Loans are secured by stock and options in the Company held by the borrowers. The Company has no personal recourse against the borrowers beyond the pledged shares and options with respect to the Liquidity Loans. In 2013, the Company reserved the total outstanding principal of all the then outstanding loans and the interest on the loan to one former employee as the loans are secured by pledged shares and options which had a limited liquid market for the holder to liquidate the holdings to repay the loans and collectability of the outstanding principal on the loans is not assured. The net principal and interest receivable under the Liquidity Loans as of December 31, 2018 and 2017 was \$478 and \$413, respectively, and is included in the notes receivable from related parties balance in the consolidated balance sheets. Interest income related to these notes was \$64, \$111 and \$108 for the years ended December 31, 2018, 2017 and 2016, respectively. As part of the separation agreement between the Company and its former CEO entered into in March 2015, the Company agreed that it would forgive one-half of the then outstanding principal balance of the former CEO's Liquidity Loans if the Company completed a liquidity event, as defined in the agreement, prior to the maturity of such loans. A liquidity event includes a change of control of the Company and a firm commitment underwritten public offering of the Company's securities. As of December 31, 2018 and 2017, the former CEO's Liquidity Loans had an outstanding aggregate principal balance of \$2,000. As of December 31, 2018 and 2017, the current CEO's Liquidity Loan had an outstanding aggregate principal balance of \$0 and \$997, respectively. As of December 31, 2018 and 2017, the Liquidity Loan to one former employee had an outstanding aggregate principal balance of \$350. As of December 31, 2018 and 2017, the Option Loan to one former employee totaled \$635 and was secured by 675,990 shares of Class A common stock held by the former employee.

Interest on the Option Loans accrued at various rates ranging from 2.30%—3.86% per annum, compounded annually. There was no interest income related to the Option Loans for 2018, 2017 and 2016. The Option Loans were also secured by stock and options in the Company held by the borrowers. The Company has full recourse against such pledged shares and options and personal recourse against the borrower for up to 50% of the original principal amount of the Option Loan and 100% of the accrued interest owed to the Company. In accordance with the applicable accounting guidance, the principal balance of the Option Loans was reported as an offset to additional paid-in capital from the exercise of the options. On August 21, 2014, two officers satisfied their outstanding Option Loans by exchanging shares of Organogenesis Inc. common stock being held as collateral equal to the value of their outstanding Option Loans plus accrued interest thereon.

The Employer Loans accrue interest at various rates ranging from 2.30%—3.86% per annum, compounded annually. The total principal and interest receivable under the Employer Loans as of December 31, 2018 and 2017 was \$2,937 and \$3,873, respectively. The value of the stock and options securing the Employer Loans as of December 31, 2018 and 2017 was \$4,448 and \$3,646, respectively. During 2017, the Company recorded an

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impairment of \$113 on the Employer Loan to our CEO to reserve the total outstanding interest of the loan as uncollectible. The Company did not record any impairment on the employee loans during the year ended December 31, 2018.

As of December 31, 2018 and 2017, notes receivable from related parties consisted of the following:

Balance as of December 31, 2016	\$ 415
Accrued interest	111
Impairment	(113)
Balance as of December 31, 2017	413
Accrued interest	64
Balance as of December 31, 2018	<u>\$ 477</u>

In connection with the Avista Merger (see Note 1), the Company forgave the outstanding aggregate principal balance of \$997 and \$133 of accrued interest related to the current CEO's Liquidity Loans immediately prior to consummation of the Avista Merger. Concurrently with the loan forgiveness, the Company also made a bonus payment of \$904 to the current CEO to cover certain taxes associated with the loan forgiveness, which was recorded within selling, general and administrative expense on the consolidated statement of operations. As discussed above, the total outstanding aggregate principal balance and interest were previously reserved for in prior years when deemed uncollectible and therefore were carried at \$0 on the consolidated balance sheets at the time of the loan forgiveness.

12. Goodwill and Intangible Assets

During 2017, the Company recorded \$19,446 of goodwill associated with the acquisition of NuTech Medical (see Note 5). Goodwill was \$25,539 as of December 31, 2018 and 2017, respectively. There were no impairments recorded against goodwill during the years ended December 31, 2018 or 2017.

Identifiable intangible assets consisted of the following as of December 31, 2018:

	<u>Original Cost</u>	<u>Accumulated Amortization</u>	<u>Net Book Value</u>
Developed technology	\$29,820	\$ (8,454)	\$ 21,366
Trade names and trademarks	2,000	(413)	1,587
Independent sales agency network	4,500	(1,569)	2,931
Non-compete agreements	260	(53)	207
Total	<u>\$36,580</u>	<u>\$ (10,489)</u>	<u>\$ 26,091</u>

Identifiable intangible assets consisted of the following as of December 31, 2017:

	<u>Original Cost</u>	<u>Accumulated Amortization</u>	<u>Net Book Value</u>
Developed technology	\$29,820	\$ (6,389)	\$ 23,431
Trade names and trademarks	2,000	(238)	1,762
Independent sales agency network	4,500	(181)	4,319
Non-compete agreements	260	(13)	247
Total	<u>\$36,580</u>	<u>\$ (6,821)</u>	<u>\$ 29,759</u>

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Amortization of intangible assets, calculated on a straight-line basis, was \$3,669, \$2,037 and \$1,617 for the years ended December 31, 2018, 2017 and 2016, respectively. Estimated future annual amortization expense related to these intangibles assets is as follows:

2019	5,993
2020	3,192
2021	3,257
2022	3,247
2023	3,283
Thereafter	7,119
Total	<u>\$ 26,091</u>

13. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2018	2017
Accrued compensation	\$ 15,218	\$ 11,826
Accrued professional fees	309	539
Accrued interest - capital lease obligations	4,174	3,950
Accrued litigation	1,000	1,000
Accrued royalties	2,463	3,610
Accrued interest - deferred acquisition consideration	618	318
Other	1,633	1,308
	<u>\$ 25,415</u>	<u>\$ 22,551</u>

14. Long-Term Debt—Affiliates

Long-term debt payable to affiliates consisted of the following:

	December 31,	
	2018	2017
2010 Loans	\$—	\$ 19,850
2015 Loans	—	11,396
2016 Loans	—	17,000
Accrued interest	—	9,241
	—	57,487
Less debt discount	—	(5,345)
	<u>\$—</u>	<u>\$ 52,142</u>

Due to affiliates consisted of the following:

	December 31,	
	2018	2017
65 Dan Road SPE, LLC	\$—	\$ 200
85 Dan Road Associates	—	3,900
275 Dan Road SPE, LLC	—	400
	<u>\$—</u>	<u>\$ 4,500</u>

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The Company borrowed the 2010 Loans and the 2015 Loans, collectively the “Loans,” from its affiliates, or entities controlled by its affiliates. The Loans are subordinated to amounts outstanding under the Credit Agreement and the Master Lease Agreement (“ML Agreement”) (see Note 15). The Loans are secured by substantially all the assets of the Company and require the Company to adhere to certain non-financial covenants. The Company has accrued but not paid interest on the Loans since inception until the payoff in December 2018 as discussed below. Events of default have been waived by the lenders each year through the payoff in December 2018.

The 2010 and 2015 Loans bear interest at an annual rate of 1.6%. The principal plus accrued interest on the loans were due upon or the repayment of the debt to which these notes were subordinated. Therefore, they were classified as long-term liabilities in the consolidated balance sheet as of December 31, 2018 and 2017. Interest expense on these loans totaled \$470, \$540 and \$503 for the years ended December 31, 2018, 2017 and 2016, respectively. The accrued interest on the loans totaled \$0 and \$4,436 as of December 31, 2018 and 2017, respectively.

In June 2013, the Company entered into a secured financing arrangement with 65 Dan Road SPE, LLC, 85 Dan Road Associates and 275 Dan Road SPE, LLC, referred to as the Real Estate Loans. The Real Estate Loans bear interest at a rate of 1.6% per annum, and were secured by substantially all of the personal property and assets of the Company and were subordinated to amounts outstanding under the Credit Agreement, ML agreement and the sellers of NuTech Medical. The Company had accrued but not paid interest on the Loans since inception until the payoff in December 2018. Interest expense on these loans totaled \$68 and \$45 for the years ended December 2018 and 2017, respectively. The accrued interest on the loans totaled \$0 and \$325 as of December 31, 2018 and 2017, respectively.

In April 2016, the Company issued the 2016 Loans in the aggregate principal amount of \$17,000. The 2016 Loans accrued interest at an annual rate of 15%, and required monthly interest-only payments beginning January 2017, with all outstanding principal and accrued interest due upon the repayment of the debt to which these notes were subordinate. The 2016 Loans also required an additional fee of \$680 initially to be paid in January 2017 but further extended to be paid upon the repayment of the 2016 Loans. The 2016 Loans were collateralized by substantially all assets of the Company and were subordinated to indebtedness under the Credit Agreement and the Master Lease Agreement. The 2016 Loans were collateralized by substantially all assets of the Company and are subordinated to indebtedness under the Credit Agreement, ML Agreement and the sellers of NuTech Medical. Interest expense on the 2016 Loans totaled \$2,667 and \$2,735 for the years ended December 31, 2018 and 2017, respectively, which included interest expense related to the amortization of the debt discount of \$268 and \$92 during the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018 and 2017, the unamortized debt discount was \$0 and \$5,345, respectively. The accrued interest on the 2016 Loans totaled \$0 and \$4,387 as of December 31, 2018 and 2017, respectively.

The Company did not pay the fee of \$680 which is included in other liabilities or the accrued interest due on January 31, 2017 and February 28, 2017, respectively. In March 2017, the investors waived the Company’s failure to comply with the payment schedule of the original agreement and confirmed that no event of default had occurred. It was further agreed that neither the fee nor any accrued interest would be payable before April 30, 2018, but that interest would accrue on the unpaid fee beginning January 31, 2017 at a rate of 15%. In December 2018, the Company paid the fee in full as discussed below. Interest expense on the fee totaled \$96 and \$93 for the years ended December 31, 2018 and 2017, respectively. The accrued interest on the unpaid fee, which was included in long-term debt—affiliates, totaled \$0 and \$93 as of December 31, 2018 and December 31, 2017, respectively.

In March 2017, in connection with the Credit Agreement, the holders of the 2010 Loans, 2015 Loans and the 2016 Loans entered into a subordination agreement whereby the loanholders agreed to subordinate all amounts due under the 2010 Loans, the 2015 Loans and the 2016 Loans and all their security interests to the indebtedness and obligations under the Credit Agreement. The Credit Agreement matures in April 2020. In April

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2017, in connection with the ML Agreement (See Note 15), the loanholders entered into an additional subordination agreement with the lender. The loanholders also agreed to subordinate all amounts due under the 2010 Loans, 2015 Loans and 2016 Loans and all of their security interests to the indebtedness and obligations under the ML Agreement. The maturity date of this additional lender's debt was December 2022. Due to the effective change in term resulting from the March 2017 subordination agreement, the 2016 Loans were concluded to have been extinguished, and the resulting gain of \$2,043 was recorded to additional paid-in capital due to the controlling interest in the Company held by the investors. The Company also concluded that a second extinguishment occurred in April 2017 due to the change in effective maturity date. The resulting gain of \$2,534 was also recorded to additional paid-in capital. A debt discount of \$4,577 was recorded as a result of these two extinguishments. This discount was being amortized to interest expense using the effective interest method over the term of the 2016 Loans as an increase to the carrying value of the 2016 Loans on the consolidated balance sheets.

In connection with the issuance of the 2016 Loans, the Company issued to the loanholders warrants to purchase 905,774 shares of Class A common stock at an exercise price of \$3.58 per share. The warrants are exercisable immediately and expire during April 2021. The warrants contain a down round protection provision whereby the exercise price and number of shares exercisable upon either the issuance of shares or other equity linked instruments at a price less than \$3.58 per share or upon the contractual price reset of other equity linked instruments post issuance. The warrants were determined to be liability classified and were recorded at fair value (see Note 2). The resulting discount on the 2016 Loans at inception was \$464. This discount is being amortized to interest expense using the effective interest method over the term of the 2016 Loans as an increase to the carrying value of the 2016 Loans on the consolidated balance sheet (see Note 18).

In April 2018 and August 2018, the Company received \$10,000 and \$5,000, respectively, in loan proceeds from three members of its board of directors who are also stockholders (the "2018 Loans"). The amounts borrowed bear an annualized 8% interest rate, are payable on demand and are subordinated to the Credit Agreement, ML Agreement and the sellers of NuTech Medical. Interest expense on the 2018 Loans totaled \$687 for the year ended December 31, 2018. The accrued interest on the 2018 Loans totaled \$0 as of December 31, 2018.

Concurrently with the signing of the Avista Merger Agreement (see Note 1) the Company's lenders agreed to release the subordination on the affiliate debt and the affiliate guarantee on the term debt, and the holders of the affiliate debt executed and delivered to the Company an exchange agreement whereby such creditors and the Company agreed that, concurrently with the consummation of the Avista Merger, 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 the transactions contemplated by the exchange agreement, the affiliate debt is deemed fully paid and satisfied in full and discharged and terminated. As a result of the full satisfaction of the affiliated debt, the Company recorded a \$2,095 loss on the extinguishment of the affiliated debt in the consolidated statement of operations. The loss is comprised of the write-off of the unamortized debt discount of \$5,078 offset by \$2,982 which is the difference between the debt principal converted into Class A common stock less the fair value of the common stock issued for the conversion at a per share price of \$13.35.

[Table of Contents](#)**15. Line of Credit and Notes Payable**

Line of credit and notes payable consisted of the following:

	December 31,	
	2018	2017
Line of credit	\$ 26,484	\$ 17,618
Notes payable	\$ 15,885	\$ 15,895
Less debt discount	(762)	(1,079)
Less current maturities	(2,545)	—
Notes payable, net of debt discount	\$ 12,578	\$ 14,816

Credit Agreement

On March 21, 2017, the Company entered into a credit agreement (the “Credit Agreement”) with Silicon Valley Bank (“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. The amount available to borrow under both sub-facilities is dependent on a borrowing base, which is defined as a percentage of the Company’s book value of qualifying finished goods and eligible accounts receivable. The Credit Agreement requires that a portion of the proceeds be used to pay in full, all amounts then outstanding under an existing line of credit agreement. As of December 31, 2018, the Company has borrowed an aggregate of \$26,484 under the revolving credit facility and the total amount available for future revolving borrowings was \$3,516. Interest payments under the credit agreement are payable on the first business day of each calendar month with a final payment on March 21, 2020 (“the Maturity Date”) when all amounts of principal and interest under the revolving credit facility become due. The revolving credit facility accrues interest at (i) a rate per annum equal to the greater of the prime rate and the federal funds rate effective for such day plus 0.50%, plus (ii) an applicable margin of either 0.50% or 1.50% depending on the Company’s liquidity ratio for the immediately preceding 30-day period; provided, however, that in an event of default, as defined in the Credit Agreement, the interest rate applicable to borrowings will be increased by 2.00%.

In connection with the Credit Agreement, the holders of the 2010 Loans, 2015 Loans, 2016 Loans and 2018 Loans entered into a subordination agreement whereby the holders agreed to delay any payments of principal, fees or interest until the SVB Agreement terminates in 2020 (see Note 14).

In connection with the Credit Agreement, the Company has incurred costs of \$702, which is recorded within other assets on the consolidated balance sheet and amortized over the life of the agreement.

In connection with the Credit Agreement, on March 21, 2017, the Company repaid all remaining principal and accrued interest outstanding under an existing line of credit agreement. The Company did not record any associated gain or loss with the extinguishment of this line of credit.

In February 2018, the Company further amended its Credit Agreement to provide additional flexibility in the financial covenants and revised the borrowing base formula to increase availability. There were no other changes to the terms of the Credit Agreement as a result of the amendment.

In April 2018, the Company further amended its Credit Agreement in order to receive additional funding of \$5,000 through a term loan. The amendment increased the commitment under the 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 order to facilitate this amendment certain members of the board of directors provided unconditional personal guarantees with respect to the principal and accrued interest due under the \$5,000 term loan.

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In May 2018, the Company executed a forbearance and amendment to the Credit Agreement with SVB to forbear against the exercise of remedies related to existing events of default, including the failure to comply with its financial covenants for specified periods of time and to add an additional minimum revenue covenant.

Concurrently with the execution of the Agreement (see Note 1), the Company entered into a consent agreement with SVB to, among other things, waive the existing events of default related to failed financial covenants under the Credit Agreement, subject to certain conditions, and extend the forbearance period to September 30, 2018.

In September 2018, the Company entered into a waiver and amendment to the consent agreement to waive the existing events of default under the Credit Agreement, extend the period to modify the financial covenants under the Credit Agreement to October 31, 2018 and waive the financial covenant testing requirements for the period ended September 30, 2018 under the Credit Agreement.

In October 2018, the Company entered into (a) an amendment to its Credit Agreement to extend the maturity date on the \$5,000 term loan from the earlier to occur of (i) October 31, 2018 and (ii) 30 days after the date of the occurrence of an initial public offering, to December 31, 2018 and (b) an amendment to the consent agreement to extend the period to modify the existing financial covenants to December 31, 2018 and waive the financial covenant testing requirements for the periods ended October 31, 2018 and November 30, 2018.

In January 2019, the Company entered into an amendment to its Credit Agreement to extend the deadline to set covenants and to waive the financial covenant testing requirement for the period ended December 31, 2018 to March 31, 2019. Borrowings under the credit agreement are collateralized by a first priority lien on substantially all of the Company's assets. The Credit Agreement contains certain financial and nonfinancial covenants, including minimum revenue and liquidity ratios.

The Company recognized interest expense under the Credit Agreement of \$1,644 and \$736 during the years ended December 31, 2018 and 2017, respectively, which includes interest expense related to the amortization of the asset to record deferred financing of \$243 and \$145 during the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018 and 2017, the unamortized portion of the costs was \$318 and \$463, respectively, and recorded within other assets on the consolidated balance sheet. During the year ended December 31, 2018, the Company made no principal payments in connection with the Credit Agreement.

In connection with the term loan, the Company incurred costs of \$80 which are recorded as a reduction of the carrying value of the note payable on the Company's consolidated balance sheet and were amortized to interest expense through October 2018.

The Company recognized interest expense on the term loan of \$294 during the year ended December 31, 2018 which includes interest expense related to the amortization of the debt issuance costs of \$80. As of December 31, 2018, the unamortized portion of the costs was \$0. Accrued interest on the term loan totaled \$0 as of December 31, 2018.

In December 2018, the Company fully repaid and cancelled the term loan including the outstanding principal and accrued and unpaid interest.

Notes Payable

The Company had unsecured notes payable to two institutional lenders. The notes were subordinate to all amounts outstanding under the line of credit. Interest was paid monthly at an amended rate per annum of 10% (8% from January to April 2016), plus an additional 4% payment in-kind ("PIK") interest was accrued monthly for the term of the debt. Monthly principal payments totaling \$375 were scheduled to begin September 2015, subsequently amended to begin February 2016, with the principal and accrued interest payable in August 2017.

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The notes were subject to debt to equity covenants and certain non-financial covenants. The notes also included warrants to purchase shares of Class A common stock. The warrants were classified as equity and recorded at their relative fair value on the issue date and the carrying value of the debt was reduced by this amount. The notes were being accreted to their par value of \$9,000 over the term of the notes on the effective interest method.

In April 2017, the Company repaid the remaining outstanding principal amount of \$2,250 and accrued interest amount, including PIK interest amount of \$2,512 under the note. The Company did not record any associated gain or loss with this note extinguishment because the carrying value of the note was equal to the outstanding amount. The warrants remain outstanding as of December 31, 2018 (see Note 18).

Master Lease Agreement

On April 28, 2017, the Company entered into a master lease agreement with Eastward Fund Management LLC that allows the Company to borrow up to \$20,000 on or prior to June 30, 2018. The funding is made up of two tranches. The initial funding of \$14,000 occurred on the date the agreement was signed. As the Company maintains all the risks and rewards of the leased assets it has been accounted for as a loan. The ML Agreement requires monthly payments of \$122 for months 1 through 24 and \$452 for months 25- through 60, however, in an event of default, as defined in ML Agreement, the additional interest rate on all unpaid amounts due will be 1.5% and the loan will become due upon written notice. Payments under the ML Agreement are payable on the first day of each month beginning on May 1, 2017 through April 1, 2022 ("the Maturity Date") when all amounts of principal and interest become due. The ML Agreement also provides that the Company may voluntarily prepay the loan at any time; however, if the Company elects to prepay the loan or terminates the loan early within the first 24 months, the Company will pay an additional 3% of the outstanding principal, and any accrued and unpaid interest and fees. This prepayment fee decreases to 2% after the first 24 months. A final payment fee of 6.5% multiplied by the principal amount of the borrowings under the ML Agreement is due upon the earlier to occur of the first day of the final payment term month or prepayment of all outstanding principal. The Company calculates interest using the effective interest method at an annual effective interest rate of 15%.

In connection with the ML Agreement, the Company paid fees of \$308, which were recorded as a debt discount. The debt discount is reflected as a reduction of the carrying value of the loan payable on the Company's consolidated balance sheet and is being amortized to interest expense over the term of the loan using the effective interest method.

The loan is secured by substantially all of the Company's tangible and intangible assets. The agreement requires the Company to adhere to certain financial covenants.

In connection with the ML Agreement, the Company issued a warrant to purchase of 473,011 shares of Class A common stock at \$2.53 per share as a pre-condition for the agreement. The warrants became exercisable on April 27, 2017 and were recorded at the relative fair value of \$958. The warrants expire on the earlier to occur of ten years from the date of issuance or three years from the effective date of the Company's initial public offering. The warrants were classified as equity and recorded at their relative fair value on the issue date and the carrying value of the debt was reduced by this amount as a debt discount. The debt discount is being amortized to interest expense using the effective interest method over the term of the loan. 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.

In December 2017, the Company received an additional \$2,000 in funding under the ML Agreement. No additional amounts are currently available under the ML Agreement. This additional funding requires additional monthly payments of \$18 for months 1 through 24 and \$64 for months 25- through 60. Payments for this additional funding under the ML Agreement are payable on the first day of each month beginning on January 1, 2018 through December 1, 2022 when all amounts of principal and interest become due. A final payment fee of 16.5% multiplied by the principal amount of the additional funding borrowings is due upon the earlier to occur of

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the first day of the final payment term month or prepayment of all outstanding principal. The Company calculates interest using the effective interest method at an annual effective interest rate of 13.5%.

In May 2018, the Company entered into a forbearance agreement with Eastward pursuant to which Eastward agreed to forbear from exercising any and all of the rights and remedies available to it under the ML Agreement to the extent such rights and remedies arise exclusively as a result of the events of default under Credit Agreement described above as well as the Company's failure to deliver prompt notice of such events of default to Eastward.

Concurrently with the execution of the Agreement (see Note 1), the Company entered into a consent agreement with Eastward to, among other things, waive the existing events of default related to events of default under the Credit Agreement described above as well as the failure to deliver prompt notice of such events of default to Eastward.

The Company recognized interest expense under the ML Agreement of \$2,236 and \$1,309 during the years ended December 31, 2018 and 2017 respectively including interest expense related to the amortization of the debt discount of \$317 and \$187 during the years ended December 31, 2018 and 2017 respectively. As of December 31, 2018, the unamortized debt discount was \$762. During the year ended December 31, 2018, the Company paid \$10 in principal payments in connection with the ML Agreement. During the year ended December 31, 2017, the Company made no principal payments in the connection with the ML Agreement.

In March 2019, the Company prepaid the outstanding principal and accrued interest on the ML Agreement. (See Note 28).

Future payments of notes payable, as of December 31, 2018, are as follows:

2019	\$ 2,211
2020	4,646
2021	5,384
2022	3,644
Total	<u>\$15,885</u>

16. Capitalized Leases

On January 1, 2013, the Company entered into a capital lease arrangement with 275 Dan Road SPE, LLC for the property located at 275 Dan Road in Canton, MA. 275 Dan Road SPE, LLC is a related party as the owners of the entity are also stockholders of the Company. The Company assessed the entity under the VIE rules in accordance with ASC 810 and concluded that it is not a variable interest entity since it has no debt and has sufficient equity. The lease has a ten-year term and escalating monthly rental payments ending in December 2022.

In January 2013, the Company entered into a new capital lease agreement with Dan Road Associates that requires escalating monthly rent payments of approximately \$87 with future rent increases of 10% effective in each of January 2016, January 2019, and January 2022. The lease terminates on December 31, 2022 with yearly renewals for a five-year period. Rent receipts and payments and the right to use the asset and lease obligation have been eliminated in the consolidated financial statements through May 31, 2017.

In January 2013, the Company entered into a new capital lease agreement with 85 Dan Road Associates that requires escalating monthly rent payments of approximately \$70 with future rent increases of 10% effective in each of January 2016, January 2019, and January 2022. The lease terminates on December 31, 2022 with yearly renewals for a five-year period. Rent receipts and payments and the right to use the asset and lease obligation have been eliminated in the consolidated financial statements through May 31, 2017.

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In January 2013, the Company entered into a new capital lease agreement with 65 Dan Road Associates that requires escalating monthly rent payments of approximately \$57 with future rent increases of 10% effective in each of January 2016, January 2019, and January 2022. The lease terminates on December 31, 2022 with yearly renewals for a five-year period. Rent receipts and payments and the right to use the asset and lease obligation have been eliminated in the consolidated financial statements through May 31, 2017.

On June 1, 2017, in connection with the deconsolidation of the Real Estate Entities, the Company's financial statements no longer eliminated the impacts of the capital leases for Dan Road Associates, 85 Dan Road Associates and 65 Dan Road Associates. Accordingly, as of June 1, 2017, the Company recognized the capital lease agreements that the Company entered into with Dan Road Equity, Dan Road Associates and Dan Road SPE for the properties located at 150 Dan Road, Canton, Massachusetts and the office buildings in immediate proximity of the Company's facility in Canton, Massachusetts. Dan Road Equity, Dan Road Associates and Dan Road SPE are related parties as the owners of the entities are also Stockholders' of the Company. The lease agreements with Dan Road Equity I, 85 Dan Road Associates and 65 Dan Road SPE contain escalating monthly rental payments and terminate on December 31, 2022 with yearly renewals for a five-year period.

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.

The future lease payments are as follows:

2019	\$ 9,573
2020	4,308
2021	4,308
2022	4,737
	<u>22,926</u>
Less amount representing interest	(5,271)
Present value of minimum lease payments	<u>17,655</u>
Less current maturities	(7,501)
Long-term portion	<u>\$10,154</u>

The principal portion of rent in arrears on the capital leases is included in the current portion of capital lease obligations. The interest portion of rent in arrears for the Dan Road entities totaled \$4,174 and \$3,950 as of December 31, 2018 and 2017, respectively and is included in accrued expenses on the consolidated balance sheets (See Note 13). In addition to rent, the Company is responsible for payment of all operating costs and common area maintenance under the aforementioned leases. The Company also pays for repairs and improvements.

17. Stockholders' Equity

As of December 31, 2018, 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; 20,000,000 shares of \$0.0001 par value Class B common stock; and 1,000,000 shares of \$0.0001 par value preferred stock.

On August 17, 2018, the Company issued 6,538,732 shares of Class A common stock for an aggregate purchase price of \$46,000 pursuant to the Initial Avista Investment (see Note 1). The proceeds were offset by issuance costs of \$270 which include legal and professional accounting fees directly associated with this equity investment.

On December 10, 2018, the Company issued 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 pursuant to the Additional Avista Investment (see Note 1).

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Additionally on December 10, 2018, the Company converted a portion of the affiliate debt into 6,502,679 shares of ORGO Class A common stock. In addition, 1,390,993 shares of ORGO Class B common stock were converted to the same number of shares of ORGO Class A common stock in connection with the closing of the Avista Merger. No ORGO Class B common stock is outstanding.

Each share of ORGO Class A common stock entitles the holder to one vote on all matters submitted to the stockholders for a vote. ORGO Class A common stockholders are entitled to receive dividends, as may be declared by the board of directors. Through December 31, 2018, no cash dividends have been declared or paid.

Redeemable Common Stock

On March 24, 2017, the Company issued 728,549 shares of Class A common stock in connection with the NuTech Medical acquisition which were recorded at their fair value of \$8.69 per share (see Note 5). These shares include a put right allowing the holder to put the shares back to the Company at an agreed-upon exercise price of \$9.28 per share on March 24, 2019. The Company also has the right to call the shares at an agreed-upon exercise price of \$9.28 per share prior to the second anniversary of the acquisition. These shares had been classified as temporary equity and had been accreted to the full redemption amount of \$9.28 per share as the holders have the right to exercise the put right on March 24, 2019. These shares have the same rights and preferences as common stock. During the year ended December 31, 2018 and 2017, the Company recorded \$0 and \$423 related to the accretion of these shares to their redemption amount, respectively. In December 2018, the Company received notification that the put option was being exercised. Accordingly, the Company reclassified the carrying value of the redeemable Class A common stock of \$6,762 to a current liability as of December 31, 2018, which it expects to settle in March 2019.

As of December 31, 2018 and 2017, the Company had reserved 33,432,421 and 8,229,517 shares of Class A common stock, respectively, for the exercise of outstanding stock options under the Company's 2003 and 2018 Stock Incentive Plans, shares remaining available for grant under the Company's 2018 Stock Incentive Plan (see Note 19) and the exercise of outstanding warrants to purchase shares of common stock (see Note 18). As of the closing of the Avista Merger on December 10, 2018, no additional awards may be made under the Organogenesis Inc. 2003 Stock Incentive Plan.

18. Warrants

As of each balance sheet date, outstanding warrants to purchase shares of Class A common stock consisted of the following:

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

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December 31, 2017

Date Exercisable	Number of Shares Issuable	Exercise Price	Exercisable for	Classification	Expiration
November 3, 2010	109,620	\$ 3.95	Common Stock	Equity	Later of 8/31/2019 or upon repayment of the notes payable
August 31, 2013	36,540	\$ 3.95	Common Stock	Equity	Later of 8/31/2019 or upon repayment of the notes payable
August 31, 2015	36,540	\$ 3.95	Common Stock	Equity	Later of 8/31/2019 or upon repayment of the notes payable
April 12, 2016	905,774	\$ 3.58	Common Stock	Liability	April 12, 2021
April 27, 2017	473,011	\$ 2.53	Common Stock	Equity	Earlier of 4/27/2027 or three years from the effective date of the Company's filing of an initial underwritten and sale of securities registration statement
	<u>1,561,485</u>				

In connection with the notes payable issued in 2010, the Company issued warrants to two institutional lenders to purchase an aggregate 109,620 shares of Class A common stock at an exercise price of \$3.95 per share. The warrants were classified as equity and were recorded at fair value on the date they were issued. The fair value of the warrants of \$97 was recorded as additional paid-in-capital and a reduction in the carrying value of the related notes payable. Under the terms of the warrant agreement, the Company was required to issue additional warrants to the lenders if any portion of the notes were still outstanding on August 31, 2013 and August 31, 2015.

In August 2013, the Company issued additional warrants to the same lenders to purchase 36,540 shares of Class A common stock at an exercise price of \$3.95 per share. The warrants were classified as equity and were recorded at fair value on the date they were issued. The fair value of the warrants of \$9 was recorded as additional paid-in capital and interest expense.

In August 2015, the Company issued additional warrants to the same lenders to purchase 36,540 shares of Class A common stock at an exercise price of \$3.95 per share. The warrants were classified as equity and were recorded at fair value on the date they were issued. The fair value of the warrants of \$9 was recorded as additional paid-in capital and interest expense.

The fair value of the warrants was calculated on the dates of grant using the Black-Scholes option pricing model. For the warrants issued in August 2015, the Company assumed a risk-free interest rate of 1.74%, a dividend yield of 0%, an expected volatility of 43.49%, which was calculated based on the historical volatility of comparable peer companies, and a two-year expected life of the warrants.

In connection with the 2016 Loans, on April 12, 2016, the Company issued to the lenders warrants to purchase up to 905,774 shares of the Company's Class A common stock at an exercise price of \$3.58 per share. The warrants were immediately exercisable and had a five-year term, expiring on April 12, 2021. The warrants were classified as a liability and were recorded at fair value on the date of grant. The fair value of the warrants of \$464 was recorded as a warrant liability and a reduction in the carrying value of the related loan. The fair value of the warrants was calculated on the date of grant using the binomial option pricing model. The Company assumed a risk-free interest rate of 1.22%, a dividend yield of 0%, and an expected volatility of 41.36%, which was calculated based on the historical volatility of publicly-traded peer companies, and the contractual term of five years. The warrants were net exercised immediately prior to the closing of the Avista Merger on December 10, 2018 and the Company issued 444,041 shares of Class A common stock. The Company remeasured the fair value of the warrants immediately prior to the exercise on December 10, 2018. The Company

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recognized a loss of \$469 and \$1,037 in the consolidated statements of operations for the years ended December 31, 2018 and 2017, respectively, related to the change in fair value of the warrants.

In connection with the ML Agreement, on April 28, 2017, the Company issued to the lenders warrants to purchase 473,011 shares of the Company's Class A common stock at an exercise price of \$2.53 per share as a pre-condition for the agreement. The warrants were immediately exercisable and expire on the earlier of April 27, 2027 or three years from the effective date of the Company's filing of an initial underwritten and sale of securities registration statement. The warrants were classified as equity as it is exercisable into common stock only and, as such, would not require a transfer of assets and were recorded at fair value which was estimated to be \$958 using a probability weighted Black Scholes option pricing model that was based on a 40% chance of an initial underwritten and sale of securities registration statement occurring within the next 18 months. Additionally, the model incorporated the following assumptions: 44.81%-57.51% volatility, 1.73%-2.35% risk-free rate, 4.25-10 year expected term, and no dividend yield. The issuance date fair value was recorded as a debt discount and is being amortized as interest expense. The warrants were net exercised immediately prior to the closing of the Avista Merger on December 10, 2018 and the Company issued 302,443 shares of Class A common stock.

In connection with the Additional Avista Investment on December 10, 2018, the Company issued 4,100,000 warrants to purchase one half of one share of Class A common stock at an exercise price of \$11.50 per share. The warrants were classified as equity and were recorded as additional paid-in capital.

In connection with 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 from the former AHPAC Shareholders (See Note 3). The warrants were classified as equity and recorded to additional paid-in-capital.

19. Stock Options

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 Holdings Inc. 2018 Equity Incentive Plan (the "2018 Plan"). The purposes of the 2018 Plan are to (i) provide long-term incentives and rewards to those employees, officers, directors and other key persons (including consultants) of the Company and its subsidiaries who are in a position to contribute to the long-term success and growth of the Company and its subsidiaries, (ii) to assist the Company and its subsidiaries in attracting and retaining persons with the requisite experience and ability, and (iii) 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. As of December 31, 2018, the 2018 Plan is administered by the Company's board of directors. Stock options awarded under the 2018 Plan expire 10 years after the grant date. Stock options granted to employees of the Company typically vest over four or five years.

As of December 31, 2018, 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). As of December 31, 2018, options to purchase 90,000 shares of Class A common stock were outstanding under the 2018 Plan. No other awards had been issued under the 2018 Plan.

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In respect of any shares of Class A common stock under any award under the 2018 Plan which shares are forfeited, canceled, satisfied without the issuance of shares of Class A common stock, otherwise terminated, or, for shares of Class A common stock issued pursuant to any unvested full value award, reacquired by the Company at not more than the grantee's purchase price (other than by exercise) ("Unissued Shares"), such Unissued Shares shall be added back to the pool of authorized shares under the 2018 Plan except that upon the exercise of any award to the extent that the Award is exercised through tendering (or attesting to) previously owned shares or through withholding shares that would otherwise be awarded and to the extent shares are withheld for tax withholding purposes, the pool of authorized shares shall be reduced by the gross number of shares of Class A common stock being exercised without giving effect to the number of shares tendered or withheld.

Subject to the requirements of law or any stock exchange or similar rules which would require a vote of the Company's stockholders, the Administrator may, at any time, amend or discontinue the 2018 Plan and the Administrator may, at any time, amend or cancel any outstanding award for the purpose of satisfying changes in law or for any other lawful purpose, but no such action shall adversely affect rights under any outstanding award without the holder's consent.

2003 Stock Incentive Plan

The Organogenesis Inc. 2003 Stock Incentive Plan, as amended (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.

As of the closing of the Avista Merger on December 10, 2018, a total of 7,176,715 shares of Class A common stock were issuable upon exercise of outstanding options under the 2003 Plan. 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 us, will not be available for future awards; and (iii) any shares of 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 options awarded under the 2003 Plan expire 10 years after the grant date. Stock options granted to employees of the Company typically vest over four or five years.

During the years ended December 31, 2018 and 2017, the Company granted options to purchase 248,567 shares and 895,194 shares, respectively, of Class A common stock to employees under the 2003 Plan and 2018 Plan. The Company recorded stock-based compensation expense for options granted to employees of \$1,075, \$919 and \$473 within selling, general and administration expense in the consolidated statement of operations during the years ended December 31, 2018, 2017 and 2016, respectively.

The Company has historically not granted stock options to non-employees.

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Stock Option Valuation

The assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and directors were as follows, presented on a weighted average basis:

	Year Ended December 31,	
	2018	2017
Risk-free interest rate	2.73%	2.05%
Expected term (in years)	5.89	6.25
Expected volatility	42.0%	45.7%
Expected dividend yield	0.0%	0.0%
Exercise price	\$5.99	\$3.45
Fair value of common share	\$5.82	\$3.45

Stock Options

The following table summarizes the Company's stock option activity since December 31, 2017 (in thousands, except share and per share amounts):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2017	7,150,214	\$ 1.77	6.70	24,581
Granted	248,567	5.99		
Cancelled / forfeited	(76,664)	1.55		
Exercised	(55,402)	—		
Outstanding as of December 31, 2018	7,266,715	1.91	6.50	33,976
Options exercisable as of December 31, 2018	5,396,880	1.53	5.21	27,280
Options vested or expected to vest as of December 31, 2018	6,948,699	\$ 1.82	5.76	33,096

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 had exercise prices lower than the fair value of the Company's Class A common stock.

The weighted average grant-date fair value per share of stock options granted during the years ended December 31, 2018 and 2017 was \$2.39 and \$1.62, respectively.

The total fair value of options vested during the years ended December 31, 2018 and 2017 was \$963 and \$1,070, respectively.

As of December 31, 2018, the total unrecognized stock compensation expense was \$1,733 and is expected to be recognized over a weighted-average period of 2.77 years.

At December 31, 2018, there was one partial recourse note outstanding totaling \$635, which was secured with the 675,990 shares and options held by the executive (see Note 11). As a result of the loan still outstanding, the 675,990 options securing the loan are included within the options outstanding and recorded at par value with an offset to additional paid in capital.

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20. Royalties

The Company licenses the use of trademarks and domain names for one of its advanced wound care products from a major pharmaceutical company. Beginning January 2012, the Company was obligated to pay the licensor a royalty based on a percentage of net sales of the product, in perpetuity. Royalty expense was \$253, \$292 and \$287 for each of the years ended December 31, 2018, 2017 and 2016, respectively.

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, 2018 and 2017, 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, 2018 or 2017 related to this agreement.

In October 2017, the Company entered into a license agreement to resolve a patent infringement claim by 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, 2016, through the expiration date of the underlying patent, subject to minimum royalty payment provisions. The Company recorded royalty expense of \$2,059 and \$3,122 during the years ended December 31, 2018 and 2017, respectively, within selling, general and administrative expenses on the consolidated statement of operations. In July 2018, the Company made a payment of \$200 related to maintenance of the underlying patent. The Company is required to make one final payment of \$150 in April 2019, related to maintenance of the underlying patent.

As part of the NuTech Medical acquisition (see Note 5), 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. During the years ended December 31, 2018 and 2017, the Company recognized royalty expense of \$77 and \$25 within selling, general and administrative expenses on the consolidated statement of operations.

21. Income Taxes

On December 22, 2017, the U.S. enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act of 2017 (the "Tax Act"). The Tax Act made broad and complex changes to the U.S. tax code, including, but not limited to, reducing the federal corporate income tax rate to 21 percent, imposing a mandatory one-time transition tax on certain unrepatriated earnings of foreign subsidiaries and eliminating the corporate alternative minimum tax ("AMT") and changing how existing AMT credits can be realized. The Company was required to recognize the tax effect of the tax law changes in the year of enactment. In order to calculate these effects, we were required to determine the transition tax amount, remeasure our United States deferred tax assets and liabilities, and consider the impact to our AMT credit carryforwards. For the year ended December 31, 2017, we recorded provisional amounts in accordance with that guidance where it was possible for us to make reasonable estimates of the effects of the Tax Act. We evaluated the decrease in our corporate tax rate and recorded a provisional, one-time expense of \$19,761 at December 31, 2017. We fully offset out tax effect by a decrease in our valuation allowance, which resulted in no net tax effect in 2017. During the fourth quarter of 2018, we completed our accounting for all aspects of the Tax Act. We did not identify material changes from our 2017 provisional analysis.

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The components of the income tax provision (benefit) consisted of the following for the years ended December 31, 2018, 2017 and 2016:

	Year Ended December 31,		
	2018	2017	2016
(Benefit from) provision for income taxes:			
Current tax expense			
Federal	\$(212)	\$ —	\$—
State	101	214	65
Foreign	9	62	—
Total current tax expense (benefit)	<u>(102)</u>	<u>\$ 276</u>	<u>65</u>
Deferred tax expense (benefit)			
Federal	212	(6,401)	—
State	—	(900)	—
Foreign	(26)	—	—
Total deferred tax expense (benefit)	<u>\$ 186</u>	<u>\$(7,301)</u>	<u>\$—</u>
Total income tax expense (benefit)	<u>\$ 84</u>	<u>\$(7,025)</u>	<u>\$ 65</u>

At December 31, 2018, the Company had available for the reduction of future years' federal taxable income, net operating loss carry-forwards of approximately \$165,256 expiring from the year ended December 31, 2019 through 2038, and state net operating loss carry-forwards of approximately \$56,991 expiring from the year ended December 31, 2020 through 2038. At December 31, 2018, the Company had available for the reduction of future years' federal taxable income, research and development credits of approximately \$878 expiring between December 31, 2019 and December 31, 2038.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities as of December 31, 2018 and 2017 are as follows:

	December 31,	
	2018	2017
Net operating loss carryforwards		
Federal	\$ 34,707	\$ 26,725
State	3,208	1,327
Foreign	26	—
Capitalized research and development	—	101
Other	12,219	8,706
Stock-based compensation	29	293
Fresh start and intangible assets acquired	(2,765)	(3,757)
Net deferred tax assets before valuation allowance	<u>47,424</u>	<u>33,395</u>
Valuation allowance	<u>(47,186)</u>	<u>(32,971)</u>
Net deferred tax assets	<u>\$ 238</u>	<u>\$ 424</u>

At December 31, 2018 and 2017, the Company recorded a valuation allowance of \$47,186 and \$32,971, respectively, on the deferred tax assets to reduce the total to an amount that management believes will ultimately be realized. In 2018, the valuation allowance increased by \$14,215 primarily due to the federal and state net operating losses generated in 2018, which require a full valuation allowance. Realization of deferred tax assets is

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dependent upon sufficient future taxable income during the period that deductible temporary differences and carryforwards are expected to be available to reduce taxable income.

At December 31, 2018, the Company recorded a net deferred tax asset of \$238 relating to relating to AMT credits which will be 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 has been provided against this asset. At December 31, 2018, fifty percent (50%) of the AMT deferred tax asset was reclassified to prepaids and other current assets, which represents the amount of refundable AMT credit the Company will claim with the 2018 tax return.

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 percent and the reported consolidated income tax benefit (expense) are summarized as follows:

	December 31,		
	2018	2017	2016
U.S. federal statutory income tax rate	21.0%	35.0%	35.0%
Tax reform act	— %	(134.4)%	— %
State income taxes, net of federal benefit	(18.4)%	147.5%	(30.9)%
Foreign rate differential	(3.9)%	3.0%	(3.6)%
Research and development tax credits	3.5%	2.3%	2.5%
Nondeductible expenses	(2.3)%	(6.8)%	(3.2)%
Noncontrolling interest	— %	2.2%	— %
Uncertain tax position reserves	(0.1)%	(0.5)%	(0.2)%
Effective income tax rate	<u>(0.2)%</u>	<u>48.3%</u>	<u>(0.4)%</u>

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 \$3,722, \$3,801 and \$3,802 as of December 31, 2018, 2017 and 2016, respectively, which have been subject to a full valuation allowance. The net decrease primarily relates to the expiration of the statute of limitations for previously utilized Massachusetts R&D credits and accrued interest on uncertain state tax positions.

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

	Year Ended December 31,		
	2018	2017	2016
Gross balance at beginning of year	\$3,486	\$3,663	\$3,417
Additions based on tax positions related to the current period	157	231	325
Reductions for tax positions of prior years	(357)	(408)	(79)
Gross balance at end of year	<u>3,286</u>	<u>\$3,486</u>	<u>\$3,663</u>

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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, 2013. However, carryforward attributes that were generated prior to December 31, 2014 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 expense in tax expenses. There was \$209 and \$159 of interest recorded for uncertain tax positions for the years ended December 31, 2018 and 2017, respectively, which was classified in accrued expenses in the consolidated balance sheets. These amounts are not reflected in the reconciliation above.

22. Net Loss Per Share

Basic and diluted net loss per share attributable to Organogenesis Holdings Inc. was calculated as follows:

	2018	Year Ended December 31, 2017	2016
Numerator:			
Net loss	\$ (64,831)	\$ (7,525)	\$ (14,766)
Less: Net income attributable to non-controlling interests	—	863	2,221
Less: Accretion of redeemable common shares	—	423	—
Net loss attributable to Organogenesis Holdings Inc.	<u>\$ (64,831)</u>	<u>\$ (8,811)</u>	<u>\$ (16,987)</u>
Denominator:			
Weighted average common shares outstanding — basic and diluted	<u>69,318,456</u>	<u>63,876,767</u>	<u>63,196,067</u>
Net loss per share — basic and diluted	<u>\$ (0.94)</u>	<u>\$ (0.14)</u>	<u>\$ (0.27)</u>

The Company's potentially dilutive securities, which include stock options and warrants to purchase shares of Class A common stock, have been excluded from the computation of diluted net loss per share as the effect would be to 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 common stockholders is the same. The Company excluded the following potential shares of Class A of common stock, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to Organogenesis Holdings Inc. for the periods indicated because including them would have had an anti-dilutive effect:

	2018	Year Ended December 31, 2017	2016
Options to purchase common stock	7,266,715	7,150,214	5,627,881
Redeemable common stock	728,549	728,549	—
Warrants to purchase common stock	17,732,700	1,561,485	1,088,474
	<u>25,727,964</u>	<u>9,440,248</u>	<u>6,716,355</u>

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23. Product and Geographic Sales

The following table sets forth revenue by product category:

	2018	Year Ended December 31, 2017	2016
Advanced Wound Care revenue	\$164,332	\$ 178,896	\$138,732
Surgical and Sports Medicine revenue	29,117	19,612	—
Total revenue	\$193,449	\$ 198,508	\$138,732

For the years ended December 31, 2018, 2017 and 2016 revenue generated outside the US represented 1% of total revenue.

24. Commitments and Contingencies

Operating Lease

During 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 original sublease agreements called for escalating monthly rental payments and was set to expire in January 2017. These sublease agreements were renegotiated in 2016 and subsequently extended through 2021. Rent expense is being recorded on a straight-line basis over the term of the lease. Rent expense associated with this lease agreement for the years ended December 31, 2018, 2017 and 2016 was \$1,554, \$1,764, and 2,451, respectively.

During November 2011, the Company entered into vehicle lease and fleet services agreements for the lease of vehicles and service on these vehicles for certain employees. The minimum lease term for each newly leased vehicle is one year with three consecutive one year renewal terms. Lease expense associated with the lease of the vehicles for the years ended December 31, 2018, 2017 and 2016 was \$2,834, \$2,276 and \$1,735, respectively.

In conjunction with the acquisition of NuTech Medical in March 2017, the Company assumed the lease of the headquarters of NuTech Medical in Birmingham, Alabama. Under the lease, the Company is required to make monthly rental payments of \$20 through December 31, 2018. The Company has extended the lease through December 31, 2020 with a monthly rental payment of \$21. Rental expense associated with this lease, for the years ended December 31, 2018 and 2017, was \$240 and \$180, respectively.

Future minimum lease payments due under noncancelable operating lease agreements as of December 31, 2018 are as follows:

2019	\$ 4,530
2020	3,937
2021	3,209
2022	446
	<u>\$12,122</u>

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 of the Company. The Company accrues for these claims when amounts due are probable and estimable.

The Company accrued \$1,000 as of December 31, 2018 and 2017 in relation to certain pending lawsuits filed against the Company by former employees.

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As discussed in Note 5, the purchase price for NuTech Medical included \$7,500 of future payments issued as deferred acquisition consideration. As of December 31, 2018, the Company has paid \$2,500 in deferred acquisition consideration. The amount, if any, of the remaining \$5,000 of deferred acquisition consideration plus accrued interest owed to the sellers of NuTech Medical is currently in dispute. As of December 31, 2018, the Company recorded \$618 of accrued interest related to the deferred acquisition consideration which is recorded in accrued expenses and other current liabilities. The Company has asserted certain claims for indemnification that would offset in whole or in part its payment obligation and the sellers of NuTech Medical have filed a lawsuit alleging breach of contract and seeking specific performance of the alleged payment obligation and attorneys' fees.

25. Related Parties

Capital lease obligations to affiliates are further described in Notes 13 and 16, respectively. Notes receivable from related parties are further described in Note 11.

On March 24, 2017, the Company purchased NuTech Medical from its sole shareholder for approximately \$12,000 in cash, \$7,500 in deferred acquisition consideration and 3,642,746 shares of the Company's Class A common stock issued to the sole shareholder (see Note 5). In connection with the acquisition of NuTech Medical, the Company entered into an operating lease with Oxmoor Holdings, LLC, an entity that is affiliated with the sole shareholder, 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 \$20 through December 31, 2018. The Company has extended the lease through December 31, 2020.

26. Employee Benefit Plan

The Company maintains a 401(k) Savings Plan (the "Plan") for all 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, 2018 and 2017, the Company made employer contributions of \$1,883 and \$1,006, respectively.

As part of the NuTech Medical acquisition (see Note 5), the Company inherited the Savings Incentive Match Plan for Employees ("SIMPLE") IRA plan for all eligible former NuTech Medical employees. The plan, which operates as a tax deferred employer-provided retirement plan, allows eligible employees to contribute part of their pre-tax compensation to the plan. Employers are required to make either matching contributions, or non-elective contributions, which are paid to eligible employees regardless of whether the employee made salary-reducing contributions to the plan. Plan participants may elect to make pre-tax contributions up to the maximum amount allowed by the Internal Revenue Service. The Company is required to make matching contributions up to 3% for all qualifying employees. The Company terminated the SIMPLE IRA plan as of January 1, 2018.

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27. Selected Quarterly Financial Information (Unaudited)

Selected quarterly results of operations for the years ended December 31, 2018 and 2017 are as follows:

	Three Months Ended March 31, 2018	Three Months Ended June 30, 2018	Three Months Ended September 30, 2018	Three Months Ended December 31, 2018
Net revenue	\$ 35,529	\$ 43,552	\$ 50,769	\$ 63,599
Cost of goods sold	14,521	17,300	19,477	17,510
Gross profit	21,008	26,252	31,292	46,089
Operating expenses:				
Selling, general and administrative	38,165	37,735	38,583	47,478
Research and development	2,824	2,048	2,779	3,091
Write-off of deferred offering costs	—	3,494	—	—
Total operating expenses	40,989	43,277	41,362	50,569
Loss from operations	(19,981)	(17,025)	(10,070)	(4,480)
Other income (expense), net:				
Interest expense	(2,429)	(2,801)	(2,960)	(2,663)
Interest income	19	20	20	5
Change in fair value of warrants	(74)	(175)	(50)	(170)
Loss on the extinguishment of debt	—	—	—	(2,095)
Other expense, net	5	(2)	9	150
Total other income (expense), net	(2,479)	(2,958)	(2,981)	(4,773)
Net loss before income taxes	(22,460)	(19,983)	(13,051)	(9,253)
Income tax expense	(28)	(27)	(27)	(2)
Net loss	(22,488)	(20,010)	(13,078)	(9,255)
Net income attributable to non-controlling interest in affiliates	—	—	—	—
Net loss attributable to Organogenesis Holdings Inc.	\$ (22,488)	\$ (20,010)	\$ (13,078)	\$ (9,255)
Net loss per share attributable to Organogenesis Holdings Inc.—basic and diluted	\$ (0.35)	\$ (0.30)	\$ (0.19)	\$ (0.12)
Weighted average common shares outstanding—basic and diluted	64,320,931	66,361,998	69,496,279	76,952,174

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	Three Months Ended March 31, 2017	Three Months Ended June 30, 2017	Three Months Ended September 30, 2017	Three Months Ended December 31, 2017
Net revenue	\$ 39,837	\$ 54,071	\$ 51,458	\$ 53,142
Cost of goods sold	13,305	15,406	16,087	16,422
Gross profit	26,532	38,665	35,371	36,720
Operating expenses:				
Selling, general and administrative	27,952	33,716	35,662	36,387
Research and development	1,551	2,454	2,325	2,735
Total operating expenses	29,503	36,170	37,987	39,122
Loss from operations	(2,971)	2,495	(2,616)	(2,402)
Other income (expense), net:				
Interest expense	(1,592)	(2,031)	(2,233)	(2,283)
Interest income	38	35	28	28
Change in fair value of warrants	55	(505)	(534)	(53)
Other expense, net	62	(119)	(1)	49
Total other income (expense), net	(1,437)	(2,620)	(2,740)	(2,259)
Net loss before income taxes	(4,408)	(125)	(5,356)	(4,661)
Income tax (expense) benefit	6,683	156	(47)	233
Net income (loss)	2,275	31	(5,403)	(4,428)
Net income attributable to non-controlling interest in affiliates	590	273	—	—
Net income (loss) attributable to Organogenesis Holdings Inc.	\$ 1,685	\$ (242)	\$ (5,403)	\$ (4,428)
Net (loss) income per share attributable to Organogenesis Holdings Inc.—basic	\$ 0.02	\$ (0.00)	\$ (0.08)	\$ (0.07)
Net (loss) income per share attributable to Organogenesis Holdings Inc.—diluted	\$ 0.02	\$ (0.00)	\$ (0.08)	\$ (0.07)
Weighted average common shares outstanding—basic	63,311,814	64,022,549	64,040,527	64,121,501
Weighted average common shares outstanding—diluted	66,670,850	64,022,549	64,040,527	64,121,501

28. Subsequent Events

The Company has evaluated subsequent events through March 18, 2019, the date on which these consolidated financial statements were issued.

Lease agreement

On March 13, 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 lease commenced on March 13, 2019. The rent commencement date will be February 1, 2020. The initial lease term is ten years from the rent commencement date and includes an early 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, in addition to

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the five year early extension term, 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 with increase of \$44 during the first year of the early extension term and \$33 during years 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.

New Credit Agreement

In March 2019, the Company and its subsidiaries, Organogenesis Inc. and Prime Merger Sub, LLC (collectively, and jointly and severally, “Borrower”), and Silicon Valley Bank, as Administrative Agent, Issuing Lender and Swingline Lender, and the several other lenders thereto (the “Lenders”) entered into a Credit Agreement (the “New Credit Agreement”) providing for a term loan (the “Term Loan Facility”) and a revolving credit facility (the “Revolving Facility”, and together with the Term Loan Facility, the “Debt Facility”) in an aggregate principal amount of \$100,000.

The Term Loan Facility is structured in three tranches, as follows: (i) the first tranche of \$40,000 was made available to Borrower and fully funded on March 14, 2019; (ii) the second tranche of \$10,000 shall be made available to Borrower until September 30, 2019 upon: (a) the Lenders’ receipt of financial statements for the quarter ended June 30, 2019, (b) Borrower’s demonstrated compliance with the financial covenants in the New Credit Agreement and (c) Borrower’s achievement of trailing twelve month revenue of at least \$221,250 and a trailing three month EBITDA (as defined in the New Credit Agreement) loss not in excess of \$5,000; and (iii) the third tranche of \$10,000 shall be made available to Borrower until March 31, 2020 upon the Lenders’ confirmation of Borrower’s compliance with the financial covenants in the Credit Agreement through December 31, 2019; provided, however, that if Borrower does not achieve the milestones required for the second tranche, the amount that may become available under the third tranche shall be increased from \$10,000 to \$20,000. The interest rate for term loan advances made under the Term Loan Facility is a per annum interest rate equal to 3.75% above the Wall Street Journal Prime Rate. The New Credit Agreement requires Borrower to make monthly interest-only payments on outstanding balances under the Term Loan Facility through March 14, 2021. Thereafter, each term loan advance shall be repaid in thirty six equal monthly installments of principal, plus accrued interest, with the Term Loan Facility maturing on March 14, 2024 (the “Term Loan Maturity Date”).

Borrower’s final payment on the Term Loan Facility, due on the Term Loan Maturity Date, shall 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 6.25%. Borrower may prepay the Term Loan Facility, subject to paying the Prepayment Premium (described below) and the Final Payment. The Prepayment Premium is equal to 3.00% of the outstanding principal amount of the Term Loan Facility if the prepayment occurs on or prior to the one year anniversary of the closing, 2.00% of the outstanding principal amount of the Term Loan Facility if the prepayment occurs after such one year anniversary and prior to the second anniversary of the closing, and 1.00% of the outstanding principal amount of the Term Loan Facility if the prepayment occurs after the two year anniversary but prior to the three year anniversary of the closing, and 0% 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 (as defined in the New Credit Agreement). The interest rate for advances under the Revolving Facility is a floating per annum interest rate equal to the *Wall Street Journal* Prime Rate. In the event that the aggregate amount of interest earned by the Lenders from the Revolving Facility in any given month is less than the interest that would have been earned if Borrower had average outstanding advances in an amount equal to 25% of the then-available Revolving Commitments (as defined in the New Credit Agreement) then Borrower must pay the

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Agent Minimum Interest (as defined in the New Credit Agreement) in an amount equal to interest that would have accrued if average outstanding advances under the Revolving Facility had been 25% of the then-available Revolving Commitments less any interest actually earned by the Lenders. Borrower 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 14, 2024.

Borrower 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 4.00% of the aggregate Revolving Commitments so reduced or terminated if the reduction or termination occurs on or prior to the one year anniversary of the closing, 3.00% of the aggregate Revolving Commitments so reduced or terminated if the reduction or termination occurs after such one year anniversary 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 two year anniversary but prior to the three year anniversary of the closing, and \$0 thereafter.

The New Credit Agreement requires Borrower to pay an aggregate non-refundable facility fee of \$500 on March 14, 2019 and \$100 on each anniversary of the closing until March 14, 2023.

Under the New Credit Agreement, Borrower is required to achieve Minimum Trailing Twelve Month Consolidated Revenue (as defined in the New Credit Agreement), tested quarterly, at the following levels: \$200,000 for the trailing twelve months ending March 31, 2019; \$213,500 for the trailing twelve months ending June 30, 2019; \$221,250 for the trailing twelve months ending September 30, 2019; and \$231,500 for the trailing twelve months ending December 31, 2019, with minimum revenue covenant levels for 2020 to be agreed between the Lenders and the Borrower no later than February 15, 2020. In addition, Borrower is required to maintain Minimum Liquidity (as defined in the New Credit Agreement) equal to the greater of (i) 6 months Monthly Burn (as defined in the New Credit Agreement) and (ii) \$10,000. Finally, on or prior to December 31, 2019, Borrower is obligated to enter into amended lease agreements with the owners of its facilities on Dan Road in Canton, Massachusetts providing for a lease term ending on a date that is later than March 14, 2024 and including arm's length terms with respect to assignability, bankruptcy, early termination and other provisions as the Lenders deem reasonably necessary.

The New Credit Agreement requires Borrower to make representations and warranties and comply with covenants that are customary in loan agreements of this type, including restrictions on the payment of dividends, repurchase of stock, incurrence of indebtedness, dispositions and acquisitions. The New Credit Agreement also contains customary events of default, including non-payment of principal or interest, violations of covenants, bankruptcy, change of control, material adverse effect, cross defaults to other debt and material judgments. Borrower's obligations to the Lenders are secured by substantially all of Borrower's assets, including intellectual property.

In March 2019, in connection with entering into the New Credit Agreement, all amounts due under the Credit Agreement, including unpaid principal and accrued interest, and all amounts due under the ML Agreement, including unpaid principal, accrued interest and early termination penalty, were repaid with proceeds from the New Credit Agreement and the Credit Agreement and ML Agreement were terminated.