# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

Amendment No. 1

# to FORM S-1 REGISTRATION STATEMENT

**UNDER** THE SECURITIES ACT OF 1933

# ORGANOGENESIS HOLDINGS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization) (Primary Standard Industrial Classification Code No.)

98-1329150 (I.R.S. Employer Identification No.)

85 Dan Road Canton, MA 02021 (781) 575-0775

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Gary S. Gillheeney, Sr. President and Chief Executive Officer 85 Dan Road Canton, MA 02021

(781) 575-0775 (Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement	of proposed sale to the pul	lic: As soon as practicable after	this Registration Statement is	declared effective.
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If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act") please check the following box.  $\Box$ 

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $\Box$ 

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $\square$ 

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $\square$ 

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large ated filer," "smaller reporting company" and "emerging growth company" in Rule 12b2 of the Exchange Act. accelerated filer.'

Large accelerated files Non-accelerated filer 1 Accelerated filer

Smaller reporting company

Emerging growth company

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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 7(a)(2)(B) of the Securities Act.  $\Box$ 

### CALCULATION OF REGISTRATION FEE

	Proposed	
	maximum	
Title of each class of	aggregate	Amount of
securities to be registered	offering price(1)(2)	registration fee(3)
Class A common stock, par value \$0.0001 per share	\$83,518,750.00	\$9,111.90

- Estimated solely for the purpose of determining the amount of the registration fee pursuant to Rule 457(o) under the Securities Act. Includes the offering price attributable to shares that
- the underwriters have the option to purchase from the registrant solely to cover over-allotments, if any. Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

This amount was previously paid

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion Preliminary Prospectus dated November 10, 2020

**PROSPECTUS** 

The date of this prospectus is

, 2020.

17,500,000 Shares



Class A Common Stock

We are offering 17,500,000 shares of our Class A common stock. Our Class A common stock is listed on the Nasdaq Capital Market under the symbol "ORGO." On November 9, 2020, the last reported sale price of our Class A common stock was \$4.15 per share.

Investing in our Class A common stock involves a high degree of risk. See "Risk Factors" beginning on page 12 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Public offering price Underwriting discount(1) Proceeds, before expenses, to us	Per Share \$ \$ \$	**************************************
(1) See "Underwriting" for a description of compensation payable to the underwriters and	nd other fees payable in connection with this	s offering.
Delivery of the shares of Class A common stock in this offering is expected to be made on or	· about , 2020.	
We have granted the underwriters an option for a period of 30 days to purchase up to 2,625, offering price, less the underwriting discounts and commissions.	,000 shares of our Class A common stock fr	om us at the public
Joint Book-Running Manager	rs	
Morgan Stanley	S	VB Leerink
Co-Managers	<del>_</del>	
BTIG	Oppenh —	neimer & Co.

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Neither we nor any of the underwriters has authorized anyone to make any representations other than those contained in this prospectus. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of our Class A common stock offered by this prospectus, but only under circumstances and in jurisdictions where it is lawful to do so. The information in this prospectus is current only as of its date, regardless of the time of delivery of this prospectus or any sale of our Class A common stock.

Neither we nor any of the underwriters has taken any action to permit a public offering of the shares of our Class A common stock or the possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons who have come into possession of this prospectus in a jurisdiction outside the United States are required to inform themselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

#### PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our Class A common stock. You should read the following summary together with the more detailed information appearing in this prospectus, including our financial statements and related notes, and the information set forth under the sections titled "Risk Factors," "Cautionary Note Regarding Forward-Looking Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" before making an investment decision. Unless the context otherwise requires, the terms "Organogenesis," "ORGO," "our company," "we," "us" and "our" in this prospectus refer to Organogenesis Holdings Inc. and its subsidiaries.

#### Overview

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

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

In the Advanced Wound Care market, we focus on the development and commercialization of advanced wound care products for the treatment of chronic and acute wounds, 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 VLUs 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, 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 September 30, 2020, we had approximately 900 full-time employees worldwide. For the nine months ended September 30, 2020, we generated \$231.5 million of net revenue and had \$0.5 million of net loss compared to \$186.3 million of net revenue and \$36.1 million of net loss for the nine months ended September 30, 2019. For the year ended December 31, 2019, we generated net revenue of \$261.0 million and had a net loss of \$40.5 million as compared to net revenue of \$193.4 million and a net loss of \$64.8 million for the year ended December 31, 2018.

# **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 a greater incidence of comorbidities such as diabetes, obesity, and cardiovascular and peripheral vascular disease and smoking. We believe there is growing adoption of regenerative medicine products by the physician community due to their clinical superiority and cost effectiveness for all major stakeholders compared to traditional products.
- Comprehensive Suite of Products to Address the Clinical and Economic Needs of Wound Care Patients and Providers. Our comprehensive portfolio of wound care products allows physicians to personalize solutions to meet the needs of individual wound care patients. We engage with the

physician at the earliest incidence of the patient's healing process with our PuraPly AM product, which has antimicrobial properties that are beneficial for most types of wounds. If the underlying healing issues persist, we offer an array of bioactive products 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. Several of our existing and pipeline products in our product portfolio have FDA regulatory approval, including PMA approval, BLA approval or 510(k) clearance. Given the extensive time and cost required to conduct clinical trials and receive FDA approval, we believe our data and regulatory approvals provide us a strong competitive advantage.
- Robust and Extensive Relationships Across the Continuum of Care. We have established robust and extensive customer relationships across the entire continuum of care including hospitals, wound care centers, government facilities, ASCs and physician offices to sell our broad portfolio of products. We serve more than 3,000 health care facilities, hospital systems, IDNs and GPOs. In addition, we have developed important relationships with physicians, nurses, and other key decision makers as well as third-party payers. Given these relationships across the continuum of care, we believe we are well positioned to increase our penetration in the Advanced Wound Care market and leverage those relationships in the Surgical & Sports Medicine market.
- Differentiated In-house Customer Support Capabilities Including Third-Party Reimbursement Support. We strengthen our customer relationships with extensive in-house customer support capabilities. Through our dedicated team of experienced professionals, our "Circle of Care" program provides in-house third-party reimbursement, medical and technical support. We believe our customer support capabilities differentiate us from many of our competitors who may outsource these critical services to third parties.
- Established and Scalable Regulatory, Manufacturing and Commercial Infrastructure. We have developed significant in-house expertise on the regulatory approval process that is based on our successful management of multiple products through various FDA approval pathways including PMA approval, BLA approval and 510(k) clearance. We have also developed rigorous and proven FDA compliant manufacturing, distribution and logistics capabilities. We pair our operational capabilities with a strong commercial team of sales and marketing professionals. Our established regulatory, operational and commercial infrastructure provides a firm foundation for growth as we continue to scale our business.
- Extensive Executive Management Experience in Regenerative Medicine. Our executive management team has extensive experience in the regenerative medicine industry, boasting over 70 years of collective experience in the space. This experience allows us to operate from a deep understanding of the underlying trends in regenerative medicine and the intertwined scientific, clinical, regulatory, commercial and manufacturing issues that drive success in the industry.

# **Our Business Strategy**

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

• Drive Penetration in the Fast Growing Advanced Wound Care Market. We intend to leverage our comprehensive product portfolio and relationships with key constituents to deepen our presence in the Advanced Wound Care market. In addition, with the acquisition of NuTech Medical, we acquired

products that give us access to the rapidly growing amniotic category of the wound care market. We believe the breadth and flexibility of the portfolio we now offer allow us to address a wide variety of wound types, sizes, and reimbursement levels, offering significant new opportunities for growth. Furthermore, we believe our expanded product portfolio is enhancing the ability of our sales representatives to reach and penetrate customer accounts, contributing to strong growth over time. Additionally, we believe there is significant room for expansion of the Advanced Wound Care market as a whole and our wound biologics product category in particular as more physicians and payers are educated about the benefits of regenerative medicine technologies versus traditional therapies. We continue to invest to support physician and payer education as well as preclinical and clinical trials, real-world evidence, and other research to confirm the benefits of our products. We will continue to seek expanded payer coverage for all of our products, particularly PuraPly AM, NuShield and Affinity for which we do not yet have the broad commercial payer coverage enjoyed by Apligraf and Dermagraft.

- Continued Expansion into Surgical & Sports Medicine Market. We entered the Surgical & Sports Medicine market with the acquisition of NuTech Medical and its established and leading presence in amniotic products in 2017. We plan to continue to accelerate penetration into this market by leveraging our established commercial and operational infrastructure and building out our direct sales force to supplement our independent sales agencies. We also plan to continue to take advantage of significant opportunities to cross-sell within our established customer bases in both the Advanced Wound Care and Surgical & Sports Medicine markets. We believe that the potential of regenerative medicine in the Surgical & Sports Medicine market, particularly with respect to chronic inflammatory and degenerative conditions, continues to present a strong long-term opportunity. Given our experience in the Advanced Wound Care market and regenerative medicine in general, we believe we are well positioned to capture this opportunity.
- Launch Robust Pipeline of Products and Drive Innovation With a Proven Research and Development Platform. We have a robust pipeline of products in both the Advanced Wound Care and Surgical & Sports Medicine markets that we expect to launch in the near term. We expect these products will deepen our portfolios and allow us to address additional clinical applications. In addition, we anticipate our ongoing efforts to complete clinical studies and publish research regarding our products will further enhance physician and payer receptiveness to our products over time. Our proven research and development capabilities and established technology platforms also support a robust and adaptable product pipeline for future applications.
- Continue to Expand Sales Force and Increase Sales Productivity and Geographic Reach. We plan to continue to expand the reach and penetration of our products by growing our sales organization to serve the Advanced Wound Care and Surgical & Sports Medicine markets. This expansion should allow us to achieve more focused and effective sales coverage for specific market categories, broaden our geographic footprint, and leverage our expanding relationships with large hospital systems and GPOs. We also plan to increase our focus on sales outside of the United States, including the European Union and the Middle East. Currently, substantially all of our sales are in the United States.
- Supplement Organic Growth Through Selective Acquisitions. We have demonstrated our ability to successfully identify and integrate assets that complement our strategy through the acquisitions of Dermagraft and TransCyte from Shire and our amniotic products from NuTech Medical. We believe TransCyte has the ability to address a \$200 million burn market, which includes 500,000 burns that require medical attention and 40,000 burns that require hospitalization annually in the United States. We continue to evaluate tuck-in acquisitions which complement our existing portfolios in both the Advanced Wound Care and Surgical & Sports Medicine markets and will leverage our established commercial and manufacturing infrastructure.

#### **Summary of Risk Factors**

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors" in this prospectus. These risks include, but are not limited to, the following:

- Our operating results may fluctuate significantly as a result of a variety of factors, many of which are outside of our control.
- We have incurred significant losses since our inception and, while we reported positive net income in the quarter ended September 30, 2020, we may incur losses in the future.
- Our success will depend in part on the extent to which coverage and adequate reimbursement for the costs of our products and related treatments will be available from government health administration authorities, private health insurers and other third-party payers and we do not know whether such reimbursement will be available or, if such reimbursement is available, the rate at which it will be available. The rate of reimbursement and coverage for the purchase of our products has been and may continue to be unstable, unpredictable and subject to changes in government and private payer policies that could adversely affect our business, results of operations and financial condition. Currently, not all of our products are covered by all payers.
- Many existing and potential customers for our products are members of GPOs and/or IDNs, including accountable care organizations or
  public-based purchasing organizations, and our business is partly dependent on major contracts with these organizations. Costcontainment efforts of our customers, GPOs, IDNs, third-party payers and governmental organizations could adversely affect our
  business, results of operations and financial condition.
- Medicare, which is the major source of revenue for most of our customers, reimburses the same amount for most of our products and the products of our competitors targeting the same indication in the hospital outpatient setting. Because in some sites of care the reimbursement amount is not based on the cost we charge our customers for our products or the cost our competitors charge for products targeting the same indication, our customers may elect to use products cheaper than ours in order to increase their margins, which could have a material adverse effect on our business, results of operations and financial condition.
- We have identified multiple 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 face significant and continuing competition, which could adversely affect our business, results of operations and financial condition.
- Rapid technological change could cause our products to become obsolete and if we do not enhance our product offerings through our research and development efforts, we may be unable to effectively compete.
- To be commercially successful, we must convince physicians that our products are safe and effective alternatives to existing treatments and that our products should be used in their procedures.
- Our failure to comply with regulatory obligations could result in negative effects on our business.
- The FDA may determine that certain of our products that are, or are derived from, human cells or tissues, such as Affinity, NuCel, NuShield and ReNu, do not qualify for regulation solely under Section 361 of the Public Health Services Act, or PHSA. To the extent that any of these products are

deemed not to be HCT/Ps or Section 361 HCT/Ps, the FDA may require that we revise our labeling and marketing claims for these products or that we suspend sales of such products until FDA approval is obtained, which could adversely affect our business, results of operations and financial condition.

- Because we depend upon a limited group of suppliers and manufacturers for our Apligraf, Affinity, Dermagraft and NuShield products,
  we may incur significant product development costs or experience material delivery delays if there is an interruption in supply from any
  one of these suppliers or manufacturers, which could materially impact sales of our products.
- We are dependent on the proper functioning of our and third-party manufacturing facilities, our supply chain and our sales force, all of
  which could be negatively impacted by the global COVID-19 pandemic in a manner that could materially adversely affect our business,
  financial condition or results of operations.
- Significant disruptions of our information technology systems or breaches of information security could adversely affect our business, results of operations and financial condition.
- Our patents and other intellectual property rights may not adequately protect our products.
- We engage in transactions with related parties and the transactions present possible conflicts of interest that could have an adverse effect on our business, results of operations and financial condition.
- We are a "controlled company" within the meaning of Nasdaq Global Market rules and, as a result, qualify for exemptions from certain corporate governance requirements. The Controlling Entities, which include affiliates of each member of our board of directors, will effectively control the outcome of all matters requiring shareholder approval, including charter amendments, mergers, consolidations and asset sales.

### **Industry Overview**

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

Our products use regenerative medicine technologies to provide solutions in the Advanced Wound Care and Surgical & Sports Medicine markets. Based on industry reports and management estimates, we believe that our addressable Advanced Wound Care and Surgical & Sports Medicine markets total approximately \$14.9 billion, which includes an estimated \$8.9 billion addressable market for Advanced Wound Care and an estimated \$6.0 billion addressable market for Surgical & Sports Medicine. Within the Advanced Wound Care market, 54% of treatments are used in advanced wound dressings, 17% are used in biologics, 20% are used in negative pressure wound therapy and 9% are used in other treatments. The skin substitute sub-market, within biologics, grew at a CAGR of 15% from 2016 to 2018 and less than 5% of addressable wounds are currently being treated with skin substitutes. Within the Surgical & Sports Medicine market, the bone fusion sub-market accounted for approximately \$2.7 billion, the tendon and ligament injuries sub-market accounted for approximately \$1.0 billion and the chronic inflammatory and degenerative condition sub-market accounted for approximately \$2.4 billion.

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.

# **Our Products**

Our products address both the Advanced Wound Care and Surgical & Sports Medicine markets. The following table summarizes our principal product offerings in each of our target end-markets:

Product (Launch Year) Affinity (2014)†	Description Fresh amniotic membrane containing many types of viable cells, growth factors/cytokines, and extracellular matrix, or ECM, proteins	Regulatory Pathway 361 HCT/P	Market and Clinical Application Advanced Wound Care, Chronic and acute wounds Surgical & Sports Medicine, Tendon, ligament and other soft tissue injuries
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	Advanced Wound Care, 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	Advanced Wound Care, DFUs
NuCel (2009)†+	Cellular suspension, stem cell- containing allograft derived from human amnion tissue and amniotic fluid	361 HCT/P	Surgical & Sports Medicine, Orthopedic surgical procedures including bony fusion

#### Regulatory Pathway Product (Launch Year) Description **Market and Clinical Application** NuShield (2010)† Dehydrated placental tissue graft 361 HCT/P Advanced Wound Care, Chronic preserved to retain all layers of the and acute wounds native tissue including both the Surgical & Sports Medicine, amnion and chorion membranes, Tendon, ligament and other soft with the epithelial layer and the tissue injuries spongy / intermediate layer intact PuraPly AM (2016) Purified native collagen matrix with 510(k) Advanced Wound Care, Chronic and acute wounds (except broad-spectrum polyhexamethylene biguanide, or PHMB, antimicrobial 3rd degree burns) agent Surgical & Sports Medicine, Surgical treatment of open wounds ReNu (2015)†+ Cryopreserved suspension of 361 HCT/P Surgical & Sports Medicine, amniotic fluid cells and morselized Chronic inflammatory and amnion tissue from the same donor degenerative conditions; soft tissue injuries such as tendinosis and fasciitis

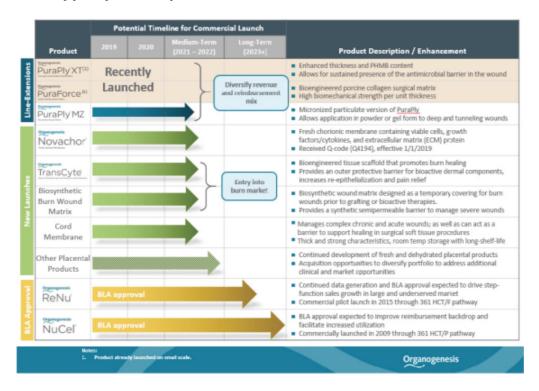
Launched by NuTech Medical; acquired by Organogenesis in 2017.

<sup>\*</sup> Launched by Smith & Nephew; acquired by Organogenesis in 2014.

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

### **Our Product Pipeline**

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



## **Recent Developments**

# **CPN Biosciences Acquisition**

As part of our strategy to make selective acquisitions, on September 17, 2020, we purchased substantially all of the assets of CPN Biosciences. CPN utilizes an innovative physician office management solution that has helped over 900 physician offices enhance their practices. This service and CPN's complementary advanced wound care products further broaden our physician offering and should accelerate our office strategy. We purchased CPN's assets for approximately \$5.8 million in cash and issued approximately 1.9 million shares of our Class A common stock at closing. We held back an additional \$0.6 million and 0.2 million shares of our Class A common stock at closing as security for possible indemnification claims. All or a portion of the additional cash and shares will be paid or issued, as applicable, 18 months after the closing, subject to any indemnification claims. In addition, we will make one earn-out payment to CPN if CPN's products achieve certain revenue growth over a twelve month period following the closing of the acquisition.

# **Executive Offices**

Our principal executive offices are located at 85 Dan Road, Canton, MA 02021, and our telephone number is (781) 575-0775. Our corporate website address is www.organogenesis.com. The information contained on, or that may be accessed through, our website is not part of, and is not incorporated into, this prospectus.

# Implications of Being a Controlled Company and a Smaller Reporting Company

We are presently a "controlled company" under the Nasdaq Marketplace Rules because Alan A. Ades, Albert Erani and Glenn H. Nussdorf, current and former members of our board of directors, together with Dennis Erani, Starr Wisdom and certain of their respective affiliates, control a majority of the voting power of our outstanding Class A common stock. As a "controlled company" we are entitled to rely on certain exemptions to Nasdaq's corporate governance requirements, including the requirement (i) that a majority of the board of directors consist of independent directors, (ii) to have a governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities, (iii) to have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities, (iv) that the compensation committee consider certain independence factors when engaging legal counsel and other committee advisors and (v) for an annual performance evaluation of the governance and compensation committees. We expect to continue to be treated as a "controlled company" for the foreseeable future.

We are also a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than \$250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than \$100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than \$700 million measured on the last business day of our second fiscal quarter.

### Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of disclosure and other requirements that are reduced in comparison with those otherwise applicable generally to public companies.

We may take advantage of these reduced requirements until the earliest to occur of (i) the last day of the fiscal year (a) following October 14, 2021, the fifth anniversary of our initial public offering, (b) in which the Company has total annual gross revenue of at least \$1.07 billion or (c) in which the Company is deemed to be a large accelerated filer, which means the market value of the Company Class A common stock that 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. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of certain reduced reporting burdens in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have 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 our 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 OFFERING

Class A common stock offered by ORGO 17,500,000 shares

Class A common stock to be outstanding after this

offering

124,957,154 shares (or 127,582,154 shares in the event the underwriters elect to exercise in full their option to purchase additional shares from us)

Use of proceeds

We estimate that the net proceeds from this offering will be approximately \$67.7 million, or approximately \$77.9 million if the underwriters exercise their option to purchase additional shares in full, based on an assumed public offering price of \$4.15 per share, which was the last reported sales price of our Class A common stock on the Nasdaq Capital Market on November 9, 2020, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We expect to use the net proceeds from this offering, together with other available funds, for working capital and general corporate purposes, including, but not limited to, facility expansion and manufacturing enhancements, salesforce expansion and to conduct clinical studies of, obtain regulatory approvals and additional commercial insurance coverage for our products. See "Use of Proceeds."

Risk Factors

You should read the "Risk Factors" section and other information included in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our Class A common stock.

Nasdaq Capital Market symbol

"ORGO"

The number of shares of our Class A common stock to be outstanding after this offering set forth above is based on the 107,457,154 shares of our Class A common stock outstanding as of September 30, 2020, and excludes:

- 6,788,655 shares of our Class A common stock issuable upon the exercise of stock options outstanding as of September 30, 2020 under our 2018 Equity Incentive Plan, or 2018 Plan, and our 2003 Stock Incentive Plan, or 2003 Plan, at a weighted average exercise price of \$2.40 per share;
- 819,248 shares of our Class A common stock issuable upon vesting and settlement of outstanding restricted stock units as of September 30, 2020 under our 2018 Plan; and
- 6,819,449 shares of Class A common stock reserved for future issuance under our 2018 Plan.

Except as otherwise noted, all information in this prospectus reflects and assumes no exercise by the underwriters of their option to purchase 2,625,000 additional shares of Class A common stock from us.

#### RISK FACTORS

Investing in our Class A common stock involves a high degree of risk. Before you decide to invest in our Class A common stock, you should consider carefully the risks described below, together with the other information contained in this prospectus, including our financial statements and the related notes appearing at the end of this prospectus. We believe the risks described below are the risks that are material to us as of the date of this prospectus. If any of the following risks actually occur, our business, results of operations and financial condition would likely be materially and adversely affected. In these circumstances, the market price of our Class A common stock could decline, and you may lose part or all of your investment.

# Risks Related to Organogenesis and its Business

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

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

- the announcement or introduction of new products by our competitors;
- failure of government health benefit programs and private health plans to cover our products or to timely and adequately reimburse the users of our products;
- the rate of reimbursement for purchases of our products by government and private insurers;
- any change in Medicare payment policy which provides a competitive advantage to our competitor's products;
- any change in government health benefit programs' and private health plans' policies regarding sales and reimbursement of durable medical equipment, including a prohibition on physician-owned DME supplier entities;
- whether our products or our competitors' products are granted pass-through reimbursement status or included in the "bundled" reimbursement structure;
- our ability to upgrade and develop our systems and infrastructure to accommodate growth;
- our ability to attract and retain key personnel in a timely and cost effective manner;
- our ability to offer our wound care supplies using our existing distribution network;
- the amount and timing of operating costs and capital expenditures relating to the expansion of our business, operations and infrastructure;
- changes in, or enactment of new laws or regulations promulgated by federal, state or local governments;
- cost containment initiatives or policies developed by government and commercial payers that create financial incentives not to use our products;
- our inability to demonstrate that our products are cost-effective or superior to competing products;
- our ability to develop new products;
- discovery of product defects during the manufacturing process;
- initiation of a government investigation into potential non-compliance with laws or regulations;
- issuance of government advisory opinions or program bulletins that could negatively affect one or more of our sales models;
- sanctions imposed by federal or state governments due to non-compliance with laws or regulations;
- recall of one or more of our products by the FDA due to noncompliance with FDA requirements; and

general economic conditions as well as economic conditions specific to the healthcare industry.

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

We have incurred significant losses since our inception, and while we reported positive net income in the quarter ended September 30, 2020, we may incur losses in the future.

To date, we have financed our operations primarily through debt and equity financings, and we have incurred losses from operations in many years since our inception. Our loss attributable to Organogenesis Holdings Inc. was \$40.5 million, \$64.8 million and \$8.4 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of September 30, 2020, we had an accumulated deficit of \$171.6 million. We expect to incur significant sales and marketing costs as we expand our operations to support the sale of our products. Our prior losses, combined with any future losses, 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, including a material weakness identified in connection with the audit of our financial statements for the year ended December 31, 2019. 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 the following material weaknesses:

- (1) 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;
- (2) 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.

Although we have made significant progress and have remediated the material weakness pertaining to the policies, processes, and controls over accounting for and disclosing certain complex transactions, the remaining material weakness continued to exist as of December 31, 2019 and September 30, 2020. Specifically, we did not design and maintain formal accounting, business operations, and Information Technology policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including (i) formalized policies and procedures for reviews over account reconciliations, journal entries, and other

accounting analyses and memos and procedures to ensure completeness and accuracy of information used in these review controls and (ii) controls to support the objectives of proper segregation of the initiation of transactions, the recording of transactions, and the custody of assets.

We are committed to remediating the material weakness described above and commenced remediation efforts during 2018 that continued during 2019 and 2020. We added additional accounting resources with requisite background and knowledge; we engaged external experts to complement internal resources; we began implementation of a new companywide enterprise resource planning system and we have designed more effective controls that should remediate these deficiencies once they have been implemented and have had sufficient time for them to operate effectively. We plan to continue to take additional steps to remediate the material 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.

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

The technologies underlying our products are subject to rapid and profound technological change. Competition intensifies as technical advances in each field are made and become more widely known. We can give no assurance that others will not develop services, products, or processes with significant advantages over the products, services, and processes that we offer or are seeking to develop. Any such occurrence could have a material and adverse effect on our business, results of operations and financial condition.

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

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

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

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

We believe physicians will only adopt our products if they determine, based on experience, clinical data and published peer reviewed journal articles, that the use of our products in a particular procedure is a favorable alternative to conventional methods. Physicians also are more interested in using cost-effective products and may practice in settings like Accountable Care Organizations, or ACOs, or Medical Homes, where they face considerable cost-containment pressure. In general, physicians may be slow to change their medical treatment practices and use of our products for the following reasons, among others:

- their lack of experience using our products;
- lack of evidence supporting additional patient benefits from use of our products over conventional methods;
- pressure to contain costs;
- preference for other treatment modalities or our competitors' products;
- perceived liability risks generally associated with the use of new products and procedures;
- limited availability of coverage and/or reimbursement from third party payers; and
- the time that must be dedicated to training.

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

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

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

We believe recommendations for, and support of our products by, influential physicians are essential for market acceptance and adoption. If we do not receive this support (e.g., because we are unable to demonstrate favorable long-term clinical data), physicians and hospitals may not use our products, which would significantly reduce our ability to achieve expected revenue and would prevent us from sustaining profitability.

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

# We face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance.

Our business exposes us to the risk of product liability claims that are inherent in the manufacturing, processing, investigating and marketing of medical devices and human tissue products. We are, and may in the future be, subject to product liability claims and lawsuits, including potential class actions or mass tort claims, alleging that our products have resulted or could result in an unsafe condition or injury. Product liability claims may be made by patients and their families, healthcare providers or others selling our products. Defending a lawsuit, regardless of merit, could be costly, divert management attention and result in adverse publicity, which could result in the withdrawal of, or reduced acceptance of, our products in the market. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- harm to our business reputation;
- investigations by regulators;
- significant defense costs;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- decreased demand for our products.

Although we have product liability insurance that we believe is adequate, this insurance is subject to deductibles and coverage limitations and we may not be able to maintain this insurance. Also, it is possible that claims could exceed the limits of our coverage or be excluded from coverage under our policy. If we are unable to maintain product liability insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect ourselves against potential product liability claims or we underestimate the amount of insurance we need, we could be exposed to significant liabilities, which may harm our business. One or more product liability claims could cause our stock price to decline and, if our liability exceeds our insurance coverage, could adversely affect our business, results of operations and financial condition.

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

Our products are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as strict company and government standards for the manufacture and storage of our products, subjects us to production risks. In addition to ongoing production risks, process deviations or unanticipated effects of approved process changes may result in non-compliance with regulatory requirements including stability requirements or specifications. Most of our products must be stored and transported within a specified temperature range. For example, if environmental conditions deviate from that range, our products' remaining shelf-lives could be

impaired or their safety and efficacy could be adversely affected, making them unsuitable for use. These deviations may go undetected. The occurrence of actual or suspected production and distribution problems can lead to lost inventories, and in some cases recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can cause production delays and result in substantial additional expenses. Production of our Affinity product, for example, was suspended in the first quarter of 2019 due to production issues at one of our suppliers. Although our supplier has implemented certain corrective measures, we have determined that the current process does not meet our production standards. As a result, we identified an alternate supplier, and were only able to resume commercial-scale production in the second quarter of 2020. This disruption in supply resulted in reduced Affinity revenue. Although we were able to partially offset the lost Affinity revenue by increasing production of our other products, there can be no assurance that we will be able to do so in the event of any future suspensions or failures in the storage or manufacturing of Affinity, Dermagraft (including in connection with the expected suspension of manufacturing of Dermagraft in the fourth quarter of 2021) or our other products. Any future failure in the storage or manufacture of our products or loss in supply could result in a loss of our market share and negatively affect our revenues and operations.

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

We obtain some of the components for our products from a limited group of suppliers. For us to be successful, our suppliers must be able to provide us with these components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. Our efforts to maintain a continuity of supply and high quality and reliability may not be successful. Manufacturing disruptions experienced by our suppliers may jeopardize our supply of these components. Due to the stringent regulations and requirements of the FDA regarding the manufacture of our products, we may not be able to quickly establish additional or replacement sources for certain components or materials. A change in suppliers could require significant effort or investment in circumstances where the items supplied are integral to product performance or incorporate unique technology. A reduction or interruption in manufacturing, or an inability to secure alternative sources of raw materials or components, could have a material effect on our business, results of operations and financial condition. Due to our substantial indebtedness, one or more of our suppliers may refuse to extend us credit with respect to our purchasing or leasing equipment, supplies, products or components, or may only agree to extend us credit on significantly less favorable terms or subject to more onerous conditions. This could significantly disrupt our ability to purchase or lease required equipment, supplies, products and components in a cost-effective and timely manner and could have a material adverse effect on our business, results of operations and financial condition. Any casualty, natural disaster or other disruption of any of our sole-source suppliers' operations, or any unexpected loss of any existing exclusive supply contract, could have a material adverse effect on our business, results of operations and financial condition.

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

Many of the products that we manufacture require that we obtain human tissue. The success of our business depends upon, among other factors, the availability of tissue from human donors. Any failure to obtain tissue from our sources will interfere with our ability to effectively meet demand for our products incorporating human tissue. The processing of human tissue for our products is very labor-intensive and it is therefore difficult to maintain a steady supply stream. The availability of donated tissue could also be adversely impacted by regulatory changes, public opinion of the donor process as well as our own reputation in the industry. The challenges we may face in obtaining adequate supplies of human tissue involve several risks, including limited control over availability, quality and delivery schedules. In addition, any interruption in the supply of any human tissue component could materially harm our ability to manufacture our products until a new source of supply, if

any, could be found. We may be unable to find a sufficient alternative supply channel in a reasonable time period or on commercially reasonable terms, if at all, which would have a material adverse effect on our business, results of operations and financial condition.

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

Our profitability is affected by the prices of the raw materials used in the manufacture of our products. These prices may fluctuate based on a number of factors beyond our control, including changes in supply and demand, general economic conditions, labor costs, fuel related delivery costs, competition, import duties, excises and other indirect taxes, currency exchange rates, and government regulation. Due to the highly competitive nature of the healthcare industry and the cost containment efforts of our customers and third-party payers, we may be unable to pass along cost increases for key components or raw materials through higher prices to our customers. If the cost of key components or raw materials increases, and we are unable fully to recover these increased costs through price increases or offset these increases through other cost reductions, we could experience lower margins and profitability. Significant increases in the prices of raw materials that cannot be recovered through productivity gains, price increases or other methods could adversely affect our business, results of operations and financial condition.

# We continue to invest significant capital in expanding our internal sales force, and there can be no assurance that these efforts will result in significant increases in sales.

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

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

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

We intend to develop relationships and arrangements with additional independent sales agencies in order to increase our sales with respect to certain of our products. However, we may fail to develop such relationships, in which case we may not be able to increase our sales. Our success is partially dependent upon our ability to retain and motivate our independent sales agencies and their representatives to sell our products in certain territories. They may not be successful in implementing our marketing plans. Some of our independent sales agencies may

not sell our products exclusively and may offer similar products from other companies. Our independent sales agencies may terminate their contracts with us, may devote insufficient sales efforts to our products, or may focus their sales efforts on other products that produce greater commissions for them, which could have an adverse effect on our business, results of operations and financial condition. We also may not be able to find additional independent sales agencies who will agree to market and/or distribute those products on commercially reasonable terms, if at all. If we are unable to establish new independent sales agency relationships or renew current sales agency agreements on commercially acceptable terms, our business, results of operations and financial condition could be materially and adversely affected. In addition, because we do not control these independent sales agencies as closely as our employees, while we may take steps to mitigate the risks associated with noncompliance by independent sales agencies, there remains a risk they do not comply with regulatory requirements or our requirements or our policies which could also adversely affect our business.

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

Managing our growth may be more difficult than we expect. We anticipate that a period of significant expansion will be required to penetrate and service the markets for our existing and anticipated future products and to continue to develop new products. This expansion will place a significant strain on management, operational and financial resources. To manage the expected growth of our operations and personnel, we must both modify our existing operational and financial systems, procedures and controls and implement new systems, procedures and controls. We must also expand our finance, administrative, and operations staff. Management may be unable to hire, train, retain, motivate and manage necessary personnel or to identify, manage and exploit existing and potential strategic relationships and market opportunities.

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

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

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

Any of these items could materially and adversely affect our revenues, financial condition, and profitability. Business acquisitions also involve the risk of unknown liabilities associated with the acquired business, which could be material. Our acquisition of NuTech Medical and CPN Biosciences expanded our wound care portfolio and our acquisition of NuTech Medical broadened our addressable market to include the Surgical & Sports Medicine market. We may not realize the increased revenues, cost savings and synergies that we anticipate from this acquisition in the near term or at all due to many factors, including delays in the integration process, an inability to successfully penetrate the amniotic category of the wound care market or an inability to obtain necessary regulatory approvals. Additional liabilities related to acquisitions could include lack of compliance with government regulations that could subject us to investigation and civil and criminal sanctions. For example, we may acquire a company that was not compliant with FDA quality requirements or was making payments or other forms of remuneration to physicians to induce them to use their products. Incurring unknown liabilities or the failure to realize the anticipated benefits of an acquisition could materially and adversely affect our business and we may lose our entire investment or be unable to recover our initial investment, which could include the cost of acquiring licenses or distribution rights, acquiring products, purchasing initial inventory, or investments in early stage companies. Inability to recover our investment, or any write off of such investment, associated goodwill, or assets, could have a material and adverse effect on our business, results of operations and financial condition.

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

From time to time, we may implement or may acquire new lines of business, such as our Surgical & Sports Medicine products that were acquired in connection with our acquisition of NuTech Medical, and our wound care supplies that were acquired in connection with our acquisition of CPN Biosciences, 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 such as the regulation of physician-owned durable medical equipment suppliers that sell our wound care supplies. 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 our information technology systems or breaches of information security could adversely affect our business, results of operations and financial condition.

We rely to a large extent upon sophisticated information technology systems to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property). We also have outsourced significant elements of our operations to third parties, including significant elements of our information technology infrastructure and, as a result, we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our information technology and information security systems, and those of our third-party vendors with whom we contract (and the large amounts of confidential information that is present on them), make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from malicious attacks by third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. While we have invested significantly in the protection of data and information technology, and will continue to do so, there can be no assurance that our efforts will prevent service interruptions or security breaches. For example, in August 2020, our information technology ("IT") systems were exposed to a ransomware attack, which partially impaired certain IT systems for a short period of time. We are investigating the incident, together with legal counsel and other incident response professionals. We do not

believe that we have experienced any material losses related to the ransomware attack and were able to recover all data quickly, with only a minimal and temporary interruption to our business. While we have implemented measures to protect our data security and information technology systems, such measures may not prevent these events. Although we have cyber-insurance coverage that may cover certain events described above, this insurance is subject to deductibles and coverage limitations and we may not be able to maintain this insurance. Also, it is possible that claims could exceed the limits of our coverage. Any interruption or breach in our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us or allow third parties to gain material, inside information that they use to trade in our securities.

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

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

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

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

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

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

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

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

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

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

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

Our long-term assets include property, plant and equipment of \$47.2 million and \$39.6 million as of December 31, 2019 and 2018, respectively. Approximately \$21.7 million of each of these amounts is attributable to certain leasehold improvements that we made to the buildings we lease at 275 Dan Road as part of our Canton, Massachusetts corporate headquarters. We review our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The build out to this property was suspended prior to completion and we are currently evaluating our future use of this property. If we decide that we do not intend to complete this buildout, either due to insufficient funding for this purpose or other business reasons, then these assets would be impaired. If an asset is determined to be impaired, the asset is written down to fair value, which is determined based on appraised value. Any such impairment could result in a non-cash charge equal to the full value of these improvements. During the years ended December 31, 2019, 2018

and 2017, we did not recognize an impairment charge in relation to these leasehold improvements. Changes in our assumptions with respect to our expected use of these assets may result in an impairment charge in the future, which could adversely affect our business, results of operations and financial condition.

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

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

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

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

In addition, the manufacture of our products is dependent on the availability of sufficient quantities of source tissue, which is the primary component of our products. Source tissue includes donated human tissue, porcine tissue and bovine tissue. We acquire donated human tissue directly through institutional review board approved protocols at multiple hospitals, as well as through tissue procurement firms engaged by us or by our contract manufacturers. Any failure to obtain tissue from our sources, including any failures related to COVID-19, will interfere with our ability to effectively meet demand for our products. Any interruption in the supply of source tissue could materially harm our ability to manufacture our products until a new source of supply, if any, could be found. We may be unable to find a sufficient alternative supply channel in a reasonable time period or on commercially reasonable terms, if at all, which would have a material adverse effect on our business, results of operations and financial condition.

Our sales may be materially adversely impacted by the coronavirus.

Our current Advanced Wound Care portfolio is sold throughout the United States via an experienced direct sales force, which focuses its efforts on outpatient wound care. We use a mix of direct sales representatives and independent agencies to service the Surgical & Sports Medicine market. These sales representatives are supported by teams of professionals focused on sales management, sales operations and effectiveness, ongoing training, analytics and marketing.

Our direct sales force functions by meeting in person with physicians and health care providers to discuss our products. COVID-19 may negatively affect demand for our products by limiting the ability of our sales

personnel to maintain their customary contacts with physicians and health care providers. We may also find that the independent agencies that we use will have to prioritize their workload and may be forced to slow their activities as a result of COVID-19. As a result, we cannot assure you that our direct sales representatives or independent agencies will increase or maintain our current sales levels, which could have a material adverse effect on our business, results of operations, financial condition and cash flows. The support for our sales force may also be impacted, thereby reducing the effectiveness of our sales force.

We may also experience significant and unpredictable reductions in demand for certain of our products if patients are unable to access certain advanced therapies due to stay-at-home orders or providers prioritizing resources to address the COVID-19 pandemic.

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

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

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

# Risks Related to Regulation of Our Products and Other Government Regulations

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 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 i

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, we believe 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. We are initiating clinical efforts necessary to obtain FDA approval of a BLA for NuCel and Renu, and compliance with applicable pre- and post-market regulatory requirements will involve significant time and substantial costs. We may also be required to suspend sales of NuCel and ReNu until FDA approval is obtained. Thus, any action by the FDA to apply the principles set forth in the 361 HCT/P Guidance to the HCT/Ps that we distribute could have adverse consequences for us and make it more difficult or expensive for us to conduct our business. The 361 HCT/P Guidance originally indicated that the FDA was providing a 36-month enforcement grace period to allow time for distributors of HCT/Ps to make any regulatory submissions and obtain any premarket approvals necessary to comply with the guidance. In July 2020, the FDA announced that the enforcement grace period would be extended until May 2021 as a result of the challenges presented by the COVID-19 public health emergency. If we are unable to obtain BLA approvals for NuCel and ReNu within the enforcement grace period, we may be required to suspend sales of those products until FDA approval is obtained. The ability to obtain approval for the uses for which the product is currently marketed cannot be assured. We cannot guarantee that the FDA will not take enforcement action during or after the grace period. Moreover, even for those products that will remain regulated as Section 361 HCT/Ps, increasing regulatory scrutiny within the industry in which we operate could lead to heightened requirements, compliance with which could be costly. The costs and other resource burdens associated with any of these regulatory outcomes may limit the resources available to us to fully exploit our technologies or may otherwise limit our ability to carry out other business activities.

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

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 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 Quality System Regulation, or 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 meet

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.

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

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

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

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

Defects, failures or quality issues associated with our products could lead to product recalls or safety alerts, adverse regulatory actions, litigation, including product liability claims, and negative publicity that could erode our competitive advantage and market share and materially adversely affect our reputation, business, results of operations and financial condition.

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

In addition, we cannot predict the results of future legislative activity or future court decisions, any of which could increase regulatory requirements, subject us to government investigations or expose us to unexpected litigation. Any regulatory action or litigation, regardless of the merits, may result in substantial costs, divert management's attention from other business concerns and place additional restrictions on our sales or the use of our products. In addition, negative publicity, including regarding a quality or safety issue, could damage our reputation, reduce market acceptance of our products, cause us to lose customers and decrease demand for our products. Any actual or perceived quality issues may also result in issuances of physician's advisories against our products or cause us to conduct voluntary recalls. Any product defects or problems, regulatory action, litigation, negative publicity or recalls could disrupt our business and have a material adverse effect on our business, results of operations and financial condition.

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

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

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

Sponsors of products for which the FDA has approved a BLA are obligated by the Pediatric Research Equity Act, or PREA, to carry out clinical trials of the products in pediatric populations, unless those requirements are waived. In 2012, we obtained FDA approval of a BLA for an oral tissue-engineered product to be marketed under the trade name Gintuit. Although Gintuit was not intended to be used in pediatric populations, the FDA imposed a requirement to conduct a pediatric study following approval. We originally planned to complete these studies within the timeframes established in the Gintuit approval letter. However, in 2014, we made a business decision to suspend commercialization of Gintuit; all manufacturing, commercial and clinical activities for the product were discontinued. At that time, we informed the FDA of this decision and requested suspension of the pediatric study requirement, at which time the FDA placed Gintuit on its discontinued products list. Notwithstanding our request that the pediatric study requirement be suspended, we were notified by the FDA on June 29, 2017 that the FDA had determined that we had not complied with our PREA obligations. We responded and submitted a formal request for an extension for the pediatric study requirement for Gintuit. However, on October 5, 2017, the FDA advised that our request had been denied. Although we believe that we are not currently subject to penalties for noncompliance because Gintuit is not on the market and there is accordingly no foreseeable use of the product in pediatric populations, the product could be viewed as misbranded and subject to seizure or other enforcement action if marketing is resumed without completion of the required pediatric study.

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

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

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for, the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal physician self-referral law, which prohibits a physician from referring a patient to an entity with which the physician (or an immediate family member) has a financial relationship, for the furnishing of certain designated health services for which payment may be made by Medicare, unless an exception applies;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other government payers that are false or fraudulent;
- Section 242 of HIPAA codified at 18 U.S.C. § 1347, which created new federal criminal statutes that prohibit a person from knowingly and
  willfully executing a scheme or from making false or fraudulent statements to defraud any healthcare benefit program (i.e., public or private);
- federal transparency laws, including the so-called federal "sunshine" law, which requires the tracking and disclosure to the federal government by pharmaceutical and medical device manufacturers of payments and other transfers of value to physicians and teaching hospitals as well as ownership and investment interests that are held by physicians and their immediate family members; and
- state law equivalents of each of these federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical and medical device companies to comply with their industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict certain payments that may be made to healthcare providers and other potential referral sources; state laws that require drug and medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that prohibit giving gifts to licensed healthcare professionals; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances, such as specific disease states.

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

Because of the breadth of these laws and the narrow scope of the statutory or regulatory exceptions and safe harbors available, our business activities could be challenged under one or more of these laws. Relationships

between medical product manufacturers and health care providers are an area of heightened scrutiny by the government. We engage in various activities, including the conduct of speaker programs to educate physicians, the provision of reimbursement advice and support to customers, and the provision of customer and patient support services, that have been the subject of government scrutiny and enforcement action within the medical device industry.

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

If a government entity opens an investigation into possible violations of any of these laws (which may include the issuance of subpoenas), 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 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.

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

There have been and continue to be laws enacted by the federal government, state governments, regulators and third party payers to control healthcare costs, and generally, to reform the healthcare system in the United States. For example, the Patient Protection and Affordable Care Act of 2010 ("PPACA") and the Medicare Access and CHIP Reauthorization Act of 2015 substantially changed the way healthcare is delivered and financed by both governmental and private insurers. These changes included the creation of demonstration programs and other value-based purchasing initiatives that provide financial incentives for physicians and hospitals to reduce costs, including incentives for furnishing low cost therapies for chronic wounds even if those therapies are less effective than our products. 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 passed that includes provisions that impact healthcare insurance coverage and payment such as the elimination of the tax penalty for individuals who do not maintain health insurance coverage (the so-called "individual mandate"). Such actions or similar actions could have a negative effect on the utilization of our products. We expect such efforts to continue and that there will be additional reform proposals at federal and state levels. On December 18, 2019, the United States Court of Appeals for the Fifth Circuit upheld a lower court's determination in *Texas v. Azar*, 4:18-cv-00167, that the individual mandate was unconstitutional and remanded the case to the lower court for further analysis as to whether PPACA as a whole is unconstitutional because the individual mandate is not severable from other provisions of the law. The United States Supreme Court has agreed to review the case and a hearing is scheduled to take place on November 10, 2020. We cannot predict they may have on us, but any such proposals could have a negative impact on our busin

General legislative action may also affect our business. For example, the Budget Control Act of 2011 included provisions to reduce the federal deficit. The Budget Control Act, as amended, resulted in the imposition of reductions of up to 2% in Medicare payments to providers which began in April 2013 and 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.

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

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

Compliance with these regulations and laws is costly, and failure to comply with applicable legal and regulatory obligations could adversely affect us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities.

These risks may limit or disrupt our expansion, restrict the movement of funds or result in the deprivation of contractual rights or the taking of property by nationalization or expropriation without fair compensation. Operating in international markets also requires significant management attention and financial resources.

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

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

### Risks Related to Reimbursement for our Products

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

Sales of almost all of our products depend partly on the ability of our customers to obtain reimbursement for the cost of our products under government health benefit programs such as Medicare and Medicaid and from other global government authorities. Government health benefit programs and private health plans continuously seek to reduce healthcare costs. For example, in 2014, Medicare unexpectedly established a policy to stop making separate payment for our products in certain clinical settings. This policy required us to reduce prices for our products which caused significant reduction in our revenue. As of January 1, 2018, our PuraPly AM and PuraPly products no longer qualified for separate payments under Medicare and this change resulted in a reduction in our revenue as compared to prior periods.

In March 2018, the United States Congress passed, and the President signed into law, the Consolidated Appropriations Act of 2018, or the Appropriations Act. The Appropriations Act restored the pass-through status effective October 1, 2018 for drugs or biologicals whose period of pass-through payment status ended on December 31, 2018 and for which payment was packaged into a covered hospital outpatient service furnished beginning on January 1, 2018; PuraPly and PuraPly AM met these conditions. As a result, PuraPly and PuraPly AM were included in the "bundled" payment structure from January 1, 2018 through September 30, 2018 after which time Medicare resumed making pass-through payments to hospitals when they use PuraPly and PuraPly AM in the outpatient hospital setting and in ASCs. PuraPly and PuraPly AM retained this "pass-through" reimbursement status through September 30, 2020. During that time, our other skin substitute products remained 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 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. In fact, Medicare has signaled that it may discontinue its two-tier bundling policy because it solicited comments on alternatives in its calendar year 2020 rulemaking. Changes in the policy could occur as early as calendar year 2021 and could include the establishment of a single bundle for all products which could place our products at a significant competitive disadvantage. Possible reductions in, or eliminations of, coverage or reimbursement by third-party payers, or the denial of, or provision of uneconomical reimbursement for new products, as a result of these changes may affect our customers' revenue and ability to purchase our products. Any changes in the healthcare regulatory, payment or enforcement landscape relative to our customers' healthcare services also have the potential to significantly affect our operations and revenue. In addition, Medicare uses regional contractors called Medicare Administrative Contractors, or MACs, to process claims, develop coverage policies and make payments within designated geographic jurisdictions. While our products are currently covered by most MACs, we cannot be certain they will be in the future.

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

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

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

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

Furthermore, Medicare has signaled that it may revise its two-tiered bundled payment policy for skin substitutes. Medicare solicited comments in calendar year 2019 related to proposed updates and policy changes under the Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System. Medicare specifically solicited comments on whether it should eliminate with the two-tiered bundle policy and establish a single bundle for all products. Based on the statements made in the proposed rule, it is possible that Medicare will revise its payment policy in calendar year 2021 or calendar year 2022. Any revised policy could result in decreased reimbursement for our products which could decrease utilization and reduce our revenues. Moreover, any new policy could result in a financial incentive for hospitals and ASCs to use our competitor's products, thereby reducing our market share and revenue.

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

Many existing and potential customers for our products within the United States are members of GPOs and/or IDNs, including accountable care organizations or public-based purchasing organizations, and our business is partly dependent on major contracts with these organizations. Our products can be contracted under national tenders or with larger hospital GPOs. GPOs and IDNs negotiate pricing arrangements with healthcare product manufacturers and distributors and offer the negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. At any given time, we are typically at various stages of responding to bids and negotiating and renewing GPO and IDN agreements, including agreements that would otherwise expire. Bids are generally solicited from multiple manufacturers or service providers with the intention of obtaining lower pricing. Due to the highly competitive nature of the bidding process and the GPO and IDN contracting processes in the United States, we may not be able to obtain or maintain contract positions with major GPOs and IDNs across our product portfolio. Failure to

be included in certain of these agreements could have a material adverse effect on our business, financial condition and results of operations. In addition, while having a contract with a major purchaser, such as a GPO or IDN, for a given product category can facilitate sales, sales volumes of those products may not be maintained. For example, GPOs and IDNs are increasingly awarding contracts to multiple suppliers for the same product category. Even when we are the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN generally are free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause upon 60 to 90 days' notice. The healthcare industry has been consolidation, and the consolidation among third-party payers into larger purchasing groups will increase their negotiating and purchasing power. Such consolidation may result in greater pricing pressure on us due to pricing concessions and may further exacerbate the risks described above.

## **Risks Related to Our Intellectual Property**

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

Our ability to compete effectively will depend, in part, on our ability to maintain the proprietary nature of our technology and manufacturing processes. We rely on manufacturing and other know-how, patents, trade secrets, trademarks, license agreements and contractual provisions to establish our intellectual property rights and protect our products. These legal means, however, afford only limited protection and may not adequately protect our rights. The failure to obtain, maintain, enforce or defend such intellectual property rights, for any reason, could allow third parties to make competing products or impact our ability to develop, manufacture and market our own products on a commercially viable basis, or at all, which could have a material adverse effect on our revenues, financial condition or results of operations.

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

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

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

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

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

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

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

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

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

Competitors may infringe or misappropriate the patents or other intellectual property that we own or license. In response, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us, such

as alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent that we own or license is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or conclude that there is no infringement. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

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

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

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

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

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

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

Periodic maintenance fees, renewal fees, annuity fees and other fees on patents and patent applications will be due to be paid to the U.S. Patent and Trademark Office and similar foreign agencies in several stages over the

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

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

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

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

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

#### Risks Related to Our Indebtedness

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

We have a significant amount of indebtedness. As of September 30, 2020, we had approximately \$99.4 million of aggregate principal amount of indebtedness outstanding under our 2019 Credit Agreement. Our substantial level of indebtedness increases the risk that we may be unable to generate cash sufficient to pay amounts due in respect of our indebtedness. Our substantial indebtedness could have other important consequences to our debt holders and significant effects on our business. For example, it could:

- increase our vulnerability to adverse changes in general economic, industry and competitive conditions;
- require us to dedicate a substantial portion of our cash flow from operations to making payments on our indebtedness, thereby reducing the availability of our cash flow to fund working capital, capital expenditures and other general corporate purposes;

- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;
- expose us to the risk of increased interest rates as certain of our borrowings are at variable rates, and we may not be able to enter into interest rate swaps and any swaps we enter into may not fully mitigate our interest rate risk;
- restrict us from capitalizing on business opportunities;
- make it more difficult to satisfy our financial obligations, including payments on our indebtedness;
- place us at a competitive disadvantage compared to our competitors that have less debt; and limit our ability to borrow additional funds for
  working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy or other general corporate
  purposes.

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

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

We may incur significant additional indebtedness in the future. Although the credit agreements governing our senior secured and subordinated credit facilities limit our ability and the ability of our present and future subsidiaries to incur additional indebtedness, the terms of the senior secured and subordinated credit facilities permit us to incur significant additional indebtedness under certain circumstances. In addition, the credit agreements governing our senior secured and subordinated credit facilities do not prohibit us from incurring obligations that do not constitute indebtedness as defined therein. To the extent that we incur additional indebtedness or such other obligations, the risk associated with our substantial indebtedness described above, including our potential inability to service our debt, will increase.

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

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

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

harm our ability to incur additional indebtedness on commercially reasonable terms or at all. Our inability to generate sufficient cash flow to satisfy our debt service obligations, or to refinance or restructure our obligations on commercially reasonable terms or at all, would have an adverse effect, which could be material, on our business, results of operations and financial condition, as well as on our ability to satisfy our obligations in respect of the senior and subordinated secured credit facilities and our other indebtedness.

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

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

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

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

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

As a result of these covenants and restrictions, we are and will be limited in how we conduct our business, and we may be unable to raise additional debt or equity financing to compete effectively or to take advantage of new business opportunities. In addition, our senior secured credit facility requires us to comply with a minimum consolidated revenue covenant (measured on a trailing twelve month basis) and a minimum monthly liquidity ratio (measured as of the last day of each month). The operating and financial restrictions and covenants in the senior secured credit facility, as well as any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. Our ability to comply with these covenants may be affected by events beyond our control, and we may not be

able to meet those covenants. For example, in the past, we have not been in compliance with certain financial covenants in our debt agreements, which may occur again in the future. We cannot guarantee that we will be able to maintain compliance with these covenants in the future and, if we fail to do so, that we will be able to obtain waivers from the lenders and/or amend the covenants.

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

#### Risks Related to Our Class A Common Stock

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

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

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

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

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

The Controlling Entities collectively beneficially own approximately 63% 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 Exchange Act or the rules and regulations promulgated thereunder, for which federal courts have exclusive jurisdiction.

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

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

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

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

The Company qualifies as an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, which we refer to as the "JOBS Act." As such, the Company takes advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as it continues to be an emerging growth company, including (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act, (ii) the exemptions from say-on-pay, say-on-frequency and say-on-golden parachute voting requirements and (iii) reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements. As a result, the Company's stockholders may not have access to certain information they deem important. the Company will remain an emerging growth company until the earliest of (i) the last day of the fiscal year (a) following October 14, 2021, the fifth anniversary of the IPO, (b) in which the Company has total annual gross revenue of at

least \$1.07 billion or (c) in which the Company is deemed to be a large accelerated filer, which means the market value of the Company common stock that is held by non-affiliates exceeds \$700.0 million as of the last business day of the Company's prior second fiscal quarter, and (ii) the date on which the Company has issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

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

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

The Company cannot predict if investors will find the Company 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.

#### **General Risk Factors**

Future sales and issuances of our Class A common stock or rights to purchase Class A common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including for working capital requirements, capital expenditure, debt service payments and potential acquisitions. To raise capital, we may sell Class A common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell Class A common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our Class A common stock, including shares of Class A common stock sold in this offering.

### You will experience immediate and substantial dilution in the net tangible book value of the shares you purchase in this offering.

If you purchase shares of our Class A common stock in this offering, you will experience immediate and substantial dilution, as the public offering price of our Class A common stock will be substantially greater than the net tangible book value per share of our Class A common stock. Based on an assumed offering price of \$4.15 per share, which was the last reported price of our Class A common stock on the Nasdaq Capital Market on November 9, 2020, if you purchase our Class A common stock in this offering, you will suffer immediate and substantial dilution of approximately \$3.57 per share. If the underwriters exercise their over-allotment option, or if outstanding options to purchase our Class A common stock are exercised, you will experience additional dilution. For a further description of the dilution that you will experience immediately after this offering, see the section entitled "Dilution."

# Our board of directors and management will have broad discretion over the use of the proceeds we receive in this offering and might not apply the proceeds in ways that increase the value of your investment.

Our board of directors and management will have broad discretion to use the net proceeds from this offering, including for any of the purposes described in the section entitled "Use of Proceeds," and you will be relying on the judgment of our board of directors and management regarding the application of these proceeds. You will not have the opportunity to influence our decisions on how to use the proceeds, and we may not apply the net proceeds of this offering in ways that increase the value of your investment. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

# A significant portion of our total outstanding shares are eligible to be sold into the market, which could cause the market price of our Class A common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our Class A common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of our Class A common stock intend to sell shares, could cause the market price of our Class A common stock to decline significantly.

Upon completion of this offering, based on our shares outstanding as of September 30, 2020, we will have 124,957,154 shares of Class A common stock outstanding based on the issuance and sale of 17,500,000 shares of our Class A common stock in this offering. Of these shares, only 94,130,774 are subject to a contractual lock-up with the underwriters for this offering for a period of ninety days following this offering. Morgan Stanley & Co. LLC and SVB Leerink LLC, the representatives of the underwriters, may release these stockholders from their lock-up agreements with the underwriters at any time, which would allow for earlier sales of shares in the public market. The balance of our outstanding shares of Class A common stock, including any shares purchased in this offering, may be resold into the public market immediately without restriction, unless owned or purchased by our affiliates.

In addition, as of September 30, 2020, we had outstanding stock options to purchase an aggregate of 6,788,655 shares of our Class A common stock and 819,248 shares of our Class A common stock issuable upon vesting and settlement of outstanding restricted stock units under our equity incentive plans, and the issuance of

all of these shares is registered under the Securities Act of 1933, as amended, or the Securities Act, on a registration statement on Form S-8. These shares, once vested and issued upon exercise, will be able to be freely sold in the public market, subject to the volume limits of Rule 144 under the Securities Act in the case of our affiliates and the lock-up agreements described above, to the extent applicable.

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

We face significant and continuing competition in our business, which is characterized by rapid technological change and significant price competition. Market share can shift as a result of technological innovation and other business factors. Our customers consider many factors when selecting a product, including product reliability, clinical outcomes, economic outcomes, price and services provided by the manufacturer. Our ability to compete depends in large part on our ability to provide compelling clinical and economic benefits to our customers and payers, develop and commercialize new products and technologies and anticipate technological advances. Product introductions or enhancements by competitors which may have advanced technology, better features or lower pricing may make our products obsolete or less competitive. In addition, consolidation in the healthcare industry continues to lead the demand for price concessions or to the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, results of operations or financial condition. The presence of this competition in our market may lead to pricing pressure, which would make it more difficult to sell our products at a price that will make us profitable or prevent us from selling our products at all. As a result, we will be required to devote continued efforts and financial resources to bring our products under development to market, deliver cost-effective clinical outcomes, expand our geographic reach, enhance our existing products and develop new products for the advanced wound care and soft tissue repair markets. Even if we develop cost effective and/or new products, they may not be covered or reimbursed due to cost-containment and other financial pressures from payers.

# Our future capital needs are uncertain and we may need to raise funds in the future, and such funds may not be available on acceptable terms or at all.

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

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

Our operating plan may change as a result of many factors currently unknown to us and we may need additional funds sooner than planned. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. Furthermore, if we issue equity or convertible debt securities to raise capital, you may experience dilution, and the new equity or convertible debt securities may have rights, preferences and privileges that are senior to or otherwise adversely affect your rights as a stockholder. In addition, if we raise

capital through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our products, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise capital on acceptable terms, we may not be able to develop our product candidates, enhance our existing products, execute our business plan, take advantage of future opportunities, or respond to competitive pressure, changes in our supplier relationships, or unanticipated customer requirements. Any of these events could adversely affect our ability to achieve our development and commercialization goals, which could have a material adverse effect on our business, results of operations and financial condition.

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

We are highly dependent on our executive officers, the loss of whose services may adversely impact the achievement of our objectives. In particular, we depend on Gary Gillheeney, our President and Chief Executive Officer. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives and scientific personnel in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous medical device companies for individuals with similar skill sets. The inability to recruit or loss of the services of any executive, key employee, consultant or advisor may impede the progress of our research, development and sales growth objectives.

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

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

Many of the companies that we compete against for qualified personnel have substantially greater financial and other resources and different risk profiles than we do. They may also provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we can offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can discover, develop and commercialize product candidates will be limited.

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

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

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

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

In addition, the preparation of financial statements in conformity with GAAP requires management to make assumptions, estimates and judgments that affect the amounts reported in the consolidated financial statements and accompanying notes. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. The results of these estimates form the basis for making judgments about the carrying values of assets, liabilities and equity, and the amount of net revenues and expenses that are not readily apparent from other sources. Our operating results may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of securities analysts and investors, resulting in a decline in our stock price.

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

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

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

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

Our officers, employees, independent contractors, principal investigators, consultants and commercial partners may engage in misconduct or activities that are improper under other laws and regulations, which would create liability for us.

We are exposed to the risk that our officers, employees, independent contractors (including contract research organizations, or CROs), principal investigators, consultants and commercial partners may engage in

fraudulent conduct or other illegal activity and/or may fail to disclose unauthorized activities to us. Misconduct by these parties could include, but is not limited to, intentional, reckless and/or negligent failures to comply with:

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

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

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

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

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

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

The Company is subject to income 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;
- 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.

#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes "forward-looking statements" within the meaning of Section 27A of the Securities Act, and Section 21E of the Exchange Act. All statements, other than statements of historical facts, contained in this prospectus, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements with respect to our operations, strategies, prospects and other aspects of our business are based on current expectations that are subject to known and unknown risks and uncertainties, which could cause actual results or outcomes to differ materially from expectations expressed or implied by such forward-looking statements. These factors include, but are not limited to the following:

- we have incurred significant losses since inception and, while we reported positive net income in the quarter ended September 30, 2020, we may incur losses in the future;
- we face significant and continuing competition, which could adversely affect our business, results of operations and financial condition;
- rapid technological change could cause our products to become obsolete and if we do not enhance our product offerings through our research and development efforts, we may be unable to effectively compete;
- to be commercially successful, we must convince physicians that our products are safe and effective alternatives to existing treatments and that our products should be used in their procedures;
- our ability to raise funds to expand our business;
- the impact of any changes to the reimbursement levels for our products including the impact of the loss of preferred "pass through" status for PuraPly AM and PuraPly on October 1, 2020;
- our ability to maintain compliance with applicable Nasdaq Marketplace Rules
- changes in applicable laws or regulations;
- the U.S. Food and Drug Administration may determine that certain of our products that are, or are derived from, human cells or tissues, including NuCel and ReNu, do not qualify for regulation solely under Section 361 of the Public Health Service Act, and may require that the products be removed from the market until we obtain premarket clearance or approval;
- interruptions in the supply of our products, including as a result of the disruptions in the availability of tissue from human donors, or inventory loss may adversely affect our business, results of operations and financial condition;
- significant disruptions of our information technology systems or breaches of information security could adversely affect our business, results of operations and financial condition;
- the possibility that we may be adversely affected by other economic, business, and/or competitive factors;
- the accuracy of our estimates regarding our expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- our use of proceeds from this offering;
- our and third-party manufacturing facilities, our supply chain and our sales force, all of which could be negatively impacted by the global COVID-19 pandemic in a manner that could materially adversely affect our business, financial condition or results of operations; and

other risks and uncertainties described in our filings with the SEC.

These forward-looking statements speak only as of the date of this prospectus and are subject to risks, uncertainties and assumptions described under the sections "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this prospectus. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make.

You should read this prospectus, any free writing prospectus prepared by us or on our behalf, and the documents that we have filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

## INDUSTRY AND OTHER DATA

This prospectus contains estimates, projections and other information concerning our industry, our business and the markets for our products, including data regarding the estimated size of those markets, their projected growth rates, the perceptions and preferences of patients and physicians regarding certain therapies and other patient data and reimbursement data, as well as market research, estimates and forecasts prepared by our management. We obtained the industry, market and other data throughout this prospectus from our own internal estimates and research, as well as from industry publications and research, surveys and studies conducted by third-parties, including governmental agencies. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information.

#### **USE OF PROCEEDS**

We estimate that the net proceeds from this offering will be approximately \$67.7 million, or approximately \$77.9 million if the underwriters exercise their option to purchase additional shares in full, based on an assumed public offering price of \$4.15 per share, which was the last reported sales price of our Class A common stock on the Nasdaq Capital Market on November 9, 2020, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We expect to use the net proceeds from this offering, together with other available funds, for working capital and general corporate purposes, including, but not limited to, facility expansion and manufacturing enhancements, salesforce expansion and to conduct clinical studies of, obtain regulatory approvals and additional commercial insurance coverage for our products. The expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures depend on numerous factors. As a result, our management will have broad discretion in applying the net proceeds from this offering. Pending the use of the net proceeds from this offering, we intend to invest the net proceeds in cash items, certificates of deposit or direct or guaranteed obligations of the United States.

#### MARKET PRICE OF OUR COMMON STOCK

#### **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. On December 14, 2018, Nasdaq filed a Form 25 Notification of Removal from Listing and/or Registration under Section 12(b) of the Exchange Act for the Units. Pursuant to the Hearing Panel's decision, we were required to demonstrate to the satisfaction of Staff and the Hearings Panel that we had 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 became effective on March 22, 2019 (ten days after the Form 25 was filed). All of the outstanding public warrants were exchanged for an aggregate of 2,925,731 shares of our Class A common stock in August and September 2019.

As of October 1, 2020, a total of 107,457,154 shares of our Class A common stock were outstanding and we had 96 holders of record of our Class A common stock. This number does not include shareholders for whom shares are held in "nominee" or "street" name.

## Securities authorized for issuance under equity compensation plans

We have one equity compensation plan under which awards are currently authorized for issuance, the 2018 Plan. In connection with the consummation of the business combination in December 2018, our board of directors discontinued any new issuances under the 2003 Plan. If options outstanding under the 2003 Plan expire unexercised, they will not become available for future issuance. Both the 2018 Plan and the 2003 Plan were approved by our stockholders. The following table provides information regarding securities authorized for issuance as of December 31, 2019 under our equity compensation plans.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights, and vesting of outstanding restricted stock units (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)		Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)	
Equity compensation plans approved					
by security holders	6,503,646(1)	\$	2.09	9,008,996(2)	
Equity compensation plans not					
approved by security holders	<del>_</del>	\$	_	<del>_</del>	
Total	6,503,646	\$	2.09	9,008,996	

Consists of shares of our Class A common stock issuable upon exercise of outstanding options issued under the 2018 Plan and the 2003 Plan. Consists of shares of our Class A common stock reserved for future issuance under the 2018 Plan. (1)

## DIVIDEND POLICY

We have never declared or paid any cash dividends on our Class A common stock. We currently intend to retain all available funds and future earnings, if any, to finance the growth and development of our business. We do not expect to pay any cash dividends on our Class A common stock in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in any current or future financing instruments, provisions of applicable law and other factors our board of directors deems relevant. See "Risk Factors—Risks Related to This Offering," "Risk Factors—Risks Related to Our Class A Common Stock," "Risk Factors—Risks Related to our Indebtedness" and "Description of Certain Indebtedness." Further, the credit agreement governing our credit facility imposes significant operating and financial restrictions and limit our ability to declare dividends. We do not currently intend to pay dividends on our Class A common stock and, consequently, your ability to achieve a return on your investment will depend on the appreciation in the market price of our Class A common stock.

#### CAPITALIZATION

The following table sets forth our consolidated cash, cash equivalents and short-term investments, current position of long-term obligations and capitalization as of September 30, 2020:

- on an actual basis;
- on an as adjusted basis after giving effect to our sale of 17,500,000 shares of Class A common stock offered hereby, assuming a public offering price of \$4.15 per share, the last reported sales price of our Class A common stock on the Nasdaq Capital Market on November 9, 2020, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with our financial statements and related notes appearing at the end of this prospectus and the sections of this prospectus titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Description of Capital Stock."

	As of September 30, 2020			
	Actual		As adjusted	
		(in thousand	, except share data)	
Cash and restricted cash	\$	36,886	\$ 104,544	
Line of credit	\$	39,353	39,353	
Term loan		47,999	47,999	
Capital lease obligations		12,239	12,239	
Deferred rent and other liabilities		15,118	15,118	
Stockholders' equity (deficit):				
Class A common stock, \$0.0001 par value; 400,000,000 shares authorized, 108,185,702 shares issued and				
107,457,154 shares outstanding, actual; 400,000,000 shares authorized, 125,685,702 shares issued and				
124,957,154 shares outstanding, as adjusted		11	13	
Additional paid-in capital		237,015	304,671	
Accumulated deficit		(171,552)	(171,552)	
Total stockholders' equity		65,474	133,132	
Total capitalization	\$	180,183	\$ 247,841	

A \$1.00 increase (decrease) in the assumed public offering price of \$4.15 per share, which is the last reported price of our Class A common stock on the Nasdaq Capital Market on November 9, 2020, would increase (decrease) the pro forma as adjusted amount of each of cash and restricted cash, total stockholders' equity and total capitalization by approximately \$16.5 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, a one million share increase (decrease) in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) each of cash and cash equivalents, total stockholders' equity and total capitalization by \$3.9 million, assuming the assumed public offering price of \$4.15 per share remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

#### DILUTION

If you invest in our Class A common stock, your equity interest in our company will be diluted immediately to the extent of the difference between the public offering price per share you will pay in this offering and the as adjusted net tangible book value (deficit) per share of our Class A common stock after this offering.

Our net tangible book value as of September 30, 2020 was \$4.7 million, or \$0.04 per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our Class A common stock outstanding as of September 30, 2020. Dilution with respect to net tangible book value per share represents the difference between the amount per share paid by investors purchasing shares of Class A common stock in this offering and the net tangible book value per share of our Class A common stock immediately after this offering.

After giving effect to the sale of 17,500,000 shares of our Class A common stock in this offering, assuming a public offering price of \$4.15 per share, which was the last reported sales price of our Class A common stock on the Nasdaq Capital Market on November 9, 2020, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2020 would have been approximately \$72.4 million, or \$0.58 per share. This represents an immediate increase in net tangible book value of \$0.54 per share to existing stockholders and immediate dilution of \$3.57 per share to investors purchasing our Class A common stock in this offering. The following table illustrates this dilution on a per share basis:

	Per S	hare
Public offering price per share		\$4.15
Net tangible book value per share as of September 30, 2020	\$0.04	
Increase in net tangible book value per share attributable to investors in this offering	0.54	
As adjusted net tangible book value per share as of September 30, 2020, after giving effect to this offering		\$0.58 \$3.57
Dilution per share to investors purchasing our Class A common stock in this offering		\$3.57

A \$1.00 increase (decrease) in the assumed public offering price of \$4.15 per share, the last reported sales price of our Class A common stock on the Nasdaq Capital Market on November 9, 2020, would increase (decrease) our as adjusted net tangible book value per share after this offering by approximately \$0.13, and the dilution per share to new investors purchasing shares in this offering by \$0.87, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares to be issued in this offering. An increase (decrease) of 1,000,000 shares offered by us would increase (decrease) our as adjusted net tangible book value per share by \$0.03, and (decrease) increase the dilution per share to new investors purchasing shares in this offering by \$0.03, respectively, assuming that the assumed public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering as determined between us and the underwriters at pricing.

If the underwriters exercise in full their option to purchase additional shares, our as adjusted net tangible book value per share after this offering would be \$0.65 per share, representing an immediate increase in as adjusted net tangible book value per share of \$0.60 to existing stockholders and immediate dilution of \$3.50 per share to new investors purchasing Class A common stock in this offering, assuming a public offering price of \$4.15 per share, the last reported sales price of our Class A common stock on the Nasdaq Capital Market on November 9, 2020.

The above discussion and table are based on 107,457,154 shares of our Class A common stock outstanding as of September 30, 2020, which excludes:

- 6,788,655 shares of our Class A common stock issuable upon the exercise of stock options outstanding as of September 30, 2020 under our 2018 Plan and our 2003 Plan, at a weighted average exercise price of \$2.40 per share;
- 819,248 shares of our Class A common stock issuable upon vesting and settlement of outstanding restricted stock units as of September 30, 2020 under our 2018 Plan; and
- 6,819,449 shares of Class A common stock reserved for future issuance under our 2018 Plan.

To the extent that outstanding options outstanding as of September 30, 2020 have been or may be exercised or other shares of Class A common stock are issued, investors purchasing our Class A common stock in this offering may experience further dilution. We will require more capital to continue investing in product development, sales and marketing and customer support for our products. In addition, we may also choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read together with our consolidated financial statements and the related notes included elsewhere in this prospectus. This discussion contains forward-looking statements and involves numerous risks and uncertainties, including but not limited to those described in the "Risk Factors" section of this prospectus. Actual results may differ materially from those contained in any forward-looking statements. You should read "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors."

#### 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. Several 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.

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 venous leg ulcers ("VLUs") and diabetic foot ulcers ("DFUs"); Dermagraft for the treatment of DFUs; PuraPly AM to address biofilm across a broad variety of wound types; and Affinity and NuShield to address a variety of wound sizes and types. We have a highly trained and specialized direct wound care sales force paired with exceptional customer support services.

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

For the nine months ended September 30, 2020, we generated \$231.5 million of net revenue and had \$0.5 million of net loss compared to \$186.3 million of net revenue and \$36.1 million of net loss for the nine months ended September 30, 2019. We generated net revenue of \$261.0 million, \$193.4 million and \$198.5 million for the years ended December 31, 2019, 2018 and 2017, respectively. We had a net loss of \$40.5 million,

\$64.8 million and \$8.4 million for the years ended December 31, 2019, 2018 and 2017, respectively. We have incurred significant losses since inception and, while we have reported net income for the three months ended September 30, 2020, we may incur operating losses in the future as we expend resources as part of our efforts to grow our organization to support the planned expansion of our business. As of September 30, 2020, we had an accumulated deficit of \$171.6 million. Our primary sources of capital to date have been from sales of our products, borrowings from related parties and institutional lenders and proceeds from the sale of our Class A common stock. We operate in one segment of regenerative medicine.

On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 a pandemic, and the virus continues to spread throughout the United States and the rest of the world. Various public and private sector measures have been taken and may continue to be taken to reduce its transmission, such as the imposition of social distancing, stay-at-home and shelter-in-place orders, which are having the effect of suspending or severely curtailing operations for most industries and businesses. We are one of many companies providing essential services during this national emergency related to the COVID-19 pandemic. We have implemented a number of measures designed to protect the health and safety of our employees, support our customers and promote business continuity. We have reviewed and implemented cost-saving measures and we will continue to review and implement additional cost-saving measures, as necessary. These measures have included discontinuing or delaying all non-essential services and programs, and instituting controls on travel, events, marketing and clinical studies to adapt our financial business plan for the evolving COVID-19 challenges.

While the COVID-19 pandemic has not materially adversely affected our financial results and business operations through the third quarter ended September 30, 2020, the pandemic may pose significant risks to our business. We cannot currently quantify the impact the continuing COVID-19 pandemic may have on our revenue for the remainder of our fiscal year ending December 31, 2020 or beyond, but the public health actions being undertaken to reduce the spread of the virus may create significant disruptions with respect to: (i) the demand for our products, (ii) the ability of our sales representatives to reach our healthcare customers, (iii) our ability to maintain staffing levels to support our operations, (iv) our ability to continue to manufacture certain of our products, (v) the reliability of our supply chain and (vi) our ability to achieve the financial covenants required under the 2019 Credit Agreement. Accordingly, management continues to evaluate the Company's liquidity position, communicate with and monitor the actions of our customers and suppliers, and review our near-term financial performance as we manage the Company through this period of uncertainty. Please see "Risk Factors" in this prospectus for an additional discussion of risks and potential risks of the COVID-19 pandemic on our business, financial condition and results of operations.

## **CPN** Acquisition

On September 17, 2020, we acquired certain assets and assumed certain liabilities of CPN Biosciences, LLC ("CPN") pursuant to an asset purchase agreement dated July 24, 2020. This transaction was accounted for as a business combination using the acquisition method of accounting in accordance with ASC Topic 805, *Business Combinations*. The aggregated consideration amounted to \$19.0 million as of the acquisition date which consisted of \$6.4 million in cash, 2,151,438 shares of our common stock with a fair value of \$8.8 million, and a contingent consideration (the "Earnout") with a fair value of \$3.8 million. At the closing, we paid \$5.8 million in cash and issued 1,947,953 shares of our Class A common stock. The remaining consideration was held back and will be paid or issued, as applicable, eighteen months after the closing date, subject to any offsetting indemnification claims against CPN. The results of operations of CPN have been included in our consolidated financial statements beginning on the acquisition date. Revenue and expenses of CPN since the acquisition date were not material.

## **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 \$12.0 million in cash at closing, \$7.5 million of deferred

acquisition consideration, 137,543 fully vested common stock options and 3,642,746 shares of our Class A common stock. Upon the closing of the merger, NuTech Medical merged with and into Prime Merger Sub, LLC (a wholly-owned subsidiary organized for the purpose of this transaction), 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 since 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, 85 Dan Road Associates, LLC, and 65 Dan Road Associates, LLC, 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.

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

### Management's Use of Non-GAAP Measures

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

We define EBITDA as net income (loss) 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 assets and liabilities, write-off of IPO costs, costs incurred with the Avista Merger, transaction costs related to a warrant exchange transaction and a loss on the extinguishment of debt. We have presented Adjusted EBITDA in this prospectus because it is a key measure used by our management and board of directors to understand and evaluate our operating performance, generate future operating plans and make strategic decisions regarding the allocation of capital. In particular, we believe that the exclusion of certain items in calculating Adjusted EBITDA can produce a useful measure for period-to-period comparisons of our business.

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

- Adjusted EBITDA excludes stock-based compensation expense as it has recently been, and will continue to be for the foreseeable future, a significant recurring non-cash expense for our business and an important part of our compensation strategy;
- Adjusted EBITDA excludes depreciation and amortization expense and, although these are non-cash expenses, the assets being depreciated
  may have to be replaced in the future;
- Adjusted EBITDA excludes net interest expense, or the cash requirements necessary to service interest, which reduces cash available to us;
- Adjusted EBITDA excludes the impact of the changes in the fair value of our warrant liability, our contingent consideration forfeiture asset, and the fair value of interest rate swaps;
- Adjusted EBITDA excludes the write-off of the costs in connection with an abandoned public offering and the costs incurred in connection with the Avista Merger;
- Adjusted EBITDA excludes costs incurred in connection with the Company's warrant exchange transaction;
- Adjusted EBITDA excludes 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 from net loss attributable to Organogenesis Holdings Inc., the most directly comparable financial measure calculated in accordance with GAAP, has been included herein.

### Components of and Key Factors Influencing our Results of Operations

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

#### Revenue

We derive our net revenue from our portfolio of Advanced Wound Care and Surgical & Sports Medicine products. We primarily sell our Advanced Wound Care products through direct sales representatives who manage and maintain the sales relationships with hospitals, wound care centers, government facilities, ASCs and physician offices. We primarily sell our Surgical & Sports Medicine products through third party agencies. As of September 30, 2020, we had approximately 295 direct sales representatives and approximately 170 independent agencies.

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

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

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

#### Cost of goods sold, gross profit and gross profit margin

Cost of goods sold includes personnel costs, product testing costs, quality assurance costs, raw materials and product costs, manufacturing costs, and the costs associated with our manufacturing and warehouse facilities. The increases in our cost of goods sold correspond with the increases in sales units driven by the expansion of our sales force and sales territories, expansion of our product portfolio offerings, and the number of healthcare facilities that offer our products.

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

## Selling, general and administrative expenses

Selling, general and administrative expenses generally include personnel costs for sales, marketing, sales support, customer support, and general and administrative personnel, sales commissions, incentive compensation, insurance, professional fees, depreciation, amortization, bad debt expense, royalties, information systems costs and costs associated with our administrative facilities. We generally expect our selling, general and

administrative expenses to continue to increase due to increased investments in market development and the geographic expansion of our sales forces as we drive for continued revenue growth.

#### Research and development expenses

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

## Write-off of deferred offering costs

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

#### Other expense, net

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

Change in fair value of warrant liability. In connection with the 2016 Loans, we issued warrants to purchase our common stock to the lenders, who are affiliates of ours. We classified the warrants as a liability on our consolidated balance sheets because these warrants provided for down-round protection, which provided that the exercise price of the warrants be adjusted if we issued equity at a price below the 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 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, outstanding principal of \$45.7 million related to the affiliate debt was exchanged for 6,502,679 shares of our Class A common stock and a cash payment of \$35.6 million, including \$22.0 million of principal and \$13.6 million of accrued interest and accrued affiliate loan fees as of and through the closing date of the Avista Merger. Following the consummation of these transactions, the affiliate debt was deemed fully paid and 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.

In March 2019, upon entering into the 2019 Credit Agreement, we paid an aggregate amount of \$17.6 million associated with the termination of the ML Agreement (as defined below), including unpaid principal, accrued interest and an early termination penalty. We recognized \$1.9 million as loss on the extinguishment of the loan for the nine months ended September 30, 2019.

Gain on settlement of deferred acquisition consideration—In February 2020, we settled the dispute on the \$5.0 million deferred purchase acquisition consideration with the sellers of NuTech Medical for \$4.0 million and assumed from the sellers of NuTech Medical the responsibilities related to a legacy lawsuit of NuTech Medical. In connection with the settlement of this dispute, we recorded a gain of \$1.3 million for the three months ended March 31, 2020. The assumed legacy lawsuit was settled in October 2020 and we recorded a gain of \$1.0 million from the decrease in legal accrual for the three months ended September 30, 2020.

#### Income taxes

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

In determining whether a valuation allowance for deferred tax assets is necessary, 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 liabilities would be expected to reverse to determine whether the taxable temporary difference amounts serve as an adequate source of future taxable income to support 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 position. Based on a consideration of the factors discussed above, including the fact that through the period ended September 30, 2020, our results reflected a three-year cumulative loss position, we have determined that a valuation allowance is necessary against the full amount of our net U.S. deferred tax assets, excluding alternative minimum tax credits. On March 27, 2020, the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") which provides for an accelerated refund of the remaining alternative minimum tax credit ("AMT credit") carryforward which was held as a deferred tax asset of \$0.1 million as of December 31, 2019. The CARES Act modifications to the limitation on business interest expense and net operating loss provisions are not expected to have a material impact on our consolidated financial statement.

#### **Results of Operations**

The following table sets forth, for the three and nine months ended September 30, 2020 and 2019, our results of operations:

		Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019	
Net revenue	\$100,799	\$ 64,265	\$231,491	\$ 186,336	
Cost of goods sold	22,964	19,131	61,799	55,557	
Gross profit	77,835	45,134	169,692	130,779	
Operating expenses:					
Selling, general and administrative	51,146	49,475	150,261	147,325	
Research and development	3,709	3,924	13,787	11,159	
Total operating expenses	54,855	53,399	164,048	158,484	
Income (loss) from operations	22,980	(8,265)	5,644	(27,705)	
Other expense, net:					
Interest expense, net	(2,969)	(2,427)	(8,391)	(6,392)	
Loss on the extinguishment of debt	_	_	_	(1,862)	
Gain on settlement of deferred acquisition consideration	951		2,246	_	
Other income (expense), net	44	(1)	90	11	
Total other expense, net	(1,974)	(2,428)	(6,055)	(8,243)	
Net income (loss) before income taxes	21,006	(10,693)	(411)	(35,948)	
Income tax expense	(72)	(48)	(134)	(108)	
Net income (loss)	\$ 20,934	\$(10,741)	\$ (545)	\$ (36,056)	

# **EBITDA and Adjusted EBITDA**

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

The following is a reconciliation of GAAP net loss to non-GAAP EBITDA and non-GAAP Adjusted EBITDA for the three and nine months ended September 30, 2020 and 2019:

2019
ds) (36,056)
6,392
108
2,553
4,526
22,477)
700
_
1,862
916
_
_
_
(18,999)
d

<sup>(1)</sup> The amounts reflect the gain recognized related to the settlement of the deferred acquisition consideration dispute with the sellers of NuTech Medical in February 2020 as well as the settlement of the assumed legacy lawsuit from the sellers of NuTech Medical in October 2020.

<sup>(2)</sup> The amount reflects the loss recognized on the extinguishment of the Master Lease Agreement upon repayment.

<sup>(3)</sup> The amount reflects legal, advisory and other professional fees incurred in the quarter ended September 30, 2019 related directly to the warrant exchange transactions in August 2019.

<sup>(4)</sup> The amount reflects the collection of certain notes receivable from related parties previously reserved.

<sup>(5)</sup> The amounts reflect the legal, advisory and other professional fees incurred in the three and nine months ended September 30, 2020 related directly to the CPN acquisition.

	Yea	r Ended Decembe	er 31
	2019	2018	2017
	4.40.004	(in thousands)	* * * * * * * * * * * * * * * * * * * *
Net revenue	\$260,981	\$193,449	\$198,508
Cost of goods sold	75,948	68,808	61,220
Gross profit	185,033	124,641	137,288
Operating expenses:			
Selling, general and administrative	199,693	161,961	133,717
Research and development	14,799	10,742	9,065
Write-off of deferred offering costs		3,494	
Total operating expenses	214,492	176,197	142,782
Loss from operations	(29,459)	(51,556)	(5,494)
Other expense, net:			
Interest expense, net	(8,996)	(10,789)	(8,010)
Change in fair value of warrants	_	(469)	(1,037)
Loss on the extinguishment of debt	(1,862)	(2,095)	_
Other income (expense), net	13	162	(9)
Total other expense, net	(10,845)	(13,191)	(9,056)
Net loss before income taxes	(40,304)	(64,747)	(14,550)
Income tax (expense) benefit	(150)	(84)	7,025
Net loss	(40,454)	(64,831)	(7,525)
Net income attributable to non-controlling interest in affiliates	<u></u>		863
Net loss attributable to Organogenesis Holdings Inc.	\$ (40,454)	\$ (64,831)	\$ (8,388)

# **EBITDA and Adjusted EBITDA**

The following table presents a reconciliation of net loss attributable to Organogenesis Holdings Inc., to Adjusted EBITDA, for the years ended December 31, 2019, 2018 and 2017:

	Year 1	Ended December	· 31,
	2019	2018	2017
		(in thousands)	
Net loss attributable to Organogenesis Holdings Inc.	\$ (40,454)	\$ (64,831)	\$ (8,388)
Interest expense, net	8,996	10,789	8,010
Income tax expense (benefit)	150	84	(7,025)
Depreciation	3,388	3,309	3,591
Amortization	6,043	3,669	2,037
EBITDA	(21,877)	(46,980)	(1,775)
Stock-based compensation expense	936	1,075	919
Change in contingent consideration forfeiture asset(1)		589	(212)
Change in fair value of interest rate swaps(2)	_	_	6
Change in fair value of warrant liability <sup>(3)</sup>	_	469	1,037
Write-off of deferred offering costs <sup>(4)</sup>	_	3,494	
Avista merger transaction costs(5)		3,072	
Loss on extinguishment of debt(6)	1,862	2,095	
Exchange offer transaction costs(7)	916		
Adjusted EBITDA	\$(18,163)	\$ (36,186)	\$ (25)

<sup>(1)</sup> Amounts reflect the change in fair value of the common shares associated with the shares issued in connection with the acquisition of NuTech Medical that were forfeitable upon the occurrence of the FDA requiring approval of certain products acquired from NuTech Medical.

- (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. The interest rate swaps were not 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 the change in the fair value of the instruments recognized as a component of other expense, net in the consolidated statement of operations. Upon deconsolidation of the Real Estate Entities in June, 2017, the assets and liabilities associated with the interest rate swaps were derecognized.
- (3) In connection with our 2016 Loans, 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 the 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 an abandoned public offering which 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 which were expensed as incurred.
- (6) Amounts reflect the amount of loss recognized on the extinguishment of the Master Lease Agreement upon repayment in 2019 and the amount of loss recognized on the repayment and conversion to equity of the affiliated debt in December 2018.
- (7) Amount reflects legal, advisory and other professional fees incurred in the quarter ended September 30, 2019 related directly to the warrant exchange transactions in Note "12. Stockholders' Equity".

# Comparison of the Three and Nine Months Ended September 30, 2020 and 2019

#### Revenue

	Three Mor Septem		Chang	e	
	2020	2019	\$	%	
	(in t	(in thousands, except for percentage			
Advanced Wound Care	\$ 89,990	\$ 54,310	\$35,680	66%	
Surgical & Sports Medicine	10,809	9,955	854	9%	
Net revenue	\$100,799	\$ 64,265	\$36,534	57%	
	Nine Mon Septem	ber 30,	Chang		
	2020	2019	\$	%	
	(in t	(in thousands, except for percentages)			
Advanced Wound Care	\$201,009	\$157,365	\$43,644	28%	
Surgical & Sports Medicine	30,482	28,971	1,511	5%	
Net revenue	\$231,491	\$186,336	\$45,155	24%	

Net revenue from our Advanced Wound Care products increased by \$35.7 million, or 66%, to \$90.0 million in the three months ended September 30, 2020 from \$54.3 million in the three months ended September 30, 2019. Net revenue from our Advanced Wound Care products increased by \$43.6 million, or 28%, to \$201.0 million in the nine months ended September 30, 2020 from \$157.4 million in the nine months ended September 30, 2019. The increase in Advanced Wound Care net revenue was primarily attributable to the expanded sales force, increased sales to existing and new customers and increased adoption of our amniotic product portfolio, including our Affinity product.

Net revenue from our Surgical & Sports Medicine products increased by \$0.9 million, or 9%, to \$10.8 million in the three months ended September 30, 2020 from \$10.0 million in the three months ended September 30, 2019. Net revenue from our Surgical & Sports Medicine products increased by \$1.5 million, or 5%, to \$30.5 million in the

nine months ended September 30, 2020 from \$29.0 million in the nine months ended September 30, 2019. The increase in Surgical & Sports Medicine net revenue was primarily attributable to the expanded sales force and penetration of existing and new customer accounts, partially offset by postponement or cancellation of medical procedures as a result of COVID-19.

Included within net revenue is PuraPly revenue of \$40.9 million and \$31.8 million for the three months ended September 30, 2020 and 2019, respectively, and \$102.0 million and \$86.9 million for the nine months ended September 30, 2020 and 2019, respectively. PuraPly had pass-through status in both of the periods. The increase in PuraPly revenue in the three and nine month periods was due to the expanded sales forces and increased sales to existing and new customers.

# Cost of goods sold, gross profit and gross profit margin

	Three Mon	Three Months Ended			
	Septem	ber 30,	Chan	ge	
	2020	2019	\$	%	
	(in	thousands, except	for percentages)		
Cost of goods sold	\$ 22,964	\$ 19,131	\$ 3,833	20%	
Gross profit	\$ 77,835	\$ 45,134	\$32,701	72%	
Gross profit%	77%	70%			
	Septem	Nine Months Ended September 30,			
	2020	2019 thousands, except	S for normantages	<u>%</u>	
Cost of goods gold				11%	
Cost of goods sold	\$ 61,799	\$ 55,557	\$ 6,242	11%	
Gross profit	\$169,692	\$130,779	\$38,913	30%	
Gross profit%	73%	70%			

Cost of goods sold increased by \$3.8 million, or 20%, to \$23.0 million in the three months ended September 30, 2020 from \$19.1 million in the three months ended September 30, 2019. Cost of goods sold increased by \$6.2 million or 11% to \$61.8 million in the nine months ended September 30, 2020 from \$55.6 million in the nine months ended September 30, 2019. The increase in cost of goods sold was primarily due to increased unit volumes, additional manufacturing and quality control headcount.

Gross profit increased by \$32.7 million, or 72%, to \$77.8 million in the three months ended September 30, 2020 from \$45.1 million the three months ended September 30, 2019. Gross profit increased by \$38.9 million, or 30%, to \$169.7 million in the nine months ended September 30, 2020 from \$130.8 million in the nine months ended September 30, 2019. The increase in gross profit resulted primarily from increased sales volume due to the strength in our Advanced Wound Care and Surgical & Sports Medicine products as well as a shift in product mix to our higher gross margin products.

# Selling, General and Administrative Expenses

	Three Mon	ths Ended			
	Septem	September 30,		ge	
	2020	2019	\$	%	
	(in th	2020 2019 \$ (in thousands, except for percentages)			
Selling, general and administrative	\$51,146	\$49,475	\$1,671	3%	
Selling general and administrative as a percentage of net revenue	51%	77%	<del></del>		

	Nine Month	Nine Months Ended			
	Septembe	ptember 30, Chai		e	
	2020	2019	\$	%	
	(in thousa	nds, except for po	ercentages)		
Selling, general and administrative	\$150,261	\$147,325	\$2,936	2%	
Selling, general and administrative as a percentage of net revenue	65%	79%		_	

Selling, general and administrative expenses increased by \$1.7 million, or 3%, to \$51.1 million in the three months ended September 30, 2020 from \$49.5 million in the three months ended September 30, 2019. The increase in selling, general and administrative expenses was primarily due to a \$6.4 million increase related to additional headcount, primarily in our direct sales force and increased sales commissions due to increased sales, a \$0.4 million increase in credit card processing fees due to increased collection and \$0.2 million increase in royalties due to increased sales. These increases were partially offset by a \$3.3 million decrease related to reduced travel and marketing programs amid travel restrictions in place due to the COVID-19, a \$0.6 million decrease in amortization associated with intangible assets amortized using an accelerated method, a \$0.6 million decrease in legal, consulting fees and other costs associated with the ongoing operations of our business and a \$0.8 million decrease in bad debt primarily due to the collection of the previously reserved related party receivables.

Selling, general and administrative expenses increased by \$2.9 million, or 2%, to \$150.3 million in the nine months ended September 30, 2020 from \$147.3 million in the nine months ended September 30, 2019. The increase in selling, general and administrative expenses was primarily due to a \$10.5 million increase related to additional headcount, primarily in our direct sales force and increased sales commissions due to increased sales, a \$2.0 million cancellation fee for certain product development and consulting agreements, and a \$0.9 million increase in credit card processing fees due to increased collection. These increases were partially offset by a \$6.4 million decrease related to reduced travel and marketing programs amid travel restrictions in place due to the COVID-19, a \$1.4 million decrease in legal, consulting fees and other costs associated with the ongoing operations of our business, a \$2.0 decrease in amortization associated with the intangible assets amortized using an accelerated method and a \$0.8 million decrease in bad debt primarily due to the collection of the previously reserved related party receivables.

# Research and Development Expenses

	Three Moi Septem		Chang	ge .	
	2020	2019	\$	%	
	(i	(in thousands, except for percentages)			
Research and development	\$ 3,709	\$ 3,924	\$ (215)	(5%)	
Research and development as a percentage of net revenue	4%	6%			
	Nine Mon Septem		Chang	re	
	2020	2019	\$	%	
	(i	n thousands, except	for percentages)		
Research and development	\$13,787	\$11,159	\$2,628	24%	
Research and development as a percentage of net revenue	<del></del>	<del></del> 6%	<del></del>		

Research and development expenses decreased by \$0.2 million, or (5%), to \$3.7 million in the three months ended September 30, 2020 from \$3.9 million in the three months ended September 30, 2019. The decrease was primarily due to delayed enrollment in trials and limited clinical spending due to the COVID-19. Research and development expenses increased by \$2.6 million, or 24%, to \$13.8 million in the nine months ended September 30, 2020 from \$11.2 million in the nine months ended September 30, 2019. The increase in research and

development expenses was primarily due to an increase in process development costs associated with a new contract manufacturer, increased headcount associated with our existing Advanced Wound Care and Surgical & Sports Medicine products, an increase in product costs associated with our pipeline products not yet commercialized and an increase in costs to move products through the regulatory pathway (e.g., seek BLA approval). The increase was partially offset by a decrease due to delayed enrollment in trials and limited clinical spending due to the COVID-19.

#### Other Expense, net

	Three Mon Septem		Cha	nge
	2020	2019	\$	%
	(in thousands, except for percentages) \$(2,969) \$(2,427) \$ (542)			
Interest expense, net	\$(2,969)	\$(2,427)	\$ (542)	22%
Gain on settlement of deferred acquisition consideration	951	_	951	100%
Other income (expense), net	44	(1)	45	**
Total other expense, net	<u>\$(1,974)</u>	\$(2,428)	\$ 454	(19%)
	Nine Months Ended September 30, Change			
			Cha	nge
	Septem 2020	ber 30, 2019	\$	%
	Septem 2020 (in	ber 30, 2019 n thousands, excep	\$ ot for percentages)	%
Interest expense, net	Septem 2020	ber 30, 2019	\$	%
Interest expense, net Loss on the extinguishment of debt	Septem 2020 (in	ber 30, 2019 n thousands, excep	\$ ot for percentages)	%
1	Septem 2020 (in	2019 n thousands, excep \$(6,392)	\$ ot for percentages) \$ (1,999)	31%
Loss on the extinguishment of debt	Septem 2020 (in \$(8,391) —	2019 n thousands, excep \$(6,392)	\$ of for percentages) \$(1,999) 1,862	31% (100%)

<sup>\*\*</sup> not meaningful

Other expense, net, decreased by \$0.5 million, or 19%, to \$2.0 million in the three months ended September 30, 2020 from \$2.4 million in the three months ended September 30, 2019. The decrease is primarily due to a \$1.0 million decrease in legal accruals related to the settlement of the assumed legacy lawsuit from the sellers of NuTech Medical in October 2020. We assumed the legacy lawsuit as part of the resolution of the deferred acquisition consideration dispute with the sellers of NuTech Medical in February 2020. The decrease was partially offset by a \$0.5 million or 22% increase in interest expense resulting from the increased borrowings under the 2019 Credit Agreement.

Other expense, net, decreased by \$2.2 million or 27% to \$6.1 million in the nine months ended September 30, 2020 from \$8.2 million in the nine months ended September 30, 2019. Interest expense, net, increased by \$2.0 million or 31% primarily due to the increased borrowings under the 2019 Credit Agreement. The loss on the extinguishment of debt of \$1.9 million for the nine months ended September 30, 2019 reflected the write-off of unamortized debt discount upon repayment of the Master Lease Agreement as well as early payment penalties in March 2019. The gain of \$2.2 million for the nine months ended September 30, 2020 was related to the settlement of the deferred acquisition consideration dispute with the sellers of NuTech Medical in February 2020 as well as the decrease in legal accruals related to the settlement of a legacy lawsuit in October 2020. We assumed the legacy lawsuit from the sellers of NuTech Medical as part of the resolution of the aforementioned dispute.

#### Comparison of the Year Ended December 31, 2019, 2018 and 2017

#### Revenue

	Years	Years Ended December 31,			Change		
	2019	2018	2017	2019 to 2	2019 to 2018		17
	•	(in thousands, except for percentages)					
Advanced Wound Care	\$220,744	\$164,332	\$178,896	\$56,412	34%	\$(14,564)	(8%)
Surgical & Sports Medicine	40,237	29,117	19,612	11,120	38%	9,505	48%
Net revenue	\$260,981	\$193,449	\$198,508	\$67,532	35%	\$ (5,059)	(3%)

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

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

For the year ended December 31, 2018, net revenue from our Advanced Wound Care products decreased by \$14.6 million or 8%, as compared to 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.

For the year ended December 31, 2018, net revenue from our Surgical & Sports Medicine products increased by \$9.5 million or 48%, as compared to the year ended December 31, 2017. The increase in Surgical & Sports Medicine net 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 \$126.8 million, \$69.8 million, and \$109.1 million for the years ended December 31, 2019, 2018 and 2017, respectively.

# Cost of Goods Sold, Gross Profit and Gross Margin

	Years	Years Ended December 31,			Change			
	2019	2018	2017	2019 to 20	2019 to 2018 2018 to 201		17	
		(in thousands, except for percentages)						
Cost of goods sold	\$ 75,948	\$ 68,808	\$ 61,220	\$ 7,140	10%	\$ 7,588	12%	
Gross profit	\$185,033	\$124,641	\$137,288	\$60,392	48%	\$(12,647)	(9%)	
Gross profit %	71%	64%	69%					

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

For the year ended December 31, 2019, gross profit increased by \$60.4 million or 48%, as compared to the year ended December 31, 2018. The increase in gross profit resulted primarily from increased sales volume due

to the strength in our Advanced Wound Care and Surgical & Sports Medicine products, PuraPly regaining pass-through reimbursement status for the 2-year period effective October 1, 2018, and the resulting higher margins realized as a result of manufacturing efficiencies associated with our Advanced Wound Care products.

For the year ended December 31, 2018, cost of goods sold increased by \$7.6 million, or 12%, as compared to 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.

For the year ended December 31, 2018, gross profit decreased by \$12.6 million or 9%, as compared to the year ended December 31, 2017. The decrease in gross profit resulted primarily from the decrease in our Advanced Wound Care net 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.

# Selling, General and Administrative Expenses

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

	Years Ended December 31,				Char	ıge	
	2019	2018	2017	2019 to 2018 2018 to		2018 to 20	017
	(in thousands, except for percentages)						
Selling, general and administrative	\$199,693	\$161,961	\$133,717	\$37,732	23%	\$28,244	21%
Selling, general and administrative as a percentage of net							
revenue	77%	84%	67%				

For the year ended December 31, 2019, selling, general and administrative expenses increased by \$37.7 million, or 23%, as compared to the year ended December 31, 2018. The increase in selling, general and administrative expenses is primarily due to an increase of \$30.6 million related to additional headcount, primarily in our direct sales force and increased sales commissions due to increased sales, an increase of \$2.6 million in legal, consulting fees and other costs associated with the ongoing operations of our business, an increase of \$2.4 million in amortization associated with intangible assets amortized using the economic benefits method, an increase of \$1.7 million associated with marketing and promotional materials for our products, and an increase of \$1.7 million in royalties attributable to certain product sales. These increases are partially offset by a decrease of \$1.5 million associated with transaction advisory fees incurred in 2018. We expect our selling, general and administrative expenses to continue to increase throughout 2020.

For the year ended December 31, 2018, selling, general and administrative expenses increased by \$28.2 million, or 21%, as compared to 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.

# Research and Development Expenses

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

	Years Ended December 31,		Change				
	2019	2018	2017	2019 to 2	2018	2018 to 2	2017
		(in the	ousands, except	for percenta	ages)		
Research and development	\$14,799	\$10,742	\$9,065	\$4,057	38%	\$1,677	18%
Research and development as a percentage of net revenue	6%	6%	5%		=		

For the year ended December 31, 2019, research and development expenses increased by \$4.1 million, or 38%, as compared to the year ended December 31, 2018. The increase in research and development expenses is primarily due to the increase in clinical research costs and increased headcount associated with our existing Advanced World Care and Surgical & Sports Medicine products and an increase in product costs associated with our pipeline products not yet commercialized. We expect our research and development costs to continue to increase throughout 2020.

For the year ended December 31, 2018, research and development expenses increased by \$1.7 million, or 18%, as compared to the year ended December 31, 2017. The increase in research and development expenses is primarily due to the increase in clinical research costs and increased headcount associated with our existing Advanced World Care and Surgical & Sports Medicine products.

#### Write-off of Deferred Offering Costs

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

	Years Ended December 31,		Change				
	2019	2018	2017	2019 to 2018		2018 to 2	017
	'	(in the	usands, exce	pt for percent	ages)		
Write-off of deferred offering costs	\$ <i>-</i>	\$3,494	\$ —	\$(3,494)	(100%)	\$3,494	**
Write-off of deferred offering costs as a percentage of net revenue	<del></del>	2%	0%	<del></del>		<del></del>	

<sup>\*\*</sup> not meaningful

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

# Other Expense, Net

	Years	Years Ended December 31,			Change			
	2019	2018	2017	2019 to 2018		2018 to 2	017	
	·	(in	thousands, exc	ept for perce	ntages)			
Interest expense, net	\$ (8,996)	\$(10,789)	\$(8,010)	\$1,793	(17%)	\$(2,779)	35%	
Change in fair value of warrants	_	(469)	(1,037)	469	(100%)	568	(55%)	
Loss on the extinguishment of debt	(1,862)	(2,095)	_	233	(11%)	(2,095)	**	
Other income (expense), net	13	162	(9)	(149)	(92%)	171	**	
Total other expense, net	\$(10,845)	\$(13,191)	\$(9,056)	\$2,346	(18%)	\$(4,135)	46%	

<sup>\*\*</sup> not meaningful

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

For the year ended December 31, 2018, other expense, net, increased by \$4.1 million, or 46%, as compared to the year ended December 31, 2017. Interest expense, net, increased by \$2.8 million, or 35% primarily due to the increased borrowings of \$15.0 million in connection with the 2018 Loans, and additional borrowings during 2018 under the 2017 Credit Agreement. The fair value of warrant liability continued to increase during 2018 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)

	Years F	Years Ended December 31,		Change			
	2019	2019 2018 2017		2019 to	019 to 2018 201		2017
		(i	in thousands,	except for	percentage	es)	<u>.</u>
Income tax (expense) benefit	\$(150)	\$(84)	\$ 7,025	\$(66)	79%	\$(7,109)	(101%)

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

For the year ended December 31, 2018, income tax expense increased by \$7.1 million, or 101%, 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 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.

# **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 September 30, 2020, we had \$36.5 million in cash and \$62.8 million in working capital. We expect that our cash on hand and other components of working capital as of September 30, 2020, plus net cash flows from product sales, will be sufficient to fund our operating expenses, capital expenditure requirements and debt service payments for at least 12 months. We continue to closely monitor ongoing developments in connection with the COVID-19 pandemic, which may negatively impact our commercial prospects, cash position and access to capital in fiscal 2020 or beyond. We will continue to assess our cash and other sources of liquidity and, if circumstances warrant, we will make appropriate adjustments to our operating plan. Please see "Risk Factors" in this prospectus for an additional discussion of risks and potential risks of the COVID-19 pandemic on our business, financial condition and results of operations.

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

volumes, the timing of shipments and the payment cycles of our customers and payers. Our capital expenditures consist primarily of building improvements, manufacturing equipment, computer hardware and software.

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

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

		December 31,		
	2019	2018	2017	
		(in thousands)	1	
Cash	\$ 60,174	\$21,291	\$ 2,309	
Line of credit	\$ 33,484	\$26,484	\$ 17,618	
Term loan	49,634		_	
Due to affiliates	_	_	4,500	
Notes payable	_	15,123	14,816	
Capital lease obligations	17,488	17,654	17,759	
Long-term debt—affiliates, including accrued interest			52,142	
Total debt (1)	100,606	59,261	106,835	
Net debt (2)	\$ 40,432	\$37,970	\$104,526	

<sup>(1)</sup> 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 the nine months ended September 30, 2020 and 2019:

	Nine Mont Septem	
	2020	2019
	(in thou	isands)
Net cash used in operating activities	\$ (19,475)	\$ (27,127)
Net cash used in investing activities	(16,354)	(2,776)
Net cash provided by financing activities	12,345	31,657
Net change in cash and restricted cash	\$ (23,484)	\$ 1,754

# **Operating Activities**

During the nine months ended September 30, 2020, net cash used in operating activities was \$19.5 million, resulting from our net loss of \$0.5 million and net cash used in connection with changes in our operating assets and liabilities of \$28.6 million, partially offset by non-cash charges of \$9.6 million. Net cash used in changes in our operating assets and liabilities included an increase in accounts receivable of \$19.2 million, an increase in inventory of \$7.8 million, an increase in prepaid expenses and other current assets of \$2.3 million, and a decrease in accounts payable of \$3.8 million, all of which were partially offset by an increase in accrued expenses and other liabilities of \$4.4 million.

During the nine months ended September 30, 2019, net cash used in operating activities was \$27.1 million, resulting from our net loss of \$36.1 million and net cash used in connection with changes in our operating assets and liabilities of \$3.3 million, partially offset by non-cash charges of \$12.2 million. Net cash used in changes in our operating assets and liabilities includes an increase in inventory of \$7.8 million, an increase in prepaid expenses and other current assets of \$0.7 million and a decrease in other liabilities of \$0.7 million, all of which were partially offset by a decrease in accounts receivable of \$0.6 million and an increase in accounts payable and accrued expenses and other current liabilities of \$5.4 million.

# **Investing Activities**

During the nine months ended September 30, 2020, we used \$16.4 million of cash in investing activities consisting of capital expenditures of \$12.3 million, payment of \$5.8 million related to the acquisition of CPN partially offset by notes receivable repayment of \$1.7 million from our former executives.

During the nine months ended September 30, 2019, we used \$2.8 million of cash in investing activities consisting of capital expenditures and an intangible asset purchase.

## Financing Activities

During the nine months ended September 30, 2020, net cash provided by financing activities was \$12.3 million. This consisted primarily of \$15.9 million in proceeds from our 2019 Credit Agreement, and \$1.3 million in proceeds from the exercise of common stock options. The net cash provided by financing activities was partially offset by the payment of capital lease obligations of \$1.8 million and the payment of \$3.0 million related to the NuTech Medical deferred acquisition consideration.

During the nine months ended September 30, 2019, net cash provided by financing activities was \$31.7 million. This consisted primarily of \$56.1 million in net proceeds from the 2019 Credit Agreement, and \$0.8 million in proceeds from the exercise of common stock warrants and options. The net cash provided by financing activities was partially offset by the payment of the put option on redeemable common stock of \$6.8 million, repayment of the Master Lease Agreement of \$17.6 million, and repayment of capital lease obligations of \$0.9 million.

The following table summarizes our cash flows for the years ended December 31, 2019, 2018 and 2017:

	Year	Year Ended December 31,		
	2019	2018	2017	
		(in thousands)		
Net cash used in operating activities	\$(33,528)	\$(60,635)	\$ (3,493)	
Net cash used in investing activities	(6,234)	(1,856)	(14,874)	
Net cash provided by financing activities	<u>78,727</u>	81,538	18,867	
Net increase in cash and restricted cash	\$ 38,965	\$ 19,047	\$ 500	

# **Operating Activities**

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

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

During the year ended December 31, 2017, net cash used in operating activities was \$3.5 million, resulting from our net loss of \$7.5 million and net cash used in connection with changes in our operating assets and liabilities of \$1.2 million, partially offset by non-cash charges of \$5.2 million. Net cash used in connection with changes in our operating assets and liabilities includes an increase in accounts receivable of \$7.0 million, an increase in inventory of \$1.5 million 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 \$4.0 million, an increase in accrued interest on affiliate debt of \$3.2 million and an increase in accrued expenses and other liabilities of \$2.7 million.

# **Investing Activities**

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

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

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

# Financing Activities

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

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

During the year ended December 31, 2017, net cash provided by financing activities was \$18.9 million that consisted primarily of \$15.1 million in net proceeds from the ML Agreement, \$12.7 million in net proceeds under our 2017 Credit Agreement, \$1.0 million in proceeds attributable to the Real Estate Entities in connection with cash contributions from member affiliates and \$0.2 million in proceeds from the exercise of stock options. The net cash provided by financing activities was partially offset by repayment of notes payable of \$6.3 million, repayment of Real Estate Entities mortgage notes payable of \$1.3 million and payment of \$2.5 million of deferred acquisition consideration related to our NuTech Medical acquisition.

# Indebtedness

# 2019 Credit Agreement

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

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

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

As of September 30, 2020, we were in compliance with the financial covenants under the 2019 Credit Agreement and we had outstanding borrowings under the Revolving Facility and Term Loan Facility of the 2019 Credit Agreement of \$39.4 million and \$60.0 million, respectively.

# 2017 Credit Agreement

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

#### Master Lease Agreement

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

#### 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, 2019, \$5.0 million remained payable and was accruing interest at a rate of 6% per annum. The amount of the deferred acquisition consideration plus accrued interest owed to the sellers of NuTech Medical was previously in dispute. The Company asserted certain claims for indemnification that would offset in whole or in part its payment obligation and the sellers of NuTech Medical filed a lawsuit alleging breach of contract and seeking specific performance of the alleged payment obligation and attorneys' fees. In February 2020, we entered into a settlement agreement with the sellers of NuTech Medical and settled the dispute for \$4.0 million. Refer to Note "16. Commitments and Contingencies".

## Contractual Obligations and Commitments

The table below summarizes our contractual obligations as of December 31, 2019 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods. There were no material changes to our contractual obligations and commitments as of September 30, 2020.

		Payments Due by Period			
	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years
			(in thousands)		
Operating lease obligations (1)	\$ 23,411	\$ 5,661	\$ 7,754	\$ 3,098	\$ 6,898
Capital lease obligations (2)	24,350	4,791	9,725	9,834	_
Debt obligations (3)	106,540	6,497	42,223	57,820	_
Purchase commitments (4)	16,622	16,622	_	_	_
Deferred acquisition consideration (5)	5,918	5,918	_	_	_
Acquisition of intangible assets (6)	500	250	250	_	_
Total	\$177,341	\$39,739	\$59,952	\$70,752	\$ 6,898

- (1) Amounts in the table reflect minimum payments due for our leased space and vehicles under operating leases that expire between 2020 and 2024.
- (2) Amounts in the table reflect the total cash payments on our capital lease obligations primarily related to the office and laboratory space in Canton, Massachusetts, including accrued interest of \$3.5 million for rent in arrears discussed in Note "16. Commitments and Contingencies" to our consolidated financial statements appearing at the end of this prospectus. The leases have a ten-year term and expire in December 2022 but due to the subordination agreement will be paid in 2024 upon maturity of the 2019 Credit Agreement.
- (3) Amounts in the table reflect the contractually required principal and interest payable as of December 31, 2019 pursuant to outstanding borrowings under the 2019 Credit Agreement. For the Term Loan Facility, the table reflects interest-only payments through February 2021 at an interest rate of 9.25%, as well as a final payment of \$3.1 million due upon repayment of all outstanding amounts. For the Revolving Facility, the table reflects interest payments relating to the outstanding principal due in March 2024, calculated using an interest rate of 5.5%, which was the applicable interest rate as of December 31, 2019.

- (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. In February 2020, we entered into a settlement agreement with the sellers of NuTech Medical and settled the liability for \$4.0 million of which \$2.0 million was paid immediately on February 14, 2020 (the "Settlement Date") and the remaining \$2.0 million is to be paid in four quarterly installments of \$0.5 million each with the first quarterly payment due and payable on the date that is 90 days from the Settlement Date. See Note "16. Commitments and Contingencies" to our consolidated financial statements appearing at the end of this prospectus.
- (6) Amounts in the table reflect the remaining payments due related to the acquisition of intangible assets.

# Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements have been prepared in accordance with GAAP. The preparation of our consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, 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, especially given the risks and uncertainties related to COVID-19, we may need to revise our estimates, or take other corrective actions, either of which may also have a material adverse effect on our consolidated statements of operations, liquidity and financial condition.

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

## Revenue Recognition

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

#### Accounts Receivable

Accounts receivable are stated at invoice value less estimated allowances for sales returns and doubtful accounts. We estimate the allowance for sales returns based on a historical percentage of returns over a twelve-month trailing average of sales. We continually monitor customer payments and maintain a reserve for estimated losses resulting from our customers' inability to make required payments. We consider factors such as historical experience, credit quality, age of the accounts receivable balances, 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.

#### Goodwill

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

In accordance with ASC Topic 350, *Intangibles—Goodwill and Other*, we first assess qualitative factors to determine whether it is necessary to perform the quantitative goodwill impairment test. If after assessing the totality of events or circumstances, we determine that it is more likely than not (i.e. greater than 50% likelihood) that the fair value of the reporting unit is less than its carrying amount, then the quantitative test is required. Otherwise, no further testing is required. The quantitative goodwill impairment test requires us to estimate and compare the fair value of the reporting unit with its carrying value. If the fair value of the reporting unit exceeds the carrying value of the net assets, goodwill is not impaired. If the fair value of the reporting unit is less than the carrying value, the difference is recorded as an impairment loss up to the amount of goodwill.

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

There were no impairments of goodwill recorded during 2019, 2018 or 2017.

# Impairment of Long-Lived Assets

We review other long-lived assets (including identifiable definite lived intangible assets) for impairment whenever events or changes in circumstances indicate that the useful life is shorter than originally estimated or the carrying amount of an asset or asset group may not be recoverable. If such facts and circumstances exist, we

assess the recoverability of the identified assets by comparing the projected undiscounted net cash flows associated with the related asset or group of assets over their remaining lives to their respective carrying amounts. Impairments, if any, are based on the excess of the carrying amount over the fair value of those assets and occur in the period in which the impairment determination is made.

There were no impairments of long-lived assets recorded during 2019, 2018 or 2017.

# Income Taxes

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

In determining whether a valuation allowance for deferred tax assets is necessary, 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 liabilities would be expected to reverse to determine whether the taxable temporary difference amounts serve as an adequate source of future taxable income to support 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 position. Based on a consideration of the factors discussed above, including the fact that through the year ended December 31, 2019, 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.

#### Stock-Based Compensation

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

We recognize stock-based compensation expense within the selling, general and administrative expenses in the consolidated statement of operations for all share-based payments based upon the estimated grant-date fair value for the awards expected to ultimately vest.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. Prior to the Avista Merger, there was no public market for Organogenesis Inc. common stock, and as such, we lack company-specific historical and implied volatility information for its common stock. Therefore, we estimate our expected stock price volatility based on the historical volatility of publicly traded peer companies and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our own traded stock price. The expected term of our stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that we have never paid cash dividends on common stock and do not expect to pay any cash dividends in the foreseeable future.

#### **Off-Balance Sheet Arrangements**

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

# **Recently Issued Accounting Pronouncements**

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

# **Emerging Growth Company Status**

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to use the extended transition period for complying with new or revised accounting standards (such as ASU 2016-02, *Leases (Topic 842)*) and, as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. We may take advantage of these exemptions up until the last day of the fiscal year following October 14, 2021, the fifth anniversary of our IPO, or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than \$1.07 billion in annual revenue, we have more than \$700.0 million in market value of our stock held by non-affiliates or we issue more than \$1.0 billion of non-convertible debt securities over a three-year period.

#### Quantitative and Qualitative Disclosures About Market Risk

Pursuant to Item 305(e) of Regulation S-K, the Company is not required to provide the information required by this Item as it is a "smaller reporting company," as defined by Rule 229.10(f)(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. Several of our existing and pipeline products in our portfolio have PMA approval, BLA approval or 510(k) clearance from the FDA. Given the extensive time and cost required to conduct clinical trials and receive FDA approvals, we believe that our data and regulatory approvals provide us a strong competitive advantage. Our product development expertise and multiple technology platforms provide a robust product pipeline, which we believe will drive future growth.

In the Advanced Wound Care market, we focus on the development and commercialization of advanced wound care products for the treatment of chronic and acute wounds, 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 VLUs 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, AHPAC consummated the Business Combination pursuant to the Avista Merger Agreement, by and among 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. In addition, in connection with the Business Combination, AHPAC redomesticated as a Delaware corporation. 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 September 30, 2020, we had approximately 900 full-time employees worldwide. For the nine months ended September 30, 2020, we generated \$231.5 million of net revenue and had \$0.5 million of net loss compared to \$186.3 million of net revenue and \$36.1 million of net loss for the nine months ended September 30, 2019. For the year ended December 31, 2019, we generated net revenue of \$261.0 million and had a net loss of \$40.5 million as compared to net revenue of \$193.4 million and a net loss of \$64.8 million for the year ended December 31, 2018.

# **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 a greater incidence of comorbidities such as diabetes, obesity, and cardiovascular and peripheral vascular disease and smoking. We believe there is growing adoption of regenerative medicine products by the physician community due to their clinical superiority and cost effectiveness for all major stakeholders compared to traditional products.
- Comprehensive Suite of Products to Address the Clinical and Economic Needs of Wound Care Patients and Providers. Our comprehensive portfolio of wound care products allows physicians to personalize solutions to meet the needs of individual wound care patients. We engage with the physician at the earliest incidence of the patient's healing process with our PuraPly AM product, which has antimicrobial properties that are beneficial for most types of wounds. If the underlying healing issues persist, we offer an array of bioactive products 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. Several of our existing and pipeline products in our product portfolio have FDA regulatory approval, including PMA approval, BLA approval or 510(k) clearance. Given the extensive time and cost required to conduct clinical trials and receive FDA approval, we believe our data and regulatory approvals provide us a strong competitive advantage.
- Robust and Extensive Relationships Across the Continuum of Care. We have established robust and extensive customer relationships
  across the entire continuum of care including hospitals, wound care centers, government facilities, ASCs and physician offices to sell our
  broad portfolio of products.

We serve more than 3,000 health care facilities, hospital systems, IDNs and GPOs. In addition, we have developed important relationships with physicians, nurses, and other key decision makers as well as third-party payers. Given these relationships across the continuum of care, we believe we are well positioned to increase our penetration in the Advanced Wound Care market and leverage those relationships in the Surgical & Sports Medicine market.

- Differentiated In-house Customer Support Capabilities Including Third-Party Reimbursement Support. We strengthen our customer relationships with extensive in-house customer support capabilities. Through our dedicated team of experienced professionals, our "Circle of Care" program provides in-house third-party reimbursement, medical and technical support. We believe our customer support capabilities differentiate us from many of our competitors who may outsource these critical services to third parties.
- Established and Scalable Regulatory, Manufacturing and Commercial Infrastructure. We have developed significant in-house expertise on the regulatory approval process that is based on our successful management of multiple products through various FDA approval pathways including PMA approval, BLA approval and 510(k) clearance. We have also developed rigorous and proven FDA compliant manufacturing, distribution and logistics capabilities. We pair our operational capabilities with a strong commercial team of sales and marketing professionals. Our established regulatory, operational and commercial infrastructure provides a firm foundation for growth as we continue to scale our business.
- Extensive Executive Management Experience in Regenerative Medicine. Our executive management team has extensive experience in the regenerative medicine industry, boasting over 70 years of collective experience in the space. This experience allows us to operate from a deep understanding of the underlying trends in regenerative medicine and the intertwined scientific, clinical, regulatory, commercial and manufacturing issues that drive success in the industry.

#### **Our Business Strategy**

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

- Drive Penetration in the Fast Growing Advanced Wound Care Market. We intend to leverage our comprehensive product portfolio and relationships with key constituents to deepen our presence in the Advanced Wound Care market. In addition, with the acquisition of NuTech Medical, we acquired products that give us access to the rapidly growing amniotic category of the wound care market. We believe the breadth and flexibility of the portfolio we now offer allow us to address a wide variety of wound types, sizes, and reimbursement levels, offering significant new opportunities for growth. Furthermore, we believe our expanded product portfolio is enhancing the ability of our sales representatives to reach and penetrate customer accounts, contributing to strong growth over time. Additionally, we believe there is significant room for expansion of the Advanced Wound Care market as a whole and our wound biologics product category in particular as more physicians and payers are educated about the benefits of regenerative medicine technologies versus traditional therapies. We continue to invest to support physician and payer education as well as preclinical and clinical trials, real-world evidence, and other research to confirm the benefits of our products. We will continue to seek expanded payer coverage for all of our products, particularly PuraPly AM, NuShield and Affinity for which we do not yet have the broad commercial payer coverage enjoyed by Apligraf and Dermagraft.
- Continued Expansion into Surgical & Sports Medicine Market. We entered the Surgical & Sports Medicine market with the acquisition of NuTech Medical and its established and leading presence in amniotic products in 2017. We plan to continue to accelerate penetration into this market by leveraging our established commercial and operational infrastructure and building out our direct sales force to supplement our independent sales agencies. We also plan to continue to take advantage of significant

opportunities to cross-sell within our established customer bases in both the Advanced Wound Care and Surgical & Sports Medicine markets. We believe that the potential of regenerative medicine in the Surgical & Sports Medicine market, particularly with respect to chronic inflammatory and degenerative conditions, continues to present a strong long-term opportunity. Given our experience in the Advanced Wound Care market and regenerative medicine in general, we believe we are well positioned to capture this opportunity.

- Launch Robust Pipeline of Products and Drive Innovation With a Proven Research and Development Platform. We have a robust pipeline of products in both the Advanced Wound Care and Surgical & Sports Medicine markets that we expect to launch in the near term. We expect these products will deepen our portfolios and allow us to address additional clinical applications. In addition, we anticipate our ongoing efforts to complete clinical studies and publish research regarding our products will further enhance physician and payer receptiveness to our products over time. Our proven research and development capabilities and established technology platforms also support a robust and adaptable product pipeline for future applications.
- Continue to Expand Sales Force and Increase Sales Productivity and Geographic Reach. We plan to continue to expand the reach and penetration of our products by growing our sales organization to serve the Advanced Wound Care and Surgical & Sports Medicine markets. This expansion should allow us to achieve more focused and effective sales coverage for specific market categories, broaden our geographic footprint, and leverage our expanding relationships with large hospital systems and GPOs. We also plan to increase our focus on sales outside of the United States, including the European Union and the Middle East. Currently, substantially all of our sales are in the United States.
- Supplement Organic Growth Through Selective Acquisitions. We have demonstrated our ability to successfully identify and integrate assets that complement our strategy through the acquisitions of Dermagraft and TransCyte from Shire and our amniotic products from NuTech Medical. We believe TransCyte has the ability to address a \$200 million burn market, which includes 500,000 burns that require medical attention and 40,000 burns that require hospitalization annually in the United States. We continue to evaluate tuck-in acquisitions which complement our existing portfolios in both the Advanced Wound Care and Surgical & Sports Medicine markets and will leverage our established commercial and manufacturing infrastructure.

# **Industry Overview**

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

Our products use regenerative medicine technologies to provide solutions in the Advanced Wound Care and Surgical & Sports Medicine markets. Based on industry reports and management estimates, we believe that our addressable Advanced Wound Care and Surgical & Sports Medicine markets total approximately \$14.9 billion, which includes an estimated \$8.9 billion addressable market for Advanced Wound Care and an estimated \$6.0 billion addressable market for Surgical & Sports Medicine. Within the Advanced Wound Care market, 54% of treatments are used in advanced wound dressings, 17% are used in biologics, 20% are used in negative pressure wound therapy and 9% are used in other treatments. The skin substitute sub-market, within biologics,

grew at a CAGR of 15% from 2016 to 2018 and less than 5% of addressable wounds are currently being treated with skin substitutes. Within the Surgical & Sports Medicine market, the bone fusion sub-market accounted for approximately \$2.7 billion, the tendon and ligament injuries sub-market accounted for approximately \$1.0 billion and the chronic inflammatory and degenerative condition sub-market accounted for approximately \$2.4 billion.

Key drivers of growth in these two markets include:

- favorable global demographics and aging population;
- greater incidence of comorbidities that contribute to impaired healing, such as diabetes, obesity, cardiovascular and peripheral vascular disease and smoking; and
- increasing acceptance of advanced technologies to treat complex wounds and musculoskeletal injuries.

#### Advanced Wound Care Market

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

#### Chronic Wounds

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

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

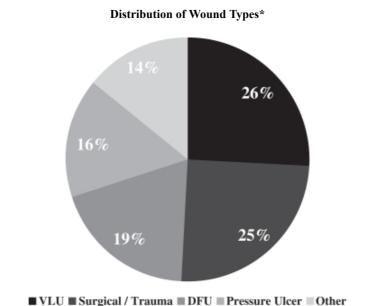
While the underlying etiology of these chronic wounds is different, at a cellular level many of the problems that result in failed healing are the same. These include uncontrolled inflammatory processes, shortages of cell types and growth factors secreted by cells that are critical to healing, and that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

#### Acute Wounds

An acute wound is an injury that causes a rapid break in the skin and sometimes the underlying tissue. Acute wounds can be traumatic wounds, such as abrasions, lacerations, penetrating injuries and burns, or surgical wounds from surgical incisions. In contrast to chronic wounds, which would normally heal but stall due to biologic factors, acute wounds are so severe that they overwhelm the body's normal healing capacity. Biofilm and other infectious conditions, particularly in acute wounds with a high risk of infection such as open fractures, may also pose challenges to the healing of acute wounds. According to BioMed GPS, in 2016 there were approximately 430,000 open traumatic wounds. In 2016, it is estimated that there were more than 500,000 burns that required medical treatment and approximately 40,000 burns required hospitalization.

# Relative Prevalence of Wounds

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



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

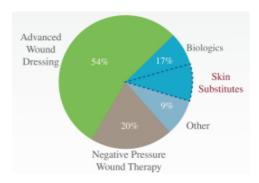
Due to the breadth of our wound care portfolio, our products are able to address both chronic and acute wounds across all of these wound types.

#### **Our Solution**

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

According to BIS Research, the global Advanced Wound Care market was estimated to be approximately \$8.9 billion in 2018 and is expected to grow at a compound annual growth rate, or CAGR, of 3.6% through 2024. This market consists of several product categories including advanced wound dressings, devices such as negative pressure wound therapy, or NPWT, and biologics such as skin substitute and growth factors. The approximate breakdown for these product categories in 2018 is set forth below.

#### **Advanced Wound Care Market**



Wound biologics represents one of the smallest segments of the Advanced Wound Care market, but is the fastest growing and has seen the highest level of innovation. According to BIS Research, the worldwide wound biologics market, which includes skin substitutes and growth factors, was estimated to be approximately \$1.5 billion in 2018, of which skin substitute products are estimated to represent approximately 64%. Skin substitutes, bioengineered or biologic grafts that cover skin defects and support healing, are one of the fastest growing categories of the Advanced Wound Care market. According to BioMed GPS SmartTrak, this market grew from almost \$725 million in 2016 to \$965 million in 2018 at an annual growth rate of 15%. Going forward, the skin substitute market is projected to continue to grow as patients with hard to heal wounds transition from other therapies to skin substitute treatment.

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

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

Finally, the skin substitute market remains substantially underpenetrated. According to BioMed GPS, over 8.3 million wounds require medical care in the United States each year, and over 3.3 million of those wounds are difficult to heal wounds where traditional therapies are unlikely to succeed. Despite this vast need and the proven advantages of advanced wound care products in general and skin substitutes in particular, only 135,000 patients, or less than five percent, are treated with skin substitutes each year. Our internal estimates indicate that if the potentially addressable market were completely penetrated today, annual skin substitute revenue in the United States alone could exceed \$9 billion.

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

# Surgical & Sports Medicine Market

The same demographic trends that are driving the growth of the wound care market are also driving growth in the Surgical & Sports Medicine market. This market has seen an increase in surgical volumes in part due to a higher incidence of comorbidities and chronic inflammatory and degenerative conditions, such as OA and tendonitis. This volume increase is fostering increased interest in regenerative medicine products, as they can help support healing and improve outcomes in older and more challenging patient populations.

While our products have applicability across a wide variety of surgical specialties, our immediate surgical focus in addition to wound care is in regenerative orthobiologics, 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 \$6.1 billion and is expected to grow at a CAGR of 8%. This market is growing rapidly due to an increase in spinal fusions, bone reconstruction surgeries and musculoskeletal injuries and degenerative conditions.

#### **Bone Fusion**

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

# Tendon and Ligament Injuries

Tendon and ligament injuries are common orthopedic conditions in an active and aging population. There are approximately 250,000 rotator cuff repairs performed in the United States annually. Additionally, in 2015, there were approximately 40,000 outpatient Achilles tendon repairs in the United States. Re-rupture and reoperation continue to be a significant source of concern with non-operative management, occurring in 4.8% of Achilles tendon repair cases and as many as 25% or more rotator cuff repair cases. Comorbidities such as diabetes and obesity, as well as age, are correlated with higher risk of failed healing and re-rupture. Regenerative tissue scaffolds may be used to support the healing of tendons, ligaments and other soft tissues. According to Technavio, the annual regenerative tissue scaffold market is estimated to exceed \$1 billion.

#### Chronic Inflammatory and Degenerative Conditions

Chronic inflammatory and degenerative orthopedic conditions are increasingly prevalent, driven in part by an aging demographic and higher levels of comorbidities such as diabetes and obesity. OA is the most common chronic condition of the joints, affecting approximately 27 million individuals in the United States. OA can affect multiple joints in the body, with arthritis of the knee being the most commonly treated. One in two adults will develop symptoms of knee OA during their lives. Other chronic inflammatory conditions such as Achilles and rotator cuff tendinosis and plantar fasciitis are also increasingly common. Similar to many of the other conditions that we seek to address, chronic inflammatory and degenerative orthopedic conditions are often correlated with smoking, obesity and diabetes, among other factors. Collectively, these and other related conditions were treated with an estimated 9 million injections in 2016, including steroids and hyaluronic acid, or HA. According to Technavio, the global chronic inflammatory and degenerative orthopedic market exceeded \$2.4 billion in 2018.

#### **Our Solution**

Conventional surgical approaches rely on mechanical fixation to temporarily approximate damaged tissues, assuming that the natural healing process will then result in a permanent repair. Patients with impaired healing may be unable to generate the necessary tissue structures, resulting in unacceptable failure rates over time.

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

OA and other degenerative conditions, as well as soft tissue injuries such as tendinosis and fasciitis, are currently treated by injection with steroids or HA. However, steroids offer pain relief for only a limited period and have been shown to further degrade some types of tissues over time, worsening the underlying condition. The evidence of HA's efficacy has been questioned, and it is clear that a significant percentage of patients do not respond to HA treatment. Patients who fail these less invasive therapies have limited options and may require surgical intervention, including total joint replacement.

Orthobiologics have been shown to be an effective alternative to traditional treatments. Due to their anti-inflammatory and pro-healing effects, they go beyond mechanical intervention to support the healing process in the damaged tissue and often result in faster healing times and shorter hospital stays. The orthobiologics market includes bone morphogenetic protein, viscosupplementation with HA, synthetic bone graft substitutes and stem cell therapy, in addition to DBM and allograft. The majority of our current and planned products in the Surgical & Sports Medicine space are based on amniotic technologies. There is a rapidly growing body of clinical and scientific evidence indicating the potential of these products in surgical applications, particularly in orthobiologics, resulting in increased adoption of these products. According to estimates from BioMed GPS, the amniotic orthobiologics market was \$88 million in 2016 and is projected to grow at a CAGR of more than 22% through 2021.

## **Our Products**

## **Advanced Wound Care**

In the Advanced Wound Care market, we focus on the development and commercialization of a broad portfolio of cellular and acellular wound care offerings that treat patients from the earliest indication of impaired healing to wound closure. Our suite of products helps treat a wide range of wounds, including, but not limited to, chronic wounds such as VLUs, DFUs, and pressure ulcers and acute wounds such as traumatic wounds and burns.

The breadth and depth of our portfolio allow physicians to tailor solutions to meet the needs of individual wound care patients. Wounds of all types normally progress through predictable phases of healing, starting with

inflammation, progressing to cell proliferation and finally remodeling to form normal skin. Wounds may stall during this process, typically in the inflammatory phase, for a variety of reasons. These reasons include biofilm or infection, uncontrolled inflammatory processes, shortages of cell types and growth factors secreted by cells that are critical to healing and disrupted cell signaling pathways.

It is increasingly recognized that addressing biofilm is an important step in healing any wound. Biofilm is generated by densely packed microbial communities that are attached to the wound surface and enclosed in a matrix of self-produced extracellular polymeric substance, or EPS. Biofilm is present in at least 78% of chronic wounds and can inhibit healing of all wound types. We engage with the physician at the earliest indication of impaired healing with our PuraPly AM product, which helps control biofilm 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.

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:

Regulatory

Product (Launch Year)	Description	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)

<sup>†</sup> Launched by NuTech Medical; acquired by Organogenesis in 2017.

Launched by Smith & Nephew; acquired by Organogenesis in 2014.

## Affinity

Affinity is a fresh, amniotic allograft for application in the care of chronic and acute wounds or surgical implantation in spine, orthopedic and sports medicine applications. We believe Affinity is one of only a few amniotic tissue products containing viable amniotic cells, and is unique in that it undergoes our proprietary AlloFresh process that hypothermically stores the product in its fresh state, never dried or frozen, which retains its native benefits and structure. Regulated as a human cells, tissues, and cellular and tissue-based product, or HCT/P, under Section 361 of the PHSA, these products are referred to as Section 361 HCT/Ps, or simply 361 HCT/Ps. Affinity'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. As part of our long-term plan to consolidate manufacturing operations in Massachusetts, we anticipate that manufacturing of Dermagraft will be suspended in the fourth quarter of 2021 and that sales of Dermagraft will be suspended in the first quarter of 2022. We currently plan to transition our Dermagraft manufacturing to our Massachusetts based manufacturing facilities following the expiration of the lease for our California based manufacturing facility, which we expect will result in substantial long-term cost savings. In the period when Dermagraft is not available, we expect our sales force will be able to drive substitution from Dermagraft to Apligraf and our amnion products and that the suspension of Dermagraft sales will not have a material impact on our net revenue.

# NuShield

NuShield is a dehydrated placental tissue 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 LayerLoc 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.

## 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	510(k)	Surgical treatment of open wounds

agent

Product (Launch Year) ReNu (2015)†\*





# Description 24

Cryopreserved suspension of amniotic fluid cells and morselized amnion tissue from the same donor

#### Regulatory Pathway 361 HCT/P

**Clinical Application** 

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.

#### 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. 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. These 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.

# **Ongoing Clinical Studies**

We believe gathering robust and comprehensive clinical and real-world outcomes data is an essential component of developing a competitive product portfolio and driving further penetration in the markets where we compete. We have six ongoing studies. We continue to invest in generating clinical data for our Advanced Wound Care and Surgical & Sports Medicine products, and believe such data enhance sales efforts with physicians and reimbursement dynamics with payers over time. The tables below summarize the status of our recent clinical studies for our Advanced Wound Care and Surgical & Sports Medicine products.

# **Advanced Wound Care**

Product	Wound Type	Design	Completion Date	Estimated Data Presentation Date H
	All Wounds	PuraPly AM RESPOND Registry Evaluating Real World Effectiveness of PPAM-Pooled Analysis (N=434 wounds)	Q2 2020 <sup>(4)</sup>	Q4 2020 SAWC <sup>11</sup> Fall Q1 2021 Publication
PuraPlyAM	Diabetic Foot Ulcers (DFU)	Comparative Effectiveness Analysis (CEA), NetHealth EMR Database of PPAM vs Theraskin (NI) (N=1032)	Q1 2020 <sup>(4)</sup>	Q2 2020 ISPOR <sup>(4)</sup> Q4 2020-Q1 2021 Publicatio
	Venous Leg Ulcers (VLU)	Comparative Effectiveness Analysis (CEA), NetHealth EMR Database of PPAM vs Grafix (NI) (N=856)	Q3 2019 <sup>(4)</sup>	Q3 2020-SAWC <sup>(1)</sup> Spring Q4 2020-Q1 2021 Publicatio
	Pressure Injuries (PRI)	Prospective Multi-center Randomized Controlled Trial (RCT) PPAM vs Standard of Care (SOC) (N=38)	Q4 2019 <sup>(1)</sup>	Q2 2021
	PRI	Comparative Effectiveness Analysis (CEA), NetHealth EMR Database of Apligraf vs Primatrix (N=1296)	Q4 2019 <sup>(1)</sup>	Q3 2020 SAWC <sup>(i)</sup> Spring Q4 2020-Q1 2021 Publicatio
Apligraf	PRI	Comparative Effectiveness Analysis (CEA), NetHealth EMR Database of Apligraf vs Epifix (N=1189)	Q1 2020 <sup>10</sup>	Q2 2020 ISPOR™ Q4 2020-Q1 2021 Publicatio
- Gray Gr	PRI	Comparative Effectiveness Analysis (CEA), NetHealth EMR Database of Apligraf vs Graffx (N=1330)	Q2 2020 <sup>(1)</sup>	Q4 2020 SAWC <sup>II</sup> Fall Q4 2020 Q1 2021 Publicatio
	V.U	Comparative Effectiveness Analysis (CEA), NetHealth EMR Database of Apligraf vs Primatrix (N=9552)	Q4 2019 <sup>(4)</sup>	Q3 2020 SAWC <sup>®</sup> Spring Q4 2020-Q1 2021 Publicatio
NuShield	DFU	Prospective Multicenter RCT, Nushield vs SOC (N=60)- Interim Analysis	Q2 2020 <sup>(c)</sup>	Q4 2020 DFCON <sup>3)</sup> and SAWC <sup>(3)</sup> Fall Q4 2020 Q1 2021 Publicatio
	DFUTT	Prospective Multicenter RCT, Nushield vs SOC (N=200)	Q3 2021	Q4 2021
Affinity	Arn	Clinical Study: Prospective Study of Changes in Wound Microenvironment (N=15)	Q8 2019 <sup>(1)</sup>	Q2 2021-Q8 2021
	A/Tito	Prospective, Multicenter RCT Affinity vs SOC (N=200)	Q4 2022	Q1 2023



#### Surgical & Sports Medicine

Product	Indication	Design	Completion Date <sup>(1)</sup>	Estimated Data Presentation Date <sup>(2)</sup>
	Knee OA	Investigation of ReNu Knee Injection: Response of Knee Function and Pain in patients with Osteoarthritis for 12 months (N=200)	Q3 2018	Q2 2020 TOBF <sup>20</sup> Q3 2021
Organogenesis	Knee OA	Rescue Arm-Investigation of ReNu Knee Injection: Response of Knee Function and Pain in patients with Osteoarthritis (N=200)	Q3 2018	Q3 2021
ReNu	Hip OA	Prospective Pilot Study Amniotic Suspension Allograft for Treatment of Woderate Hip OA: A Prospective Pilot Study (N=10)	Q3 2020	Q1 2021
	Knee OA	A Phase 3 Prospective, Multicenter, Double Blind, Randomized, Placebo-Controlled Study To Evaluate The Efficacy Of Anmiotic Suspension Allograft (ASA) in Patients With Osteoarthritis Of The Knee (N=474)	Q3 2023	Q4 2023
	Plantar Fasciitis	Comparative Study of Injectable human amniotic allograft (ReNu) versus corticosteroids for Plantar Fascilles: A Prospective, Randomized, Blinded Study (N=132)	Q1 2021	Q3 2021
Organogenesis	Lumbar Spine Vertebral Fusion	A Single-Arn Prospective, study of NuCe in patients undergoing fusion for one, two or three level degenerative disease of the lumbar spine (N=57)	Q2 2020	Q3 2021
NuCel	Lumbar Spine Vertebral Fusion	A Single-farm Prospective, multi-center study of Nucel in patients receiving interbody fusion for one- and two-level degenerative disease of the lumbar spine № 200)	Q4 2023	Q3 2024



#### **Recently Published Clinical Studies**

#### PuraPly AM

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

#### **Affinity**

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

# NuShield

In a published clinical study of clinical experience using NuShield for the management of 50 wounds (VLUs (n=14), DFUs (n=24) and other wounds (n=12)), 45 (90%) of the wounds had wound closure percentages between 60% to 100%. The median time to complete wound closure (or healing) for all wounds was 102 days

(14.6 weeks), and the percent healing rate of all wounds healed at 16 and 24 weeks was 56% and 73%, respectively. For DFUs treated with NuShield, the median time to healing was 120 days (17.1 weeks) and the percent healing rates at 16 and 24 weeks were 43% and 59%, respectively. For VLUs treated with NuShield, the median time to healing was 90 days (12.9 weeks), with percent healing rates of 56% and 85% at 16 and 24 weeks, respectively. For all other wounds treated with NuShield (including pressure ulcers, nonhealing surgical, ischemic, mixed etiology, and nonhealing amputation), the median time to healing was 48 days (6.9 weeks), with percent healing rates of 57% and 100% at 16 and 24 weeks, respectively.

# ReNu

In a randomized controlled single-blind study comparing the treatment of knee OA symptoms with ReNu (n=68), a commercially available hyaluronic acid, or HA (n=64), and saline (n=68), patients treated with ReNu reported less pain and a higher OMERACT-OARSI responder rate at 6 months follow-up than patients treated with HA or saline.



#### NuCel

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

#### **TransCyte**

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

#### Previously Published Clinical Studies for FDA-Approved Products

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

## Apligraf

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

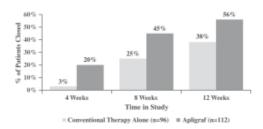
## Pivotal FDA Registration Trials

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

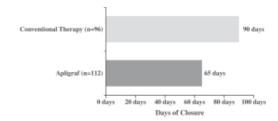
Apligraf was significantly more effective than conventional therapy for the incidence of complete wound closure over time. By 12 weeks of treatment, 56% (63 of 112 patients) of DFUs treated with Apligraf plus conventional therapy (debridement, saline dressings, total off-loading) were 100% closed, compared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

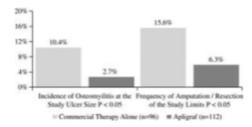
# **Incidence of 100% Wound Closure**



# Median Time to 100% Wound Closure

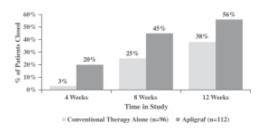


#### Reduction in Osteomyelitis and Amputation / Resection



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 matched conventional care counterparts (Apligraf was \$5,253 (p=0.49), lower per patient, while Dermagraft was \$6,991 (p=0.84) lower). These findings suggest that use of Apligraf and Dermagraft for treatment of DFU may lower overall medical costs through reduced utilization of costly healthcare services.

#### Mechanism of Action Clinical Study

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

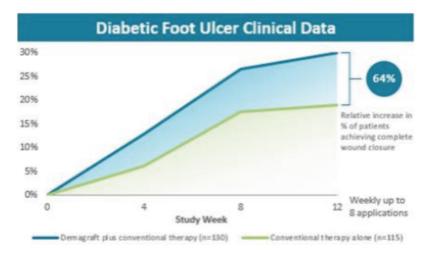
## Dermagraft

Dermagraft was approved as a Class III medical device for the treatment of DFUs based on the results of a large pivotal clinical trial. Three hundred fourteen patients were enrolled in a prospective RCT to evaluate the safety and efficacy of Dermagraft in conjunction with conventional therapy compared to a control arm of conventional therapy alone. Conventional therapy involved the sharp debridement and cleaning of the ulcer, application of a wet-to-dry gauze and the use of therapeutic, pressure-reducing footwear. Patients were eligible to be screened for the trial if they had a plantar DFU on the heel or forefoot that was greater than 1cm<sup>2</sup> and less than 20cm<sup>2</sup>. At the screening visit, the patients began receiving conventional therapy. If the DFU had not decreased in size by more than 50% during the next two weeks and the patient met all other inclusion and exclusion criteria, the patient was randomized into one of two treatment groups: Dermagraft plus conventional therapy or conventional therapy alone. Patients in the Dermagraft group received a weekly application of Dermagraft and conventional therapy for up to eight weeks. The primary endpoint for the trial was superiority in complete DFU closure by 12 weeks.

## Pivotal FDA Registration Trial

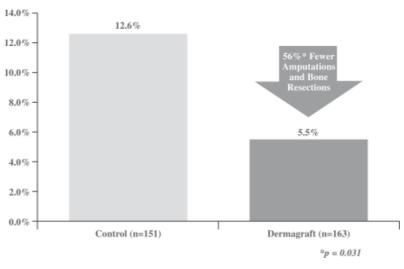
In the pivotal clinical trial, the weekly application of Dermagraft and conventional therapy for up to eight weeks increased the proportion of DFUs that achieved 100% closure at 12 weeks by 64%, when compared to the use of conventional therapy alone. Patients treated in the Dermagraft group were 1.7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

# Percent of Patients with Complete Healing by 12 Weeks



In a post-hoc analysis, it was determined that in patients treated with Dermagraft there was a significant reduction in incidence of amputations or bone resections, as compared to the control group (12.6% versus 5.5%, respectively, p=0.031). No adverse laboratory findings were associated with the use of Dermagraft and no adverse device effects were reported in the trial. In addition, no immunological responses or rejections from patients that received Dermagraft were reported in this trial or in patients treated to date. The amputation or bone resection data is presented in the figure below.

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



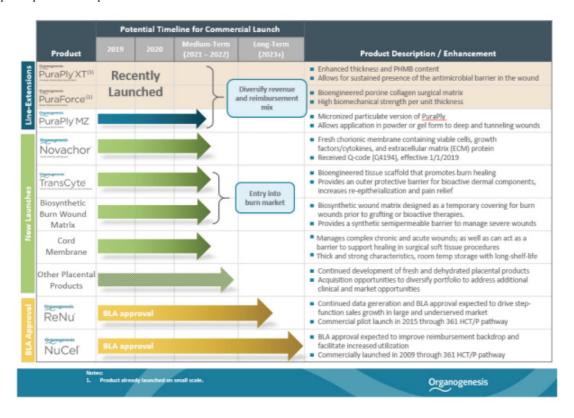
#### Comparative Effectiveness and Economic Studies

We have conducted one comparative effectiveness study with Dermagraft, which utilizes our proprietary access to data collected in the EMR database. This study, which was published in a peer-reviewed journal, compared Dermagraft outcomes to EpiFix (owned by MiMedx), and showed a 52% relative improvement in healing over EpiFix by week 24.

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

# **Product Pipeline**

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



### PuraPly XT

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

#### **PuraForce**

PuraForce is a bioengineered porcine collagen surgical matrix for use in soft tissue reinforcement applications that is intended for 510(k) indications for the reinforcement of all tendons in the body. PuraForce has high biomechanical strength per unit thickness, making it ideal for extremities applications. We commercially launched this product in 2019.

## PuraPly MZ

PuraPly MZ is a micronized particulate version of PuraPly that allows application in powder or gel form to deep and tunneling wounds. Like PuraPly, PuraPly MZ is intended for 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 2021.

#### 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 2021, following technology transfer of production to our contract manufacturers.

#### **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 2021-22. We also plan to launch in the same timeframe a derivative product, Biosynthetic Burn Wound Matrix, a Class II Medical Device for which we plan to seek 510(k) clearance.

#### Gintuit

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

## **Platform Technologies**

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

- **Bioengineered Cultured Cellular Products:** The development and production of bioengineered cultured cellular products have been a core competency of Organogenesis since its founding. Our Apligraf, Dermagraft, TransCyte and Gintuit products all draw from our expertise in this area.
- *Collagen Biomaterial Technology Platform:* Our porcine collagen biomaterial technology platform incorporates proprietary tissue cleaning processes and allows us to bioengineer products for specific applications by controlling thickness, strength and remodeling rates. We currently hold 510(k) clearances for a number of products in this platform with indications ranging from tendon

reinforcement to plastic surgery and general surgery applications. We commercially launched our PuraForce product from this platform in 2019.

• Amniotic and Placental Products: Our current amniotic products are based on significant expertise in the processing of placental tissues and fluids to yield products with desirable characteristics. We have expertise using the full array of available tissue types and multiple processing methodologies, including our proprietary AlloFresh and LayerLoc processing methods. Our proprietary AlloFresh process hypothermically stores our Affinity product in its fresh state, never dried or frozen, which retains its native benefits and structure. Our proprietary LayerLoc process technology preserves the native structure of the amnion and chorion membranes, optimized to provide excellent strength, flexibility, and handling.

#### **Commercial Infrastructure**

## Sales and Marketing

We have dedicated substantial resources to establish a multi-faceted sales capability in the United States. Our current Advanced Wound Care portfolio is sold throughout the United States via an experienced direct sales force, which focuses its efforts on outpatient wound care. We use a mix of direct sales representatives and independent agencies to service the Surgical & Sports Medicine market. As of September 30, 2020, we had approximately 295 direct sales representatives and approximately 170 independent agencies who have substantial medical device sales experience in our target end markets. These sales representatives are supported by teams of professionals focused on sales management, sales operations and effectiveness, ongoing training, analytics and marketing.

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

## **Customer Support Services**

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

# Research and Development

Our research and development team has extensive experience in developing regenerative medicine products, and works to design products that are intended to improve patient outcomes, simplify techniques, shorten procedures, reduce hospitalization and rehabilitation times and, as a result, reduce costs. We 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 control practices. We are registered with the FDA as a medical device manufacturing establishment and a HCT/P registered establishment. We are also accredited by the AATB and licensed with several states per their tissue banks regulations. All of our contract manufacturers are registered with the FDA as HCT/P establishments and are AATB accredited.

We utilize third-party raw material suppliers to support our internal manufacturing processes. We select all of our suppliers through a rigorous process to ensure high quality and reliability with the capacity to support our expanding production levels. Only raw material from approved suppliers is used in the manufacture of our products. To confirm quality and identify any risks, our approved suppliers are audited at pre-determined intervals. Historically, we have not experienced any significant difficulty locating and obtaining the suppliers or materials necessary to fulfill our production requirements. In the first quarter of 2019, however, we suspended production of our product Affinity due to production issues at one of our suppliers. As this was our sole supplier of Affinity, it resulted in a disruption of our production capabilities. We identified an alternate supplier and were able to resume commercial-scale production in the second quarter of 2020.

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

#### Reimbursement

## Overview

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

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 was 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 regained pass-through status effective on October 1, 2018 and Medicare made a pass-through payment when PuraPly AM and PuraPly was used in outpatient hospital and ASC settings. PuraPly AM and PuraPly retained pass-through status through September 30, 2020. The amount of the pass-through payment for PuraPly AM and PuraPly is equal to 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, was directed to remove all amounts attributable to PuraPly AM and PuraPly from the bundled payment amount, which did not 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.

Our wound care supply offerings receive Medicare, Medicaid, and non-government payer reimbursement. Medicare reimbursement is based upon CMS's Durable Medical Equipment, Prosthetics/Orthotics, and Supplies Fee Schedule. CMS sets the Medicare reimbursement rate for each of our wound care supplies annually, subject to quarterly adjustments.

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

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

#### 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 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.

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 continued through September 30, 2020. As a result, PuraPly AM and PuraPly were 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, remained in the bundled payment structure. The amount of the pass-through payment for PuraPly AM and PuraPly was equal to ASP + 6% for the applicable calendar quarter. Additionally, from October 1, 2018 through September 30, 2020 (the period in which PuraPly AM and PuraPly had pass-through status), CMS was directed to remove all amounts attributable to PuraPly AM and PuraPly from the bundled payment amount, but which, due to the claims data and rate-setting methodology, did not result in a decrease in the payment for skin substitute procedures that did 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.

Furthermore, Medicare has signaled that it may revise its two-tiered bundled payment policy for skin substitutes. Medicare solicited comments in calendar year 2019 related to proposed updates and policy changes under the Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System. Medicare specifically solicited comments on whether it should eliminate the two-tiered bundle policy and establish a single bundle for all products. Based on the statements made in the proposed rule, it is possible that Medicare will revise its payment policy in calendar year 2021 or calendar year 2022. Any revised policy could result in decreased reimbursement for our products which could decrease utilization and reduce our revenues. Moreover, any new policy could result in a financial incentive for hospitals and ASCs to use our competitor's products, thereby reducing our market share and revenue.

In the physician office setting, payment for skin substitutes is not bundled into the payment for the administration of the product. Skin substitutes are paid separately from the application procedure and the Medicare payment rate for all skin substitutes (including ours) is calculated based on the manufacturer's ASP on a per square centimeter basis with the total payment for the product being the per square centimeter ASP-based payment rate multiplied by the total number of centimeters. In the physician office setting the Medicare payment rates for all skin substitutes (including ours) are updated quarterly based on manufacturer reported ASP and are not geographically adjusted. The actual payment rate for skin substitutes is ASP plus 6%, which 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.

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 3M, ACell, Incorporated, Amniox Medical, Inc., Arthrex, Inc., Integra LifeSciences Holdings Corporation, Medtronic plc, MiMedx Group, Inc., Smith & Nephew plc, Misonix, Inc. and Stryker Corporation.

We also compete in the marketplace to recruit and retain qualified scientific, management and sales personnel, as well as to acquire technologies and technology licenses complementary to our products or advantageous to our business.

We are aware of several companies that compete, or are developing technologies, in our current and future product areas. As a result, we expect competition to remain intense. Our ability to compete successfully will depend on our ability to develop proprietary products that reach the market in a timely manner, receive adequate coverage and reimbursement, are cost effective and are safe and effective.

## **Intellectual Property**

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

As of September 30, 2020, we owned 28 issued patents globally, of which 12 were U.S. patents. As of September 30, 2020, we owned 10 pending patent applications, of which 6 were patent applications pending in the United States. Subject to payment of required maintenance fees, annuities and other charges, many of our issued patents are currently expected to expire between 2021 and 2036. The expiration of these patents is not expected to have a material impact on our business. In addition, many of our products, including our Apligraf, Dermagraft and NuShield products, are not covered by our issued patents or pending patent applications. Our issued patents are drawn to the following main areas: methods of making and using cultured tissue constructs, containers for shipping frozen products, bioreactor culture dish systems having an accessible sealing port, methods for preparing multi-layer stacks of living tissue, cultured three-dimensional tissues comprising a scaffold of a biocompatible non-living material, methods for treating recessed oral gingiva using cultured tissue constructs, methods of making and using osteogenic implants comprising a placental membrane sheet, wound treatment methods using amniotic stem cell solutions and placental membrane sheets, methods of generating cartilage in a skeletal joint using placental membrane preparations, hepatocyte growth factor- and hyaluronic acid-containing compositions and methods of using such compositions, methods making placental membrane preparations comprising hyaluronic acid, methods of harvesting or proliferating human prenatal stem cells, hypothermic morselized placental membrane storage methods, and adjustable debridement curette apparatuses. Our pending patent applications encompass additional areas, including wound treating methods using morselized amnion tissue and amniotic-derived cells, visco-supplement compositions and musculoskeletal inflammatory treatment methods using same, uses of human amniotic fluid for treating chronic wounds and joint diseases. Our pending patent applications may not result in issued patents and we can give no assurance that any patents that have issued or might issue in the future will protect our current or future products or provide us with any competitive advantage. See the section titled "Risk Factors—Risks Related to Our Intellectual Property" for additional information.

Additionally, we own or have rights to trademarks or trade names that are used in our business and in conjunction with the sale of our products, including 11 U.S. trademark registrations and 6 foreign trademark registrations, as of September 30, 2020.

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

#### **Government Regulation**

#### FDA Regulation of Product Registration, Manufacture and Promotion

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

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

With respect to the manufacture of medical devices and biologics, the FDA regulates and inspects equipment, facilities, laboratories and processes used in the manufacturing and testing of products prior to providing approval to market products. 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 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 make take enforcement action against the manufacturer or impose other sanctions or consequences, which may include:

- cease and desist orders;
- injunctions, or consent decrees;
- civil monetary penalties;
- recall, detention or seizure of our products;

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

In addition, we must comply with medical device reporting regulations and corrections and removal reporting regulations. Medical device reporting regulations require that manufacturers report to the FDA if their devices may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. Corrections and removal reporting regulations require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health. The FDA may also order a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death.

Certain human cells, tissues, and cellular and tissue-based products, or HCT/Ps, are regulated under Section 361 of the PHSA and are referred to as "Section 361 HCT/Ps" or simply "361 HCT/Ps," while other HCT/Ps are subject to the FDA's regulatory requirements for medical devices and/or biologics. A product that is regulated as a 361 HCT/P may be commercially distributed without prior FDA clearance or approval. Pursuant to 21 CFR 1271.10, in order to be regulated as a 361 HCT/P, and hence exempt from premarket review, an HCT/P must be minimally manipulated, intended for homologous use, and manufactured without being combined with another article (except for water, crystalloids, or sterilizing, preserving, or storage agents). The HCT/P must also either have no systemic effect and not be dependent upon the metabolic activity of living cells for its primary function or, if it has a systemic effect, be intended for autologous use, for allogeneic use in a first-degree or second-degree blood relative or for reproductive use. We believe that Affinity and NuShield generally fulfill the relevant criteria under 21 CFR 1271.10, 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. In addition, the Federal Trade Commission, or FTC, also regulates the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances and approvals, that there are adequate and reasonable scientific data to substantiate the claims, and that our promotional labeling and advertising is neither false nor misleading in any respect. The FDA and the FTC have very broad enforcement authority, and failure to abide by these regulations can result in product seizures, injunctions, civil or criminal penalties or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals.

## Government Advocacy

We engage in public policy advocacy with policymakers and continue to work to demonstrate that our therapeutic products provide value to patients and to those who pay for health care. We advocate with government policymakers to encourage a long-term approach to sustainable health care financing that ensures access to innovative medicines and does not disproportionately target FDA-regulated medical devices and biologics as a source of budget savings. In markets with historically low rates of health care spending, we encourage those governments to increase their investments and adopt market reforms in order to improve their citizens' access to appropriate health care.

## Regulations Governing Reimbursement/Fraud and Abuse

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

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

The Anti-Kickback Statute is particularly relevant because of its broad applicability. Specifically, the Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in exchange for, or to induce, either the referral of an individual, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under federal health care programs, such as the Medicare and Medicaid programs. Almost any financial interaction with a healthcare provider, patient or customer will implicate the Anti-Kickback Statute. Statutory exceptions and regulatory safe harbors protect certain interactions if specific requirements are met. However, only those interactions that represent fair market value exchanges generally are protected by a safe harbor or exception. The government can exercise enforcement discretion in taking action against unprotected activities. Many 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 ple 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.

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.

## **Corporate Overview**

Our predecessor company, AHPAC, was a blank check company incorporated on December 4, 2015 as a Cayman Islands exempted company formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses. On December 10, 2018, we consummated a merger among AHPAC, Avista Healthcare Merger Sub, Inc., a Delaware corporation and a direct wholly-owned subsidiary of AHPAC and Organogenesis Inc., a Delaware corporation. As a result of such merger, Avista Healthcare Merger Sub, Inc. merged with and into Organogenesis Inc., with Organogenesis Inc. surviving and becoming our wholly-owned subsidiary. In addition, AHPAC redomesticated as a Delaware corporation and changed its name to "Organogenesis Holdings Inc."

#### **Employees**

As of September 30, 2020, we had approximately 900 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.

#### **Facilities**

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

We also lease facilities in La Jolla, 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 25,000 square foot office in Birmingham supports the products we acquired as part of our acquisition of NuTech Medical. It was initially leased through December 31, 2020 and was subsequently extended to December 31, 2021 in the first quarter of 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 was February 1, 2020. The initial lease term is ten years from the rent commencement date, with an early option to extend the term for a period of five years if exercised within twenty-four months of the rent commencement date and an option to extend the term for a period of ten years (in addition to the five-year early extension period, if exercised).

# **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.

#### MANAGEMENT

#### **Executive Officers and Directors**

The following biographical descriptions set forth certain information with respect to our directors and our executive officers who are not directors as of November 3, 2020.

Name	Age	Position(s)
Gary S. Gillheeney, Sr.	65	Director, President and Chief Executive Officer
Henry Hagopian	53	Interim Chief Financial Officer
Patrick Bilbo	58	Chief Operating Officer
Lori Freedman	54	Vice President and General Counsel
Brian Grow	44	Chief Commercial Officer
Antonio S. Montecalvo	55	Vice President, Health Policy and Contracting
Alan A. Ades (1)	82	Director
Robert Ades	47	Director
David Erani	32	Director
Arthur S. Leibowitz(1)(2)	67	Director, Chair of Audit Committee
Wayne D. Mackie (1)(2)	71	Director, Chair of Compensation Committee
Glenn H. Nussdorf	66	Director
Joshua Tamaroff (2)	35	Director

<sup>(1)</sup> Member of the Compensation Committee.

# **Executive Officers**

Gary S. Gillheeney, Sr. has served as our President and Chief Executive Officer since 2014 and as a member of our board of directors since 2018. Previously, he served as our Executive Vice President, Chief Operating Officer and Chief Financial Officer from 2003 to 2014 and as our Chief Financial Officer from 2002 to 2003. Prior to joining Organogenesis, Mr. Gillheeney held executive positions at Innovative Clinical Solutions, Ltd., a provider of decision support and clinical knowledge solutions to healthcare staff, from 1999 to 2002, as its Chief Operating Officer, Chief Financial Officer, as well as Treasurer and Secretary. Prior to joining Innovative Clinical Solutions, Mr. Gillheeney held positions as Senior Vice President, Chief Financial Officer, Treasurer, and Assistant Secretary at Providence Energy Corporation. Mr. Gillheeney has a B.S. in Accounting from American International College and an M.B.A. from Bryant College. We believe that Mr. Gillheeney is qualified to serve on our board of directors due to his service as our President and Chief Executive Officer and his extensive knowledge of our company and industry.

Henry Hagopian has served as our Interim Chief Financial Officer since 2020. Mr. Hagopian previously served as our Assistant Vice President and Treasurer since January 2017 and prior to that served as our Corporate Controller from October 2007 through December 2016. Prior to joining Organogenesis, Mr. Hagopian served as Assistant Controller and Treasury Manager of CIRCOR International, Inc. from 2005 to 2007 and as Assistant Controller of Stratus Technologies from 2003 to 2005. Prior to joining Stratus, Mr. Hagopian held positions of increasing responsibility with Lucent Technologies finance organization, including the restructuring and spin-out from AT&T. Mr. Hagopian holds an M.B.A. in Management and an M.S. in Accounting from Boston College's Carroll Graduate School of Management and a B.S. in Economics and Finance from Farleigh Dickinson University.

<sup>(2)</sup> Member of the Audit Committee.

Patrick Bilbo has served as our Chief Operating Officer since 2017. Previously, he served as our Senior Vice President, Regulatory, Government Affairs and Administration and other executive positions from 1999 to 2017. Prior to joining Organogenesis, he was Director, Regulatory and Clinical Affairs, for Cytyc Corporation from 1994 to 1998. Mr. Bilbo earned an M.B.A. from the Boston University Questrom School of Business, an M.A. in Biology and an M.A. in Technology Strategy and Policy from the Boston University Graduate School of Arts & Sciences, and a B.S. degree in Biology from Syracuse University.

*Lori Freedman* has served as our Vice President and General Counsel since 2018 and as our General Counsel since 2017. Previously, she served as Vice President, Corporate Affairs, General Counsel and Secretary of pSivida Corp. (n/k/a EyePoint Pharmaceuticals), a specialty biopharmaceutical company, from 2001 to 2016 and as Vice President, General Counsel for Allaire Corporation, a computer software company, from 1998 to 2001. Mrs. Freedman holds a J.D. from the Boston University School of Law and a B.A. in economics and psychology from Brandeis University.

*Brian Grow* has served as our Chief Commercial Officer since 2017. Since 2004, he has served in a number of roles at Organogenesis with increasing responsibility, including as our Director of Sales, Commercial Operations, from 2013 to 2016, Associate Director, Marketing, from 2012 to 2013, Project Manager—Apligraf from 2011 to 2013, Regional Sales Manager from 2006 to 2011 and Tissue Regeneration Specialist from 2004 to 2006. Prior to joining Organogenesis, he was a pharmaceutical sales representative for Bristol-Myers Squibb from 2003 to 2004 and a tissue engineering specialist for Innovex/Novartis from 2000 to 2003. Mr. Grow earned a B.A. in Psychology from William Jewell College.

Antonio S. Montecalvo has served as our Vice President, Health Policy and Contracting since 2017. Since 2003, he has served in various roles at Organogenesis, including as Director of Customer Support Services from 2003 to 2006. Prior to joining Organogenesis, Mr. Montecalvo served as Director of Accounting for Innovative Clinical Solutions, LTD from 2000 to 2003, as Senior Contracts Specialist for UnitedHealth Group from 1996 to 2000 and as a Senior Accountant for Piccerelli, Gilstein & Company, LLP from 1994 to 1996. Mr. Montecalvo holds a B.S. in Accounting from the University of Rhode Island.

#### Directors

Below we have identified our directors (other than Mr. Gillheeney, our President and Chief Executive Officer, who is an executive officer identified above) and provided a description of their business experience.

Alan A. Ades has served as a member of our board of directors since 2003. Mr. Ades is a Co-founder and Principal Owner of A & E Stores, Inc., and has served as its President and Chief Executive Officer since 1966. Mr. Ades founded Rugby Realty Co., Inc. in 1980 and has served as its Principal since 1980. Mr. Ades has served as a director of A & E Stores, Inc. since 1967. Mr. Ades has a B.A. in Business Administration from the University of Michigan and an L.L.B. from New York University Law School. We believe Mr. Ades is qualified to serve on our board of directors due to his investment and financial experience as well as his expertise in business management. Mr. Ades is the father of Maurice Ades and the first cousin of Albert Erani, each a former director, and the father of Robert Ades.

**Robert Ades** has been a member of our board of directors since 2020. Mr. Ades has been a Principal of Rugby Realty Co., Inc. since 2005. Mr. Ades has over fifteen years of experience in commercial real estate. Mr. Ades received a B.A. in English Literature from the University of Michigan. We believe Mr. Ades is qualified to serve on our board of directors due to his business experience and the Ades family's long term significant ownership interest in the Company. Mr. Ades is the son of Alan A. Ades.

*David Erani* has served as a member of our board of directors since 2020. Mr. Erani has served as a Senior Consultant for UIC Inc. since 2015. Mr. Erani received a B.A. in Mathematics and a B.S. in Physics from Johns Hopkins University. We believe Mr. Erani is qualified to serve on our board of directors due to his business experience and the Erani family's long term significant ownership interest in the Company. Mr. Erani is the son of Albert Erani, a former director.

Glenn H. Nussdorf has served as a member of our board of directors since 2003. Mr. Nussdorf has served as Chief Executive Officer of Quality King Distributors, Inc., a distributor of health and beauty care products and prescription drugs, and its subsidiary QK Healthcare, Inc., since 1999. Previously, Mr. Nussdorf served as Chief Operating Officer of Quality King from 1997 to 1998 and as a Senior Vice President from 1994 to 1996. Mr. Nussdorf is also a major shareholder of Perfumania Holdings, Inc., a vertically integrated wholesale distributor and specialty retailer of perfumes and fragrances. Since 2017, Mr. Nussdorf has also served as a member of the board of directors of Perfumania Holdings, Inc. We believe Mr. Nussdorf is qualified to serve on our board of directors due to his investment and financial experience as well as his expertise in business management.

Arthur S. Leibowitz has been a member of our board of directors since 2018. Mr. Leibowitz is a clinical professor at the Robert B. Willumstad School of Business at Adelphi University, where he teaches courses in accounting and auditing to both graduate and undergraduate students. Mr. Leibowitz began as an adjunct professor at Adelphi University in 2008, became a full-time lecturer in 2010 and was promoted to clinical professor in 2013. Mr. Leibowitz previously served as a member of the board of directors and the audit committee of Arotech Corporation from 2009 to 2014. Before joining Adelphi University, Mr. Leibowitz was an audit and business assurance partner at PricewaterhouseCoopers. During his twenty-seven years at PwC, Mr. Leibowitz served in a national leadership role for PwC's retail industry group and was the portfolio audit partner for one of PwC's leading private equity firm clients. Mr. Leibowitz is a certified public accountant in New York State and received a B.S. in accounting from Brooklyn College and a Masters of Accountancy from Stetson University. We believe that Mr. Leibowitz is qualified to serve on our board of directors due to his experience working with public and private companies on corporate finance and accounting matters.

Wayne D. Mackie has been a member of our board of directors since 2018. Mr. Mackie served as a member of the board of directors, the nominating and corporate governance committee and as chairman of the audit committee of Exa Corporation from 2008 until November 2017. Until July 2015, Mr. Mackie served as the Vice President of CRA International, Inc., a publicly traded worldwide economic, financial, and management consulting services firm. Prior to assuming that position, Mr. Mackie served as Executive Vice President, Treasurer and Chief Financial Officer of CRA International, Inc., from 2005 to November 2014. Mr. Mackie was a member of the Board of Directors and Audit Committee of Novell, Inc. from 2003 until 2005. From 1972 through December 2002, Mr. Mackie was an employee of and, effective in 1983, a partner with Arthur Andersen LLP, where he specialized in software and high technology industry clients. Mr. Mackie is currently a Trustee and former member of the Board of Directors, Compensation Committee and Chairman of the Audit Committee for the Massachusetts Eye and Ear Infirmary. Mr. Mackie received a Master's degree from the Wharton School of the University of Pennsylvania and a Bachelor's degree from Babson College, and is a certified public accountant. We believe that Mr. Mackie is qualified to serve on our board of directors due to his experience working with public and private companies on corporate finance and accounting matters.

Joshua Tamaroff has been a member of our board of directors since 2018. Mr. Tamaroff joined Avista in 2009 and serves as a Principal. Prior to joining Avista, Mr. Tamaroff worked as an Analyst in the leveraged finance group at Lehman Brothers and Barclays Capital. Mr. Tamaroff currently serves as a director of Cosette Pharmaceuticals, Inc., GCM Holding Corporation and United BioSource Corporation, and previously served as a director of InvestorPlace Media, IWCO Direct, OptiNose, Inc. (NASDAQ: OPTN) and WideOpenWest, Inc. (NYSE: WOW). Mr. Tamaroff received a Bachelor of Science from Cornell University and a Master of Business Administration from the Wharton School at the University of Pennsylvania, where he was a Palmer Scholar. Mr. Tamaroff was selected to serve on our Board of Directors because of his private equity investment and company oversight experience and background with respect to acquisitions, debt financings and equity financings.

## **Board Composition**

Our board of directors currently consists of eight members. Organogenesis is a "controlled company" under the Nasdaq Stock Market ("Nasdaq") listing rules because Alan A. Ades, Albert Erani and Glenn H. Nussdorf, current and former members of our board of directors, together with Dennis Erani, Starr Wisdom and certain of their respective affiliates control over 50% of the voting power for the election of the Company's directors. As a controlled company, the Company is not required to have and does not have (i) a majority of independent directors on its board of directors, (ii) a nominating/corporate governance committee composed entirely of independent directors or (iii) a compensation committee composed entirely of independent directors. We intend to rely on these exemptions for the foreseeable future. Accordingly, you will not have the same protections afforded to stockholders of companies that are not controlled companies. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, our board of directors has determined that each of Mr. Leibowitz, Mr. Mackie and Mr. Tamaroff is an "independent director" as defined under Rule 5605(a)(2) of the Nasdaq Stock Market rules.

One of the key functions of our board of directors is informed oversight of our risk management process. The board of directors does not have a standing risk management committee and instead administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee will have the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee will also monitor compliance with legal and regulatory requirements.

#### **Audit Committee**

The Company has a standing audit committee consisting of Mr. Leibowitz, its chairperson, Mr. Mackie and Mr. Tamaroff. The audit committee is responsible for, among other matters: (i) reviewing and discussing with management and the independent auditor the annual audited financial statements, and recommending to the board whether the audited financial statements should be included in the Company's Form 10-K; (ii) discussing with management and the independent auditor significant financial reporting issues and judgments made in connection with the preparation of the Company's financial statements; (iii) discussing with management major risk assessment and risk management policies; (iv) monitoring the independence of the independent auditor; (v) verifying the rotation of the lead (or coordinating) audit partner having primary responsibility for the audit and the audit partner responsible for reviewing the audit as required by law; (vi) reviewing and approving related-party transactions (as required pursuant to the Company's related party transactions policy); (vii) inquiring and discussing with management the Company's compliance with applicable laws and regulations; (viii) pre-approving all audit services and permitted non-audit services to be performed by the Company's independent auditor, including the fees and terms of the services to be performed; (ix) appointing or replacing the independent auditor; (x) determining the compensation and oversight of the work of the independent auditor (including resolution of disagreements between management and the independent auditor regarding financial reporting) for the purpose of preparing or issuing an audit report or related work; and (xi) establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or reports which raise material issues regarding the Company's financial statements or accounting policies.

Our board of directors has determined that each member of the audit committee: (i) satisfies the Nasdaq independence standards and the independence standards of Rule 10A-3(b)(1) of the Exchange Act and (ii) meets the requirements for financial literacy under applicable rules and regulations of the SEC and Nasdaq. The board of directors has also determined that Mr. Leibowitz and Mr. Mackie each qualify as an "audit committee financial expert," as defined by applicable rules of Nasdaq and the SEC.

## **Compensation Committee**

The Company has a standing compensation committee consisting of Mr. Mackie, its chairperson, Mr. Alan Ades and Mr. Leibowitz. The compensation committee is responsible for recommending to the board of directors the compensation philosophy and policies of the Company in general and for its executive officers in particular. The objectives of the Company's senior management compensation program are to align compensation with business objectives, individual performance, and the interests of the Company's stockholders; motivate and reward high levels of performance; recognize and reward the achievement of Company goals; and enable the Company to attract, retain, and reward the highest quality executive talent. Among other things, the compensation committee: (i) reviews and recommends for approval by the board of directors, executive officer compensation, including salary, bonus, and short term and long term incentive compensation levels (including equity compensation) and the corporate goals and objectives relevant to executive officer compensation; (ii) oversees the evaluation of the chief executive officer and other executive officers of the Company; (iii) retains a recognized independent compensation consultant (that meets certain independence factors) to assess the competitiveness of the Company's compensation levels and practice applicable to the executive officers and directors of the Company; (iv) reviews and makes recommendations to the board of directors with respect to the Company's employee benefit plans, including all incentive-compensation plans and equity-based plans; (v) reviews and makes recommendations to the board of directors with respect to the compensation of non-employee directors, committee chairpersons, and committee members, consistent with any applicable requirements of the Nasdaq rules; (vi) reviews any stockholder proposals related to compensation matters and makes recommendations to the board of directors regarding those proposals; (vii) prepares and approves for inclusion in the Company's annual proxy statement and annual report on Form 10-K the report on executive compensation, if required by the rules of the Securities and Exchange Commission; (viii) to the extent that the Company is required to include a compensation discussion and analysis (CD&A) section in the Company's Annual Report on Form 10-K or annual proxy statement, reviews and discusses with the Company's management the CD&A, and based on such review and discussion, determines whether to recommend to the board of directors that the CD&A be so included; and (ix) reviews and discusses with management the Company's plans and practices to provide that our compensation programs, plans or practices do not encourage employees to take unnecessary risk that could threaten the Company.

## Code of Ethics and Conduct; Corporate Governance Guidelines

We have adopted a written code of ethics and conduct that applies to our directors, executive officers and employees, as well as corporate governance guidelines. Copies of the code of ethics and conduct and our corporate governance guidelines are posted on the Investor Relations (Investors > Corporate Governance > Documents & Charters) section of our website, which is located at <a href="https://www.organogenesis.com">www.organogenesis.com</a>. If we make any substantive amendments to the code of ethics and conduct or grant any waivers from the code of ethics and conduct for any executive officer or director, we will disclose the nature of such amendment or waiver on our website or on a Form 8-K.

#### **Delinquent Section 16(a) Reports**

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who beneficially own more than ten percent of a registered class of our equity securities, to file reports of ownership of, and transactions in, our securities with the Securities and Exchange Commission. These directors, executive officers and ten-percent stockholders are also required to furnish us with copies of all Section 16(a) forms they file.

Based solely on a review of the copies of such forms received by us, and on written representations from certain reporting persons, we believe that during fiscal year 2019 our directors, executive officers and ten-percent stockholders complied with all applicable Section 16(a) filing requirements, except that due to an administrative error a Form 4 with respect to the exercise of a stock option by Mr. Grow was not timely filed. In January 2020, due to an administrative error a Form 4 with respect to the exercise of a stock option by Mr. Montecalvo was not timely filed.

#### **Director Nominations**

Each year, the board of directors proposes a slate of director nominees to stockholders for election at the annual meeting of stockholders. Stockholders may also recommend candidates for election to the board of directors, as described below. The board of directors screens potential director candidates and considers criteria including experience, qualifications, attributes, skills, diversity and other characteristics in the context of the current make-up of the board of directors and the needs of the board of directors given the circumstances of the Company.

The board of directors values the input of stockholders in identifying director candidates. Accordingly, the board of directors considers recommendations for director candidates submitted by stockholders using substantially the same criteria it applies to recommendations from directors and members of management. Any such nominations should be submitted to the board of directors by mail in care of the Company's Corporate Secretary, at 85 Dan Road, Canton, Massachusetts 02021 and be accompanied by the information required by the Bylaws. The written recommendation should be submitted within the time frame described in the Bylaws.

## **Director Compensation**

Our board of directors has approved a compensation program under which our independent directors (currently Messrs. Leibowitz, Mackie and Tamaroff) are entitled to receive the following annual retainer and committee fees for their service as directors:

- for service as a director, an annual retainer of \$45,000 (increased to \$50,000 effective April 1, 2020);
- for service as a chair of the audit committee, \$105,000 (increased from \$95,000 effective January 1, 2019);
- for service as a member of the audit committee other than as chair, \$10,000; and
- for service as a chair of the compensation committee, \$95,000.

Retainer and committee fees are paid in arrears. Our independent directors received an option award with respect to 30,000 shares of our Class A common stock in connection with their initial election to our board of directors in December 2018, which vests annually over three years, subject to continuous service. Our independent directors are also entitled with respect to their service in 2019 to an option award with respect to 20,000 shares of our Class A common stock, vesting annually over three years, subject to continued service. All non-employee directors are reimbursed for customary business expenses incurred in connection with attending board and committee meetings.

The following table sets forth information regarding compensation awarded to, earned by or paid to our non-employee directors in connection with their service for the year ended December 31, 2019. We do not pay any compensation to our President and Chief Executive Officer in connection with his service on our board of directors. See "Executive Compensation" for a discussion of the compensation of Mr. Gillheeney.

	Fees ea	rned or paid in				
Name	С	ash (\$)(1)	Option awards (\$)(2)		Total (\$)	
Alan A. Ades	\$	_	\$	_	\$ —	
Maurice Ades(3)	\$	_	\$	_	\$ —	
Albert Erani <sup>(4)</sup>	\$	_	\$	_	\$ —	
Arthur S. Leibowitz	\$	150,000	\$	_	\$150,000	
Wayne D. Mackie	\$	150,000	\$	_	\$150,000	
Glenn H. Nussdorf	\$	_	\$	_	\$ —	
Joshua Tamaroff	\$	55,000	\$	_	\$ 55,000	

- (1) Represents amount earned or paid for service as a director during fiscal year 2019.
- (2) Each of Messrs. Leibowitz, Mackie and Tamaroff were awarded an option when first elected to the board of directors in December 2018. No option awards were made in the year ended December 31, 2019.
- (3) Maurice Ades resigned as a director effective November 3, 2020. The board of directors elected Robert Ades to fill the vacancy created by his resignation effective November 3, 2020.
- (4) Albert Erani resigned as a director effective November 3, 2020. The board of directors elected David Erani to fill the vacancy created by his resignation effective November 3, 2020.

The table below shows the aggregate number of option awards held as of December 31, 2019 by each of our current non-employee directors who was serving as of that date.

Name Alan A. Ades	Number of Shares Underlying Options Outstanding at December 31, 2019
Alan A. Ades	_
Maurice Ades(1)	_
Albert Erani(2)	_
Arthur S. Leibowitz	30,000
Wayne D. Mackie	30,000
Glenn H. Nussdorf	_
Joshua Tamaroff	30,000

- (1) Maurice Ades resigned as a director effective November 3, 2020. The board of directors elected Robert Ades to fill the vacancy created by his resignation effective November 3, 2020.
- (2) Albert Erani resigned as a director effective November 3, 2020. The board of directors elected David Erani to fill the vacancy created by his resignation effective November 3, 2020.

# 2020 Equity Awards

On April 22, 2020, our board of directors approved the stock option and restricted stock unit awards listed in the table below to our executive officers and independent directors. The stock options and restricted stock unit awards granted to our executive officers vest in four equal annual installments commencing April 1, 2020, and the stock options have an exercise price of \$4.04 per share. The restricted stock unit awards granted to our independent directors vest in full on April 1, 2021.

	Number of Shares Underlying April 22, 2020 Option	
Name	Awards	Restricted Stock Units
Gary S. Gillheeney, Sr.	580,842	88,181
Timothy M. Cunningham	183,424	27,847
Patrick Bilbo	224,185	34,035
Lori Freedman	177,310	26,918
Brian Grow	213,995	32,488
Antonio S. Montecalvo	158,967	24,134
Arthur S. Leibowitz	<del>-</del>	18,564
Wayne D. Mackie	<del>_</del>	18,564
Joshua Tamaroff	<del>-</del>	18,564

#### **EXECUTIVE COMPENSATION**

#### **Executive Summary**

The compensation of our executive officers is determined by our board of directors based upon the recommendation of our compensation committee. Our formal annual compensation review process generally takes place during the first half of each fiscal year, after the results of the previous fiscal year are known. Annual discretionary cash bonuses for the completed fiscal year, if any, and long-term equity-based incentive compensation awards, if any, are awarded by the board of directors on a discretionary basis based upon the recommendation of the compensation committee, generally during the first half of each fiscal year, after a review of the previous fiscal year's results.

As previously disclosed, we are a controlled company within the meaning of the rules of Nasdaq and are not required to have a compensation committee composed entirely of independent directors. In making their recommendations and determinations, our compensation committee and our board of directors take into account publicly available information concerning the compensation practices of other, similarly situated companies in the biotechnology, medical technology and biopharmaceutical industries. This information is used by the compensation committee and the board of directors informally and primarily for purposes of comparison to ascertain whether our compensation practices for our executive officers are broadly competitive. Our Chief Executive Officer makes recommendations with regard to the compensation of our executive officers, which are reviewed by the compensation committee and the board of directors. Executive officers (including Mr. Gillheeney) do not participate in the compensation committee's recommendation regarding and the board's determination of their own annual compensation.

In connection with its recommendations to the board of directors, the compensation committee periodically retains an independent compensation consultant to assess the competitiveness of the Company's compensation levels and practice applicable to the Company's executive officers. Nonetheless, the determinations made by the members of our compensation committee and board of directors are guided to a significant degree by their collective judgment and experience. During fiscal year 2019, the compensation committee engaged Pearl Meyer & Partners, LLC as an independent compensation consultant to advise on executive officer and board compensation.

Our compensation committee and board of directors has reviewed our compensation programs and believes that our compensation programs have not encouraged or rewarded excessive or inappropriate risk taking.

## **Summary Compensation Table**

The following table sets forth information regarding compensation earned by our President and Chief Executive Officer and our two next most highly paid executive officers who served during fiscal year 2019. We refer to these individuals as our named executive officers, or NEOs.

			Option		Non-Equity Incentive Plan	All Other	
Name	Year	Salary (\$)	Awards (\$)(1)	Bonus (\$)(2)	Compensation (\$)(3)	Compensation (\$)(4)	Total (\$)
Gary S. Gillheeney, Sr.	2019	819,371	_	537,068	_	81,013	1,437,452
President and Chief Executive Officer	2018	798,473	_	254,919	_	2,104,921	3,158,313
Brian Grow	2019	305,101	_	_	261,515	39,184	605,800
Chief Commercial Officer	2018	297,190	_	_	228,279	35,493	560,962
Lori Freedman	2019	360,506	_	110,638	_	37,564	508,708
Vice President and General Counsel	2018	346,484	98,293	131,285	_	18,484	594,546

<sup>(1)</sup> Represents the grant date fair value of option awards granted in fiscal year 2018 in accordance with Accounting Standards Codification Topic 718, "Compensation—Stock Compensation" ("ASC 718"). See

- Note 13 of the notes to the financial statements included elsewhere in this prospectus for a discussion of the relevant assumptions used in calculating these amounts.
- (2) The amounts reported in this column for fiscal 2018 and 2019 represent the discretionary bonuses earned by our NEOs.
- (3) "Non-Equity Incentive Plan Compensation" includes incentive bonuses paid to Mr. Grow based on the achievement of certain sales results in each of fiscal 2018 and 2019.
- (4) "All Other Compensation" for fiscal 2019 includes:
  - (i) for Mr. Gillheeney, (a) \$36,096 representing the costs related to a leased automobile, (b) a tax gross-up on the amount specified in (a) above of \$26,360, (c) \$6,336 representing the cost of group term life insurance, (d) \$1,835 representing the cost of long-term disability insurance premiums, (e) a tax gross-up on the amount specified in (d) above of \$1,986 and (f) \$8,400 representing employer matching contributions under our 401(k) plan;
  - (ii) for Mr. Grow, (a) \$20,603 representing the costs related to a leased automobile, (b) a tax gross-up on the amount specified in (a) above of \$10,762, (c) \$641 representing the cost of group term life insurance, (d) \$1,072 representing the cost of long-term disability insurance premiums, (e) a tax gross-up on the amount specified in (d) above of \$421 and (f) \$5,685 representing employer matching contributions under our 401(k) plan; and
  - (iii) for Ms. Freedman, (a) \$16,151 representing the costs related to a leased automobile, (b) a tax gross-up on the amount specified in (a) above of \$10,443, (c) \$1,781 representing the cost of group term life insurance, (d) \$1,275 representing the cost of long-term disability insurance premiums, (e) a tax gross-up on the amount specified in (d) above of \$299 and (f) \$7,615 representing employer matching contributions under our 401(k) plan.
  - "All Other Compensation" for fiscal 2018 includes:
  - (i) for Mr. Gillheeney, (a) \$29,635 representing the costs related to a leased automobile, (b) a tax gross-up on the amount specified in (a) above of \$23,216, (c) \$6,336 representing the cost of group term life insurance, (d) \$1,835 representing the cost of long-term disability insurance premiums, (e) a tax gross-up on the amount specified in (d) above of \$1,986, (f) \$8,250 representing employer matching contributions under our 401(k) plan, (g) forgiveness of a loan in the amount of \$1,129,976, inclusive of principal and accrued but unpaid interest immediately prior to the closing of the business combination on December 10, 2018 and (h) a tax gross-up on the amount specified in (g) above of \$903,687;
  - (ii) for Mr. Grow, (a) \$18,438 representing the costs related to a leased automobile, (b) a tax gross-up on the amount specified in (a) above of \$9,408, (c) \$629 representing the cost of group term life insurance, (d) \$1,052 representing the cost of long-term disability insurance premiums, (e) a tax gross-up on the amount specified in (d) above of \$441 and (f) \$5,526 representing employer matching contributions under our 401(k) plan; and
  - (iii) for Ms. Freedman, (a) \$4,614 representing the costs related to a leased automobile, (b) a tax gross-up on the amount specified in (a) above of \$4,568, (c) \$1,734 representing the cost of group term life insurance, (d) \$1,243 representing the cost of long-term disability insurance premiums, (e) a tax gross-up on the amount specified in (d) above of \$331 and (f) \$5,995 representing employer matching contributions under our 401(k) plan.

# **Narrative Disclosure to Summary Compensation Table**

## Employment Agreements, Severance and Change in Control Arrangements

We have entered into employment agreements or employment letter agreements with our named executive officers. The agreements generally provide for at-will employment and set forth the NEO's initial base salary, and eligibility for employee benefits. In addition, each of our NEOs is subject to confidentiality obligations and has agreed to assign to us any inventions developed during the term of their employment.

Agreement with Mr. Gillheeney

We entered into an employment agreement with Mr. Gillheeney, dated February 1, 2007. The agreement provides for "at-will" employment and sets forth certain agreed upon terms and conditions of employment. As of April 1, 2020, Mr. Gillheeney's annual base salary was increased from \$795,656 to \$800,000, and he is currently eligible to receive a target annual performance bonus of 80% of his base salary. In August 2018 our board of directors agreed that if Mr. Gillheeney is terminated involuntarily without cause or he resigns with good reason, these terms as defined in the employment agreement, he is entitled to the following (subject to his execution of a release in form and substance reasonably satisfactory to us): (i) his then current annual base salary payable in twelve (12) equal monthly installments, (ii) a continuation of benefit coverage for one (1) year and (iii) executive outplacement services with a mutually agreeable outplacement provider for up to one (1) year.

## Agreement with Mr. Grow

We entered into an employment letter agreement with Mr. Grow, dated May 9, 2017. The letter agreement provides for "at-will" employment and sets forth certain agreed upon terms and conditions of employment. As of April 1, 2020, Ms. Grow's annual base salary was increased from \$295,321 to \$370,000 and he is currently eligible to receive a target annual performance bonus of 45% of his base salary. For fiscal years 2018 and 2019, as noted above, Mr. Grow received a bonus based on the achievement of certain sales results. The target bonus that Mr. Grow is eligible to receive for 2020 replaces his prior bonus structure that was based on achieving certain sales results. Mr. Grow's employment letter agreement does not provide for any severance or change in control payments.

#### Agreement with Ms. Freedman

We entered into an employment letter agreement with Ms. Freedman, dated January 19, 2018. The letter agreement provides for "at-will" employment and sets forth certain agreed upon terms and conditions of employment. As of April 1, 2020, Ms. Freedman's annual base salary was increased from \$351,230 to \$370,000 and she is currently eligible to receive a target annual performance bonus of 40% of her base salary. Ms. Freedman's employment letter agreement does not provide for any severance or change in control payments.

#### **Outstanding Equity Awards at Year End**

The following table sets forth information regarding outstanding stock options held by our named executive officers as of December 31, 2019.

	Number of Securities Underlying Unexercised	Number of Securities Underlying Unexercised	Option	Option	
Name	Options (#) exercisable	Options (#) unexercisable	Exercise Price (\$)	Expiration  Date	Option Grant Date
Gary S. Gillheeney, Sr.	397,900	_	1.70	2/22/2020	2/22/2010
	704,410	_	0.99	7/24/2023	7/24/2013
	664,804	_	0.99	8/21/2024	8/21/2014
	1,637,631	_	0.99	12/8/2024	12/8/2014

<u>Name</u>	Number of Securities Underlying Unexercised Options (#) exercisable	Number of Securities Underlying Unexercised Options (#) unexercisable	Option Exercise Price (\$)	Option Expiration Date	Option Grant Date
Brian Grow	1,151		1.70	4/15/2020	4/15/2010
	958	_	1.44	10/17/2021	10/17/2011
	805	_	1.46	8/21/2022	8/21/2012
	805		4.49	7/17/2023	7/17/2013
	30,450	_	1.18	4/10/2024	4/10/2014
	958	_	1.24	1/12/2025	1/12/2015
	4,060	_	2.47	8/11/2025	8/11/2015
	61,320(1)	40,880	3.46	5/4/2027	5/4/2017
	12,180(2)	48,720	3.46	5/4/2027	5/4/2017
Lori Freedman	16,240(3)	24,360	5.40	2/21/2028	2/21/2018

<sup>(1)</sup> Twenty percent of the shares underlying this option vested on the vesting start date, December 31, 2017, and the option vested/vests with respect to an additional 20% of the shares on each anniversary of the vesting start date thereafter, such that the option will be vested in full on December 31, 2021, subject to continued employment.

Twenty percent of the shares underlying this option vested on the vesting start date, January 30, 2019, and the option vested/vests with respect to an additional 20% of the shares on each anniversary of the vesting start date thereafter, such that the option will be vested in full on January 30, 2023, subject to continued employment.

<sup>(3)</sup> Twenty percent of the shares underlying this option vested on the vesting start date, January 30, 2018, and the option vested/vests with respect to an additional 20% of the shares on each anniversary of the vesting start date thereafter, such that the option will be vested in full on January 30, 2022, subject to continued employment.

#### CERTAIN RELATIONSHIPS AND RELATED-PERSON TRANSACTIONS

## Agreements with Our Stockholders

## Leases with the Controlling Entities

The buildings we occupy in Canton, Massachusetts are owned by entities that are controlled by Alan Ades, Albert Erani, Dennis Erani and Glenn Nussdorf. These entities are: 65 Dan Road SPE, LLC; 65 Dan Road Associates; 85 Dan Road Associates; Dan Road Associates; and 275 Dan Road SPE, LLC. Mr. Ades, Mr. Albert Erani and Mr. Nussdorf are current and former members of our board of directors and greater than 5% stockholders. Mr. Ades and Mr. Albert Erani are first cousins. Together, Mr. Ades, Mr. Albert Erani, Mr. Dennis Erani and Mr. Nussdorf and certain of their respective affiliates, control a majority of the voting power of our outstanding Class A common stock. We refer to them as the Controlling Entities. Payment of the accrued, unpaid rent due under each of the leases with the Controlling Entities described below is subordinated to our obligations to Silicon Valley Bank pursuant to the terms of our March 2019 credit facility with Silicon Valley Bank.

On January 1, 2013, we entered into a capital lease with 65 Dan Road SPE, LLC related to the facility at 65 Dan Road, Canton, Massachusetts. Organogenesis made aggregate payments under the lease of \$538,982 and \$852,800 in 2018 and 2019, respectively. As of September 30, 2020, we had accrued, unpaid rent of \$1,046,060 due under the lease. Under the lease, we were required to make monthly rent payments of approximately \$62,000 through December 31, 2018. The monthly rent payments increased by 10% on January 1, 2019 to approximately \$69,000 per month and will increase by 10% on January 1, 2022 to approximately \$75,000 per month. In addition to the monthly rent payments, we are responsible for reimbursing the landlord for taxes and insurance on the property. The lease term expires on December 31, 2022.

On January 1, 2013, we entered into a capital lease with 85 Dan Road Associates related to the facility at 85 Dan Road, Canton, Massachusetts. We made aggregate payments under the lease of \$666,890 and \$1,072,400 in 2018 and 2019, respectively. As of September 30, 2020, we had accrued, unpaid rent of \$2,222,756 due under the lease. Under the lease, we were required to make monthly rent payments of \$77,000 through December 31, 2018. The monthly rent payments increased by 10% on January 1, 2019 to approximately \$85,000 per month and will increase by 10% on January 1, 2022 to approximately \$93,000 per month. In addition to the monthly rent payments, we are responsible for reimbursing the landlord for taxes and insurance on the property. The lease term expires on December 31, 2022.

On January 1, 2013, we entered into a capital lease with Dan Road Equity I, LLC related to the facility at 150 Dan Road, Canton, Massachusetts. We made aggregate payments under the lease of \$786,696 and \$1,316,450 in 2018 and 2019, respectively. As of September 30, 2020, we had accrued, unpaid rent of \$2,003,909 due under the lease. Under the lease, we were required to make monthly rent payments of approximately \$95,000 through December 31, 2018. The monthly rent payments increased by 10% on January 1, 2019 to approximately \$105,000 per month and will increase by 10% on January 1, 2022 to approximately \$115,000 per month. In addition to the monthly rent payments, we are responsible for reimbursing the landlord for taxes and insurance on the property. The lease term expires on December 31, 2022.

On January 1, 2013, we entered into capital lease arrangements with 275 Dan Road SPE, LLC for the property located on 275 Dan Road, Canton, Massachusetts. We made aggregate payments under the lease of \$463,100 and \$1,263,846 in 2018 and 2019, respectively. As of September 30, 2020, we had accrued, unpaid rent of \$5,062,788 due under the lease. Under the lease, we were required to make monthly rent payments of approximately \$92,000 through December 31, 2018. The monthly rent payments increased by 10% on January 1, 2019 to approximately \$101,000 per month and will increase by 10% on January 1, 2022 to approximately \$111,000 per month. In addition to the monthly rent payments, we are responsible for reimbursing the landlord for taxes and insurance on the property. The lease term expires on December 31, 2022.

On August 6, 2019, we entered into a Letter Agreement (the "Letter Agreement") with Dan Road Associates LLC, 85 Dan Road Associates LLC, 275 Dan Road SPE LLC and 65 Dan Road SPE LLC (collectively, the "Landlords") pursuant to which we agreed that each Landlord shall be entitled to receive interest on the accrued but unpaid rent obligations under the leases described above as of March 14, 2019, which totaled \$10,335,513.47 (the "Lease Debt") for the period commencing April 1, 2019. The interest on the Lease Debt accrues at a rate per annum equal to the greater of (A) the prime rate plus three and three-quarters of one percent (3.75%) and (B) nine and one-quarter of one percent (9.25%), which is the rate applicable to the term loans under that certain Credit Agreement dated as of March 14, 2019, as amended (the "Credit Agreement"), among us, the lenders from time to time party thereto, and Silicon Valley Bank, as administrative agent (the "Administrative Agent"). Pursuant to the terms of that certain Subordination Agreement, dated as of March 14, 2019 (the "Subordination Agreement"), among the Landlords and the Administrative Agent, the Landlords agreed to subordinate all of our obligations to the Landlords (including, without limitation, rent, interest, fees, charges, expenses, costs, professional fees and expenses, and reimbursement obligations) existing as of March 14, 2019, in each case in respect of the Lease Debt. Pursuant to the Subordination Agreement, we will not pay all or any part of the Lease Debt until the Senior Debt (as defined in the Subordination Agreement) has been fully paid. Accrued interest on the Lease Debt is payable in cash on the date when the Lease Debt is repaid (as to the principal amount so repaid) and shall not itself bear interest. As of September 30, 2020, accrued and unpaid interest under the Letter Agreement was equal to \$1,434,001.

#### Loans from the Controlling Entities

Prior to the closing of the business combination, Organogenesis Inc. had outstanding indebtedness payable to the Controlling Entities as described below under the headings "2010 Loans," "2015 Loans," "2016 Loans," "Real Estate Loans" and "2018 Loan Agreements" (collectively, the "Insider Debt"). As previously disclosed, pursuant to the terms of that certain Exchange Agreement, dated as of August 17, 2018, by and among the Company and the lenders listed on Schedule A thereto, concurrently with the closing of the business combination on December 10, 2018, \$45.7 million of the indebtedness described below was converted into 6,502,679 shares of our Class A common stock based on a conversion price of \$7.035 per share, and we made a cash payment equal to \$35.6 million in satisfaction of the remaining portion of the indebtedness, including the accrued and unpaid interest and any fees on this indebtedness. Following such transactions, the Insider Debt was deemed fully paid and satisfied in full and was discharged and terminated.

#### 2010 Loans

We entered into a Second Amended and Restated Term Loan Agreement, herein referred to as the Term Loan Agreement, an Amended and Restated Working Capital Loan Agreement, herein referred to as the Working Capital Loan Agreement and an Amended and Restated Subordinated Loan Agreement, referred to herein as the Subordinated Loan Agreement, each dated as of October 15, 2010 with Alan Ades, Albert Erani, Dennis Erani and Glenn Nussdorf in the case of the Term Loan Agreement; and with Organo PFG LLC, Organo Investors LLC, Glenn Nussdorf, Alan Ades, Albert Erani and Dennis Erani in the case of the Working Capital Agreement and the Subordinated Loan Agreement. Alan Ades and Albert Erani are managing members of Organo PFG LLC and managers of Organo Investors LLC. Alan Ades acts as Administrative Agent under the Term Loan Agreement. Organo PFG LLC acts as Administrative Agent under the Working Capital Loan Agreement and the Subordinated Loan Agreement. We refer to the Term Loan Agreement, the Working Capital Agreement and the Subordinated Loan Agreement collectively as the 2010 Loan Agreement.

Pursuant to the 2010 Loan Agreement, we had borrowed an aggregate principal of \$19,850,089, herein referred to as 2010 Loans. Interest on the 2010 Loans accrued at 1.6% per annum. The 2010 Loans were secured by substantially all of the personal property and assets of the Company pursuant to security agreements by and among it and the lenders each dated as of October 15, 2010.

A breakdown of the principal amounts that were owed to each lender under the 2010 Loans is set forth below:

Lender	Term Loan Agreement Principal Amount	Working Capital Loan Agreement	Subordinated Loan Agreement
Alan Ades	\$ 849,246	Principal Amount \$ 375,000	Principal Amount \$ 1,885,824
		\$ 373,000	
Albert Erani	\$ 583,857	_	\$ 406,496
Dennis Erani	\$ 265,389	\$ 375,000	\$ 1,639,328
Glenn Nussdorf	\$ 424,623	\$ 600,000	\$ 2,861,218
Organo PFG LLC	_	\$ 1,515,000	\$ 7,284,821
Organo Investors LLC		\$ 135,000	\$ 649,287
TOTAL	\$ 2,123,115	\$ 3,000,000	\$ 14,726,974

As noted above, the 2010 Loans (including all accrued and unpaid interest) were satisfied in full, including the payment of \$19.9 million in principal and \$4.3 million in interest, at the closing of the business combination.

#### 2015 Loans

We entered into a Loan and Security Agreement dated as of July 1, 2015 and amended as of November 20, 2015 with Alan Ades, Albert Erani, Dennis Erani, Glenn Nussdorf and Organo PFG LLC, referred to herein as the 2015 Loan Agreement, pursuant to which the Company borrowed an aggregate of \$11,396,258 evidenced by secured promissory notes referred to herein as the 2015 Loans, as follows:

Lender	Date of Loan	Principal Amount
Alan Ades	7/1/15	\$ 4,000,000
Dennis Erani	7/1/15	\$ 2,000,000
Glenn Nussdorf	7/1/15	\$ 4,000,000
65 Dan Road Associates	11/20/15	\$ 97,436
Organo PFG LLC	11/20/15	\$ 909,447
Albert Erani	12/23/15	\$ 97,344
Glenn Nussdorf	12/23/15	\$ 97,344
Alan Ades	12/31/15	\$ 194,687
TOTAL		\$ 11,396,258

The 2015 Loans accrued interest at a rate of 1.6% per annum, and were secured by substantially all of the personal property and assets of the Company. As disclosed above, the 2015 Loans (including all accrued and unpaid interest) were satisfied in full, including the payment of \$11.4 million in principal and \$0.6 million in interest, at the closing of the business combination.

# 2016 Loans

On April 12, 2016, Mr. Ades, Mr. Dennis Erani and Mr. Nussdorf entered into a Securities Purchase Agreement with us pursuant to which we issued \$17,000,000 in aggregate principal amount of subordinated notes, referred to herein as the 2016 Loans, and warrants to purchase an aggregate of 905,775 shares of our Class A common stock as set forth below:

Lender	Principal Amount of Notes	Shares Underlying Warrants
Alan Ades	\$ 6,000,000	319,685
Dennis Erani	\$ 4,000,000	213,124
Glenn Nussdorf	\$ 7,000,000	372,966
TOTAL	\$ 17,000,000	905,775

The 2016 Loans accrued interest at the rate of 15% per annum and were secured by substantially all of the personal property and assets of the Company. The warrants had an exercise price of \$3.59 per share and were net exercised prior to the closing of the business combination, resulting in the issuance of an aggregate of 444,041 shares of our Class A common stock. We were also obligated to pay a \$680,000 fee in connection with the 2016 Loans. The 2016 Loans (including all accrued and unpaid interest and fees) were satisfied in full, including the payment of \$17.0 million in principal and \$7.7 million in interest and fees, at the closing of the business combination.

## Real Estate Loans

On June 19, 2013, Organogenesis entered into a secured financing arrangement with 65 Dan Road SPE, LLC, 85 Dan Road Associates and 275 Dan Road SPE, LLC under which loans were made to the Company, referred to herein as the Real Estate Loans. The Real Estate Loans accrued interest at a rate of 1.6% per annum, and were secured by substantially all of the personal property and assets of the Company. A breakdown of the principal amounts that were owed to each lender under the Real Estate Loans is set forth below:

Lender	Principal Amount
Lender 65 Dan Road SPE, LLC	\$ 200,000
85 Dan Road Associates	\$ 3,900,000
275 Dan Road SPE, LLC	\$ 400,000
TOTAL	\$ 4,500,000

The Real Estate Loans (including all accrued and unpaid interest) were satisfied in full, including the payment of \$4.5 million in principal and \$0.4 million in interest, at the closing of the business combination.

#### 2018 Loan Agreements

On March 1, 2018, we entered into a loan agreement with Alan Ades, Albert Erani and Glenn Nussdorf, each of whom is a current or former member of our board of directors and a greater than 5% stockholder, pursuant to which Mr. Ades, Mr. Erani and Mr. Nussdorf collectively agreed to lend us, upon our request, an advance of up to the lesser of: (i) \$10,000,000 and (ii) the amount that represented 60 days of our payroll obligations, during the period beginning on March 1, 2018 and ending on the earlier of May 15, 2018 and the closing of an underwritten initial public offering (the "March Loan Agreement"). Advances were evidenced by promissory notes that accrued interest at a rate of 8% per annum and were payable upon demand. Mr. Ades and Mr. Erani each agreed to provide 40% of any amounts advanced and Mr. Nussdorf agreed to provide 20% of any amounts advanced. Advances totaling \$10,000,000 were made under the loan agreement.

On May 23, 2018, we entered into a loan agreement with Alan Ades, Albert Erani and Glenn Nussdorf, each of whom is a current or former member of our board of directors and a greater than 5% stockholder, pursuant to which Mr. Ades, Mr. Erani and Mr. Nussdorf collectively agreed to lend us an aggregate of \$10,000,000 (the "May Loan Agreement"). Advances were evidenced by promissory notes that accrued interest at a rate of 8% per annum, and were payable upon demand. Mr. Ades and Mr. Erani each agreed to provide 40% of any amounts advanced and Mr. Nussdorf agreed to provide 20% of any amounts advanced. Advances totaling \$5,000,000 were made under the May Loan Agreement.

The loans made under the March Loan Agreement and the May Loan Agreement (including all accrued and unpaid interest) were satisfied in full, including the payment of \$15.0 million in principal and \$0.7 million in interest, at the closing of the business combination.

#### Unconditional Guaranty

On April 5 2018, Mr. Ades, Mr. Albert Erani and Mr. Nussdorf entered into an Unconditional Guaranty with Silicon Valley Bank, or SVB, herein referred to as the Unconditional Guaranty, in connection with the funding of the \$5.0 million term loan under our prior SVB credit agreement. Pursuant to the Unconditional Guaranty, each of Messrs. Ades, Albert Erani and Nussdorf jointly and severally guaranteed the payment of Organogenesis' obligations with respect to the \$5.0 million term loan under the prior SVB credit agreement, plus all accrued and unpaid interest on such indebtedness and certain expenses related thereto payable to SVB pursuant to the prior SVB credit agreement. The Unconditional Guaranty terminated on December 31, 2018.

#### Loans to Related Persons

From 2010 through 2012, we lent money to Gary S. Gillheeney, Sr., our current President and Chief Executive Officer, who at the time of the loans was our Chief Operating Officer and Chief Financial Officer. The loans to Mr. Gillheeney totaled \$1,507,490 in principal amount, were interest bearing, matured on the tenth anniversary of their respective dates of issuance and were secured by a pledge to us of Mr. Gillheeney's equity interests in the Company. On August 21, 2014, Mr. Gillheeney transferred shares of common stock owned by him to the Company in full and complete satisfaction of \$654,979 in principal and accrued interest on the loans. After the August 2014 transaction, Mr. Gillheeney's aggregate loans outstanding totaled \$996,525. These outstanding loans accrued interest at rates ranging from 2.30% to 3.86% per annum and were secured by a pledge of Mr. Gillheeney's equity interests in the Company. Immediately prior to the closing of the business combination on December 10, 2018, we forgave all outstanding principal under and accrued and unpaid interest on Mr. Gillheeney's loans and made a tax gross-up payment to him in connection with the forgiveness of such amounts. The aggregate amount of the loan forgiveness and the tax gross-up payment was \$2,033,663.

#### Kenneth L. Horton and NuTech Medical

On March 24, 2017, Organogenesis Inc. purchased NuTech Medical from Kenneth L. Horton, its sole shareholder, for approximately \$19.5 million in cash, which consisted of \$12.0 million paid at closing and approximately \$7.5 million in deferred acquisition consideration, and issued him shares of Organogenesis Inc.'s common stock, which represented more than 5% of its outstanding common stock at such time. On March 24, 2019, Mr. Horton exercised a put right he was granted in connection with the acquisition of NuTech Medical and we redeemed 728,548 shares of Class A common stock at a purchase price of \$9.28 per share.

As of December 31, 2019, \$5.0 million of deferred acquisition consideration remained payable and was accruing interest at a rate of 6% per annum. The amount of the deferred acquisition consideration plus accrued interest owed to the sellers of NuTech Medical was previously in dispute. We asserted certain claims for indemnification that would offset in whole or in part our payment obligation and the sellers of NuTech Medical filed a lawsuit alleging breach of contract and seeking specific performance of the alleged payment obligation and attorneys' fees. In February 2020, we entered into a settlement agreement with the sellers of NuTech Medical and settled the dispute for \$4.0 million.

## Amended and Restated Registration Rights Agreement

In connection with the closing of the business combination on December 10, 2018, we and certain of our stockholders (including the Controlling Entities, Avista Capital Partners IV, L.P. and Avista Capital Partners (Offshore) IV, L.P.), certain of our current and former directors (Alan Ades, Albert Erani and Glenn Nussdorf) and all of our executive officers entered into the Amended and Restated Registration Rights Agreement in respect of their shares of our Class A common stock and warrants to purchase shares of our Class A common stock. These stockholders and their permitted transferees will be entitled to certain registration rights described in the Amended and Restated Registration Rights Agreement, including, among other things, customary registration rights, including demand and piggy-back rights, subject to cut-back provisions. We will bear the expenses

incurred in connection with the filing of any such registration statements, other than certain underwriting discounts, selling commissions and expenses related to the sale of shares.

## **Executive Officer Compensation**

See "Executive Compensation" for additional information regarding compensation of our NEOs.

Gary Gillheeney, Jr., our Senior Manager, Customer Service, is a child of Gary S. Gillheeney, Sr., our President and Chief Executive Officer, and he received total compensation of (i) \$94,512 in fiscal 2017, (ii) \$121,268 in fiscal 2018, (iii) \$122,049 in fiscal 2019 and (iv) \$101,711 from January 1, 2020 to September 30, 2020. James Gillheeney, one of our Tissue Regeneration Specialists, is also a child of Gary S. Gillheeney, Sr. and he received total compensation of (i) \$118,014 in fiscal 2017, (ii) \$164,346 in fiscal 2018, (iii) \$225,976 in fiscal 2019 and (iv) \$139,192 from January 1, 2020 to September 30, 2020.

## **Employment Agreements**

We have entered into employment agreements with certain of our NEOs. For more information regarding these agreements, see "Executive Compensation."

## Indemnification Agreements and Directors' and Officers' Liability Insurance

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us to indemnify each director and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, penalties fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer.

## Avista Warrant Exchange Agreement

On July 12, 2019, we entered into a Warrant Exchange Agreement (the "Warrant Exchange Agreement") with Avista Capital Partners IV L.P., a Delaware limited partnership and Avista Capital Partners IV (Offshore), L.P., a limited partnership formed under the laws of Bermuda (collectively, the "PIPE Investors") pursuant to which, the PIPE Investors agreed to exchange an aggregate of 4,100,000 warrants to purchase one-half of one share of our Class A common stock at an exercise price of \$5.75 per half share (the "PIPE Warrants") for shares of our Class A common stock at an exchange ratio equal to the exchange ratio of the Company's exchange offer (the "Exchange Offer") to all holders of the Company's issued and outstanding warrants that were issued in connection with the Company's initial public offering pursuant to a prospectus dated October 10, 2016, exercisable for Class A common stock at an exercise price of \$5.75 per half share of Common Stock (the "Public Warrants") in effect at the expiration of such Exchange Offer, which exchange ratio was 0.095 shares of Class A common stock for each public warrant. On August 21, 2019, the Company issued an aggregate of 389,501 shares of Class A common stock to the PIPE Investors in exchange for an aggregate of 4,100,000 PIPE Warrants.

## Avista Fee Letter Agreement

On November 19, 2019, we entered into a fee letter agreement (the "Letter Agreement") with Avista Capital Partners IV, L.P. ("Avista IV"), Avista Capital Partners (Offshore) IV, L.P. ("Avista IV Offshore" and together with Avista IV, the "Avista Funds") and Avista Capital Holdings, L.P., an affiliate of the Avista Funds (the "Management Company"), pursuant to which we agreed to pay the Management Company a fee in consideration for certain services rendered in connection with investments in the Company made by the Avista Funds in the Company's public offering of Class A common stock that closed on November 26, 2019. Pursuant to the Letter Agreement, the Company was required to pay the Management Company a fee in an amount equal to the portion

of the aggregate gross proceeds of the investments sold to the Avista Funds multiplied by a rate equal to the rate of the Underwriters' discount or spread in such public offering without giving effect to any investments sold to the Avista Funds (the "Fee"). In connection with the public offering, the Avista Funds purchased 6,000,000 shares of Class A common stock and we paid a Fee equal to approximately \$1.7 million. Joshua Tamaroff, one of our directors, is an employee of the Management Company to which the Company paid the Fee.

## **AHPAC's Related Party Transactions**

## Related Party Loans

AHPAC issued to Avista Acquisition Corp. (the "Sponsor") on August 11, 2017, as amended and restated on August 30, 2018 and further amended on November 8, 2018, a non-interest bearing, unsecured promissory note pursuant to which AHPAC was permitted to borrow up to \$850,000 in aggregate principal amount. As of the closing of the business combination on December 10, 2018, AHPAC had borrowed \$850,000 under such note, which amount was repaid at the closing of the business combination.

## Administrative Services Agreement

AHPAC previously occupied office space provided by an affiliate of the Sponsor. Until the closing of the business combination on December 10, 2018, the affiliate made such office space, as well as certain support services, available to AHPAC. AHPAC was required to pay the affiliate an aggregate of \$10,000 per month for such office space and support services. As of April 30, 2017, the affiliate agreed to defer payment of the monthly administrative fee under the Administrative Services Agreement until the closing of the business combination. As of the closing of the business combination on December 10, 2018, \$193,226 was accrued and included in accrued expenses related to the Administrative Services Agreement and was paid in full at the closing of the business combination.

#### **Private Placement Warrants**

The initial shareholders of AHPAC purchased 16,000,000 private placement warrants at \$0.50 per warrant (for an aggregate purchase price of \$8,000,000) in a private placement in connection with the consummation of the initial public offering of AHPAC on October 14, 2016. A portion of the proceeds from the sale of the private placement warrants were placed into AHPAC's trust account. The initial shareholders also purchased an additional 400,000 private placement warrants at \$0.50 per warrant (for an aggregate purchase price of \$200,000) simultaneously with the underwriters' exercise of the over-allotment option granted to the underwriters in connection with the AHPAC initial public offering. Each private placement warrant was exercisable for one-half of one AHPAC Class A ordinary share. In connection with the closing of the business combination and the transactions contemplated thereby on December 10, 2018, all 16,400,000 of the private placement warrants were surrendered to the Company for no consideration and were cancelled

## Founder Shares

In connection with the organization of AHPAC, on December 14, 2015, an aggregate of 8,625,000 AHPAC Class B ordinary shares (the "founder shares") were sold to the Sponsor at a price of approximately \$0.003 per share, for an aggregate price of \$25,000. In October 2016, the Sponsor transferred 50,000 founder shares to each of AHPAC's independent directors at a price per share of approximately \$0.003 per share. In addition, at such time, each of AHPAC's independent directors purchased an additional 421,250 founder shares from the Sponsor at a price per share of approximately \$0.003 per share. The 8,625,000 founder shares included an aggregate of up to 1,125,000 shares that were subject to forfeiture if the over-allotment option was not exercised in full by the underwriters of the AHPAC initial public offering in order to maintain the initial shareholders' ownership at 20% of the issued and outstanding ordinary shares upon completion of the AHPAC initial public offering. Following the partial exercise of the over-allotment option, 875,000 founder shares were forfeited in order to maintain the

initial shareholders' ownership at 20% of the issued and outstanding AHPAC ordinary shares. On August 17, 2018 the Sponsor and the other holders of founder shares agreed to surrender to the Company for no consideration an aggregate of 1,937,500 founder shares in connection with the execution of the merger agreement, which founder shares were cancelled. In connection with the closing of the business combination and the transactions contemplated thereby on December 10, 2018, an additional 4,421,507 of the founder shares were surrendered to the Company and cancelled. The remaining 1,390,993 outstanding founder shares became shares of the Company's Class A common stock upon the closing of the business combination.

Concurrently with the signing of the merger agreement, AHPAC entered into a subscription agreement with Avista Capital Partners IV, L.P. and Avista Capital Partners IV (Offshore), L.P. (together, the "PIPE Investors") for the purchase and sale of 9,022,741 shares of the Company's Class A common stock and 4,100,000 warrants to purchase one half of one share of our Class A common stock (the "equity financing") for an aggregate purchase price of \$46 million, which was consummated concurrently with the consummation of the business combination on December 10, 2018. The effective price to the PIPE Investors of the equity financing was approximately \$5.10 per share of the Company's Class A common stock. The PIPE Investors also purchased, concurrently with the execution and delivery of the merger agreement on August 17, 2018, 6,538,732 shares of our Class A common stock for an aggregate purchase price of \$46 million. The purpose of the private investment was to fund the business combination and related transactions and for general corporate purposes. The effective price of the private investment to the PIPE Investors was approximately \$5.91 per share of the Company's Class A common stock across their aggregate \$92 million investment. As a result of the incremental surrender of founder shares described above, the effective price of the equity financing to the Company was approximately \$7.035 per share of the Company's Class A common stock. The warrants surrendered did not impact these calculations, as no purchase price was allocated to the warrants in light of the exercise price of the warrants.

#### **Policies and Procedures for Related Party Transactions**

Our board of directors has adopted a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act and the policy, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds \$120,000 and a related person (including our executive officers, directors and 5% stockholders, as well as specified members of the family or household of any of these individuals or stockholders) had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our Audit Committee (composed of Mr. Leibowitz, Mr. Mackie and Mr. Tamaroff, our independent directors), but only those independent directors who are disinterested, is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction with an unrelated third party and the extent of the related person's interest in the transaction. All of the transactions described in this section that occurred prior to the closing of the business combination on December 10, 2018 occurred prior to the adoption of this policy.

#### PRINCIPAL STOCKHOLDERS

The following table sets forth certain information with respect to beneficial ownership of our Class A common stock, as of October 1, 2020, by:

- each person or entity, or group of affiliated persons or entities, known by us to beneficially own more than 5% of our Class A common stock;
- each of our directors;
- each of our named executive officers; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of October 1, 2020 are deemed outstanding, but are not deemed outstanding for computing the percentage ownership of any other person. To our knowledge, except as set forth in the footnotes to this table and subject to applicable community property laws, each person named in the table has sole voting and investment power with respect to the shares set forth opposite such person's name.

Each stockholder's percentage ownership is determined in accordance with Rule 13d-3 under the Exchange Act and is based on 107,457,154 shares of our Class A common stock outstanding as of October 1, 2020. The number of outstanding shares beneficially owned by each stockholder below was obtained from the most recent publicly filed information, as applicable.

	Number	Right to		Percentage of Shares
Name and Address of Beneficial Owner (1)	of Shares	Acquire	Total	Outstanding
Organo PFG LLC and affiliated entities (2)	34,986,622	_	34,986,622	32.6%
Avista Capital Partners IV, L.P. and affiliated entities (3)	25,517,514	_	25,517,514	23.7%
Michael W. Katz (4)	1,180,853	20,000	1,200,853	1.1%
Controlling Entities (5)	67,961,823	_	67,961,823	63.2%
Gary S. Gillheeney, Sr. (6)	397,900	3,006,845	3,404,745	3.1%
Alan A. Ades (7)	44,476,394	_	44,476,394	41.4%
Robert Ades	_	_	_	_
David Erani	_	_	_	_
Arthur S. Leibowitz (8)	5,000	10,000	15,000	*
Wayne D. Mackie (9)	100,000	10,000	110,000	*
Glenn H. Nussdorf (10)	14,938,663	_	14,938,663	13.9%
Joshua Tamaroff (11)	_	10,000	10,000	*
Lori Freedman (12)	_	24,360	24,360	*
Brian Grow (13)	3,279	123,716	125,845	*
All directors and executive officers as a group (13 individuals) (14)	60,083,341	3,619,359	63,702,700	57.4%

<sup>\*</sup> Less than one percent.

<sup>(1)</sup> Unless otherwise indicated, the business address of each of the individuals is c/o Organogenesis Holdings Inc., 85 Dan Road, Canton, Massachusetts 02021.

<sup>(2)</sup> Consists of (i) 32,134,638 shares of Class A common stock held by Organo PFG LLC and (ii) 2,851,984 shares of Class A common stock held by Organo Investors LLC. Alan A. Ades and Albert Erani are managing members of Organo PFG LLC and managers of Organo Investors LLC and they share voting and investment power over the shares of Class A common stock held by each entity. Each of Mr. Ades and Mr. Erani disclaim beneficial ownership of the shares of Class A common stock held by each of Organo

- PFG LLC and Organo Investors LLC, except to the extent of his pecuniary interest therein. The address of each of the foregoing is c/o A&E Stores, Inc., 1000 Huyler Street, Teterboro, NJ 07608.
- (3) Consists of: (i) 12,267,300 shares of Class A common stock held by Avista Capital Partners IV, L.P., (ii) 12,201,523 shares of Class A common stock held by Avista Capital Partners IV (Offshore), L.P. and (iii) 1,048,691 shares of Class A common stock held by Avista Acquisition Corp. ("Sponsor"). Avista Capital Managing Member IV, LLC exercises voting and dispositive power over the shares held by Avista Capital Partners IV, L.P. and Avista Capital Partners IV (Offshore), L.P. Voting and disposition decisions at Avista Capital Managing Member IV, LLC are made by an investment committee, the members of which are Thompson Dean, David Burgstahler, Robert Girardi and Sriram Venkataraman. None of the foregoing persons has the power individually to vote or dispose of any shares; however, Messrs. Dean and Burgstahler have veto rights over the voting and disposition of any shares. Messrs. Dean and Burgstahler are managers of Avista Acquisition, LLC, the sole shareholder of the Sponsor, and may therefore be deemed to beneficially own the securities held by the Sponsor. Messrs. Dean and Burgstahler disclaim beneficial ownership of the securities held by the Sponsor except to the extent of their pecuniary interest therein. Mr. Dean and Mr. Burgstahler each disclaims beneficial ownership of all such shares, except to the extent of his pecuniary interest. The address of each of the foregoing is c/o Avista Capital Partners, 65 E. 55th Street, 18th Floor, New York, New York 10022. This information is based solely on an Amendment to Schedule 13D filed on November 27, 2019.
- (4) Consists of: (i) 13,603 shares of Class A common stock, (ii) 1,167,250 shares or Class A common stock (the "Trust Shares") held by the GN 2016 Family Trust u/a/d August 12, 2016 (the "Trust") and (iii) 20,000 shares of Class A common stock underlying stock options that are exercisable as of October 1, 2020 or will become exercisable within 60 days after such date. Mr. Katz is the trustee of the Trust, a stockholder of the issuer that is a member of a group holding over 10% of the outstanding shares of Class A common stock of the issuer for purposes of Section 13(d) of the Exchange Act. Mr. Katz exercises voting and investment control over the Trust Shares, but Mr. Katz does not have a pecuniary interest in the Trust Shares.
- (5) Alan A. Ades, Albert Erani, Glenn H. Nussdorf, Dennis Erani, Starr Wisdom and certain of their respective affiliates, including Organo PFG LLC, Organo Investors LLC, Dennis Erani 2012 Issue Trust, Alan Ades as Trustee of the Alan Ades 2014 GRAT, Albert Erani Family Trust dated 12/29/2012, GN 2016 Family Trust u/a/d August 12, 2016 and GN 2016 Organo 10-Year GRAT u/a/d September 30, 2016, who we refer to collectively as the Controlling Entities, control a majority of the voting power of the outstanding Class A common stock. The Controlling Entities reported that they hold their shares of our stock as part of a group (as defined in Section 13(d)(3) of the Exchange Act) for the purposes of reporting beneficial ownership of the Company's securities in an Amendment to Schedule 13D filed on November 27, 2019.
- (6) Consists of (i) 397,900 shares of Class A common stock and (ii) 3,006,845 shares of Class A common stock underlying stock options that are exercisable as of October 1, 2020 or will become exercisable within 60 days after such date.
- (7) Consists of (i) 7,999,993 shares of Class A common stock, (ii) 1,489,779 shares of Class A common stock held by Alan Ades as Trustee of the Alan Ades 2014 GRAT, (iii) 32,134,638 shares of Class A common stock held by Organo PFG LLC and (iv) 2,851,984 shares of Class A common stock held by Organo Investors LLC. Mr. Ades exercises voting and investment power over the shares of Class A common stock held by Alan Ades as Trustee of the Alan Ades 2014 GRAT, Organo PFG LLC and Organo Investors LLC. Mr. Ades disclaims beneficial ownership of the shares of Class A common stock held by each of Alan Ades as Trustee of the Alan Ades 2014 GRAT, Organo PFG LLC and Organo Investors LLC, except to the extent of his pecuniary interest therein. The address of each of the foregoing is c/o A&E Stores, Inc., 1000 Huyler Street, Teterboro, NJ 07608.
- (8) Consists of 5,000 shares of Class A common stock and 10,000 shares of Class A common stock underlying stock options that are exercisable as of October 1, 2020 or will become exercisable within 60 days after such date.
- (9) Consists of 100,000 shares of Class A common stock and 10,000 shares of Class A common stock underlying stock options that are exercisable as of October 1, 2020 or will become exercisable within 60 days after such date.

- (10) Consists of (i) 2,758,663 shares of Class A common stock, (ii) 1,167,250 shares of Class A common stock held by GN 2016 Family Trust u/a/d August 12, 2016 and (iii) 11,012,750 shares of Class A common stock held by GN 2016 Organo 10-Year GRAT u/a/d September 30, 2016. Mr. Nussdorf exercises voting and investment power over the shares of Class A common stock held by GN 2016 Organo 10-Year GRAT u/a/d September 30, 2016. Mr. Michael Katz, as trustee, exercises and Mr. Nussdorf may be deemed to exercise voting and investment power over the shares of Class A common stock held by GN 2016 Family Trust u/a/d August 12, 2016. Mr. Nussdorf disclaims beneficial ownership of the shares of Class A common stock held by GN 2016 Organo 10-Year GRAT u/a/d September 30, 2016, except to the extent of his pecuniary interest therein, and each of Mr. Nussdorf and Mr. Katz disclaims beneficial ownership of the shares of Class A common stock held by GN 2016 Family Trust u/a/d August 12, 2016, except to the extent of his pecuniary interest therein. The address of each of the foregoing (other than Mr. Katz) is 35 Sawgrass Drive, Bellport, NY 11713.
- (11) Consists of 10,000 shares of Class A common stock underlying stock options that are exercisable as of October 1, 2020 or will become exercisable within 60 days after such date.
- (12) Consists of 24,360 shares of Class A common stock underlying stock options that are exercisable as of October 1, 2020 or will become exercisable within 60 days after such date.
- (13) Consists of 2,129 shares of Class A common stock and 123,716 shares of Class A common stock underlying stock options that are exercisable as of October 1, 2020 or will become exercisable within 60 days after such date.
- (14) Consists of (i) 60,083,341 shares of Class A common stock and (ii) 3,619,359 shares of Class A common stock underlying stock options that are exercisable as of October 1, 2020 or will become exercisable within 60 days after such date. As to disclaimers of beneficial ownership, see footnotes (2), (7) and (10) above.

### DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock is only a summary of the material terms of, and is qualified in its entirety by reference to, our restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus forms a part, and to the applicable provisions of the Delaware General Corporation Law.

# **Authorized and Outstanding Capital Stock**

Our restated certificate of incorporation authorizes the issuance of 421,000,000 shares of capital stock, consisting of (i) 420,000,000 shares of common stock, including 400,000,000 shares of Class A common stock, par value \$0.0001 per share (the "Class A Common Stock") and 20,000,000 shares of Class B common stock, par value \$0.0001 per share (the "Class B Common Stock"), and (ii) 1,000,000 shares of preferred stock, par value \$0.0001 per share. As of September 30, 2020, there were 107,457,154 shares of Class A common stock outstanding, no shares of Class B common stock were outstanding and no shares of preferred stock were outstanding. The outstanding shares of our Class A common stock are duly authorized, validly issued, fully paid and non-assessable.

#### Class A Common Stock

### **Voting Power**

Except as otherwise required by law or as otherwise provided in any certificate of designation for any series of preferred stock, the holders of Class A common stock possess all voting power for the election of our directors and all other matters requiring stockholder action and will at all times vote together as one class on all matters submitted to a vote of the stockholders. Holders of our Class A common stock are entitled to one vote per share on matters to be voted on by stockholders.

#### Dividends

Holders of Class A common stock will be entitled to receive such dividends and other distributions, if any, as may be declared from time to time by the board of directors (the "Board") in its discretion out of funds legally available therefor and shall share equally on a per share basis in such dividends and distributions.

### Liquidation, Dissolution and Winding Up

In the event of the voluntary or involuntary liquidation, dissolution, or winding-up of the Company, holders of Class A common stock will be entitled to receive an equal amount per share of all of our assets of whatever kind available for distribution to stockholders, after the rights of our creditors have been satisfied.

# Preemptive or Other Rights

Our stockholders have no preemptive, conversion or other subscription rights and there will be no sinking fund or redemption provisions applicable to our Class A common stock.

# **Election of Directors**

Under our restated certificate of incorporation, the Board consists of a single class, with all directors serving until our next annual meeting. There is no cumulative voting with respect to the election of directors, with the result that directors will be elected by a majority of the votes cast at an annual meeting of stockholders by holders of our Class A common stock.

#### Preferred Stock

Our restated certificate of incorporation provides for 1,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our Board to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our Board were to determine that a takeover proposal is not in the best interests of us or our stockholders, our Board could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our restated certificate of incorporation grants our Board broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of Class A common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

# **Options**

As of September 30, 2020, options to purchase 6,788,655 shares of our Class A common stock were outstanding under our equity compensation plans, at a weighted average exercise price of \$2.40 per share.

### **Dividends**

We have not paid any cash dividends on our Class A common stock to date. The payment of cash dividends in the future will be dependent upon the Company's revenues and earnings, if any, capital requirements and general financial condition. The payment of any cash dividends will be within the discretion of the board of directors at such time. In addition, the Company is not currently contemplating and does not anticipate declaring any stock dividends in the foreseeable future. Further, the credit agreement governing our credit facility imposes significant operating and financial restrictions and limit our ability to declare dividends.

## **Lock-up Agreements**

In connection with this offering, our officers, directors and certain securityholders have each entered into a lock-up agreement with the underwriters of this offering that restricts the sale of shares of our Class A common stock by those parties for a period of 90 days after the date of this prospectus. Morgan Stanley & Co. LLC and SVB Leerink LLC, on behalf of the underwriters, may, in their sole discretion, choose to release any or all of the shares of our Class A common stock subject to these lock-up agreements at any time prior to the expiration of the lock-up period without notice. For more information, see "Underwriting."

# **Registration Rights**

We and certain of our stockholders are party to an amended and restated registration rights agreement. The stockholders party to the amended and restated registration rights agreement and their permitted transferees are entitled to certain registration rights described therein. Among other things, pursuant to the amended and restated registration rights agreement, these stockholders are entitled to participate in three demand registrations, and will also have certain "piggyback" registration rights with respect to registration statements, subject to cut-back provisions. We will bear the expenses incurred in connection with the filing of any such registration statements, other than certain underwriting discounts, selling commissions and expenses related to the sale of shares. We filed a re-sale registration statement on Form S-3 pursuant to the terms of the amended and restated registration rights agreement on December 24, 2018 that was declared effective by the SEC on February 12, 2019.

### Certain Anti-Takeover Provisions of Delaware Law, Our Restated Certificate of Incorporation and Amended and Restated Bylaws

Provisions of our certificate of incorporation and bylaws and Delaware law could make it more difficult to acquire us by means of a tender offer, a proxy contest, open market purchases, removal of incumbent directors and otherwise. These provisions, summarized below, are expected to discourage types of coercive takeover practices and inadequate takeover bids and to encourage persons seeking to acquire control of us to first negotiate with us. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging takeover or acquisition proposals because negotiation of these proposals could result in an improvement of their terms.

We are a corporation incorporated under the laws of the State of Delaware, and are subject to the provisions of Section 203 of the DGCL, which we refer to as "Section 203," regulating corporate takeovers.

Section 203 prevents certain Delaware corporations, under certain circumstances, from engaging in a "business combination" with:

- a stockholder who owns fifteen percent (15%) or more of our outstanding voting stock (otherwise known as an "interested stockholder");
- an affiliate of an interested stockholder; or
- an associate of an interested stockholder, for three years following the date that the stockholder became an interested stockholder.

A "business combination" includes a merger or sale of more than ten percent (10%) of our assets. However, the above provisions of Section 203 do not apply if:

- our Board approves the transaction that made the stockholder an "interested stockholder," prior to the date of the transaction;
- after the completion of the transaction that resulted in the stockholder becoming an interested stockholder, that stockholder owned at least eighty-five percent (85%) of our voting stock outstanding at the time the transaction commenced, other than statutorily excluded shares of Class A common stock; or
- on or subsequent to the date of the transaction, the business combination is approved by our Board and authorized at a meeting of our stockholders by an affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

In addition, our restated certificate of incorporation does not provide for cumulative voting in the election of directors. Our Board is empowered to elect a director to fill a vacancy created by the expansion of the Board or the resignation, death, or removal of a director in certain circumstances; and our advance notice provisions require that stockholders must comply with certain procedures in order to nominate candidates to our Board or to propose matters to be acted upon at a stockholders' meeting.

Our restated certificate of incorporation and amended and restated bylaws provide that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. Our restated certificate of incorporation also provides that, subject to the terms of any one or more series or classes of preferred stock, any director or the entire Board may be removed from office at any time, but only for cause (as defined in the restated certificate of incorporation) and only by the affirmative vote of the holders of at least a majority of the votes which all the stockholders would be entitled to cast in any annual election of directors, voting together as a single class.

Our authorized but unissued Class A common stock and preferred stock are available for future issuances without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved Class A common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Our restated certificate of incorporation and amended and restated bylaws provide that, unless we consent in writing to an alternate forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (A) any derivative action or proceeding brought on behalf of us, (B) any action asserting a claim of breach of a fiduciary duty owed by, or any wrongdoing by, any of our directors, officers or employees to us or our stockholders, (C) any action asserting a claim arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws, (D) any action to interpret, apply, enforce or determine the validity of our certificate of Incorporation or our bylaws, or (E) any action asserting a claim governed by the internal affairs doctrine, except for, as to each of (A) through (E) above, (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 Exchange Act, or the rules and regulations promulgated thereunder, for which federal courts have exclusive jurisdiction.

### **Transfer Agent**

The transfer agent for our Class A common stock is Continental Stock Transfer & Trust Company. We have agreed to indemnify Continental Stock Transfer & Trust Company in its role as transfer agent, its agents and each of its stockholders, directors, officers and employees against all liabilities, including judgments, costs and reasonable counsel fees that may arise out of acts performed or omitted for its activities in that capacity, except for any liability due to any gross negligence, willful misconduct or bad faith of the indemnified person or entity.

### Listing on the Nasdaq Capital Market

Our Class A common stock is listed on the Nasdaq Capital Market under the symbol "ORGO."

### DESCRIPTION OF CERTAIN INDEBTEDNESS

### **SVB Credit Agreement**

On March 14, 2019, we entered into a credit agreement with Silicon Valley Bank, or SVB, which was amended on November 12, 2019, February 14, 2020 and March 26, 2020, as amended (the "2019 Credit Agreement"). The 2019 Credit Agreement provides 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 \$100.0 million. As of September 30, 2020, we had borrowed \$60.0 million under the Term Loan Facility and \$39.4 million under the Revolving Facility with \$0 available for future revolving borrowings.

*Interest Rate.* The interest rate for the Term Loan Facility is a floating per annum interest rate equal to the greater of 3.75% above the Wall Street Journal Prime Rate and 9.25%. The interest rate as of September 30, 2020 was 9.25%. The 2019 Credit Agreement requires us to make monthly interest-only payments on outstanding balances under the Term Loan Facility through February 2021. Thereafter, each term loan advance will be repaid in thirty-six equal monthly installments of principal, plus accrued interest, with the Term Loan Facility maturing on March 1, 2024.

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

The interest rate for advances under the Revolving Facility is a floating per annum interest rate equal to the greater of the Wall Street Journal Prime Rate and 5.50%. The interest rate as of September 30, 2020 was 5.50%. If the actual outstanding advances are less than 25% of the then-available Revolving Commitments, we must pay monthly interest equal to the interest that would have accrued if the average outstanding advances had been 25% of the then-available Revolving Commitments. We are also required to pay an unused line fee equal to 0.25% per annum, calculated based on the difference of \$40.0 million *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.

We may elect to reduce or terminate the Revolving Facility in its entirety at any time by repaying all outstanding principal, unpaid accrued interest and a reduction or termination fee equal to 3.00% of the aggregate Revolving Commitments so reduced or terminated if the reduction or termination occurs after the 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.

Maturity. The 2019 Credit Agreement has a scheduled maturity of March 1, 2024.

Security. We and our subsidiaries have granted SVB a first priority perfected security interest in substantially all present and future assets, including goods, accounts, equipment, inventory, contract rights, leases, license agreements, general intangibles, intellectual property, commercial tort claims, instruments, cash, deposit accounts, securities and all other investment properties.

Affirmative Covenants. The 2019 Credit Agreement contains customary affirmative covenants, including (i) maintenance of legal existence and compliance with laws and regulations, (ii) delivery of consolidated financial statements and other information, (iii) maintenance of property in good working order and condition, (iv) payment of taxes, (v) maintenance of adequate insurance and (vi) maintenance of operating accounts with SVB.

Negative Covenants. The 2019 Credit Agreement contains customary negative covenants, including restrictions on

- (i) the sale, transfer or disposition of assets and businesses;
- (ii) changes in business, management, ownership and business locations;
- (iii) mergers and consolidations;
- (iv) indebtedness other than indebtedness:
  - a. created by the Credit Agreement;
  - b. of one loan party to another loan party, between non-loan party subsidiaries or of a non-loan party subsidiary to a loan party (to the extent constituting a permitted investment);
  - c. guarantee obligations with respect to intra-company loans;
  - d. outstanding on the date of the Credit Agreement and any extensions of maturity thereof without any other change in terms;
  - e. indebtedness (including capital lease obligations) secured by permitted liens in an aggregate principal amount not to exceed \$5,000,000;
  - f. surety indebtedness in respect of letters of credit, banker's acceptances or similar arrangements that do not, in the aggregate, exceed \$250,000;
  - g. obligations existing or arising under a permitted swap agreement;
  - h. other unsecured Indebtedness not exceeding \$150,000 at any one time outstanding; and.
  - i indebtedness of a person (other than the borrower or a subsidiary) existing at the time such person is merged with or into a borrower or a subsidiary or becomes a subsidiary, provided that (i) such indebtedness was not, in any case, incurred by such other person in connection with, or in contemplation of, such merger or acquisition, (ii) such merger or acquisition constitutes a permitted acquisition (as defined in the 2019 Credit Agreement), (iii) with respect to any such person who becomes a subsidiary, such subsidiary is the only obligor in respect of such indebtedness, (iv) such indebtedness shall constitute subordinated indebtedness (as defined in the 2019 Credit Agreement), and (iv) the aggregate principal amount of such indebtedness shall not exceed \$7,500,000 at any time outstanding.
- (v) liens and other encumbrances, with customary exceptions;
- (vi) investments and dividends and other distributions on capital stock, with customary exceptions;
- (vii) transactions with affiliates; and
- (viii) the payment or amendment of subordinated debt.

Financial Covenants. We are required to comply with the following financial covenants:

(i) Minimum liquidity (as defined in the 2019 Credit Agreement) at all times must be at least equal to the greater of (i) six (6) months monthly burn (as defined in the 2019 Credit Agreement); and (ii) \$10,000,000.

- (ii) our trailing twelve month consolidated revenue (as defined in the 2019 Credit Agreement), tested quarterly, must not be less than: \$235,000,000 for the trailing twelve months ending March 31, 2020; \$253,000,000 for the trailing twelve months ending June 30, 2020; \$260,000,000 for the trailing twelve months ending September 30, 2020; and \$262,000,000 for the trailing twelve months ending December 31, 2020, with minimum revenue covenant levels for the quarterly periods ending March 31, 2021 and thereafter to be agreed between the lenders and us no later than March 31 of each applicable fiscal year.
- (iii) our trailing twelve month non-PuraPly revenue (as defined in the 2019 Credit Agreement), tested quarterly beginning with the quarter ended September 30, 2020, must not be less than: \$136,500,000 for the trailing twelve months ended September 30, 2020; and \$145,000,000 for the trailing twelve months ending December 31, 2020, with minimum revenue covenant levels for the quarterly periods ending March 31, 2021 and thereafter to be agreed between the lenders and us no later than March 31 of each applicable fiscal year.

Events of Default. The 2019 Credit Agreement contains customary events of default (with customary grace periods and thresholds), including (i) failure to pay principal, interest or other obligations when due, (ii) failure to perform or observe covenants, (iii) a material adverse event affecting us, (iv) attachment or seizure of or levy on our assets, (v) bankruptcy and insolvency, (vi) cross-defaults to other indebtedness in an amount in excess of \$250,000, (vii) monetary judgments in an amount in excess of \$500,000, (viii) incorrectness of representations and warranties in any material respect and (ix) the termination of any guaranty or a material impairment in the perfection or priority of SVB's lien.

*Additional Information.* The foregoing is a brief summary of the material terms of the 2019 Credit Agreement. We have filed a copy of the complete 2019 Credit Agreement as an exhibit to the registration statement of which this prospectus forms a part.

# CERTAIN MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS

The following is a general discussion of the material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their purchase, ownership and disposition of shares of our Class A common stock. This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our Class A common stock should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our Class A common stock.

This discussion is based on current provisions of the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences to non-U.S. holders described in this prospectus. We assume in this discussion that a non-U.S. holder holds shares of our Class A common stock as a capital asset (generally, property held for investment).

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address, except to the limited extent discussed below, any aspects of U.S. federal estate or gift taxes, or state, local or non-U.S. taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- banks;
- insurance companies;
- tax-exempt organizations;
- financial institutions;
- brokers or dealers in securities or currencies;
- regulated investment companies;
- pension plans;
- controlled foreign corporations;
- passive foreign investment companies;
- persons subject to the U.S. federal alternative minimum tax or the 3.8% tax on net investment income;
- owners that hold our Class A common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- certain U.S. expatriates.

In addition, this discussion does not address the tax treatment of partnerships or other pass-through entities, or persons who hold our Class A common stock through partnerships or other pass-through entities, for U.S. federal income tax purposes. A partner in a partnership or other pass-through entity that will hold our Class A common stock should consult his, her or its tax advisor regarding the tax consequences of acquiring, holding and disposing of our Class A common stock through a partnership or other pass-through entity, as applicable.

We have not sought and will not seek any ruling from the U.S. Internal Revenue Service, which we refer to as the IRS, with respect to the statements made and the conclusions reached in the following discussion. There can be no assurance that the IRS will not challenge one or more of the tax consequences described herein, or that any such challenge would not be sustained by a court.

NON-U.S. HOLDERS ARE URGED TO CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL TAX LAWS TO THEIR PURCHASE, OWNERSHIP AND DISPOSITION OF OUR CLASS A COMMON STOCK IN LIGHT OF THEIR PARTICULAR SITUATIONS, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER THE LAWS OF ANY STATE, LOCAL, NON-U.S. OR OTHER TAXING JURISDICTION OR UNDER ANY APPLICABLE TAX TREATY.

### Non-U.S. Holder Defined

For purposes of this discussion, a non-U.S. holder means a beneficial owner of our Class A common stock that, for U.S. federal income tax purposes, is an individual, corporation, estate or trust that is not a U.S. person. For purposes of this discussion, a U.S. person is:

- an individual who is a citizen or resident of the United States for U.S. federal income tax purposes;
- a corporation, or any other entity or organization taxable as a corporation for U.S. federal income tax purposes, created or organized in the United States or under the laws of the United States, any political subdivision thereof, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust if (1) a U.S. court is able to exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all of the trust's substantial decisions or (2) the trust has a valid election in effect to be treated as a U.S. person.

### Distributions on Our Class A Common Stock

We have not made distributions on our Class A common stock and do not plan to make any distributions for the foreseeable future. However, if we do make distributions of cash or property on our Class A common stock, those payments generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in the Class A common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "— Gain on Sale, Exchange or Other Disposition of Our Class A Common Stock."

Subject to the discussion below on backup withholding and FATCA (defined below), dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30.0% rate or such lower rate as may be specified by an applicable income tax treaty. A non-U.S. holder of our Class A common stock who claims the benefit of an applicable income tax treaty generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or other appropriate version of IRS Form W-8 or successor form) and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30.0% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements by providing a properly executed IRS Form W-8ECI (or successor form). However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to U.S. persons. In addition, any U.S. effectively connected income received by a non-U.S. holder that is a corporation (or other entity that is treated as a corporation for U.S. federal income tax purposes) may also, under certain circumstances, be subject to an additional U.S. federal branch profits tax at a 30.0% rate or such lower rate as may be specified by an applicable income tax treaty.

A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing a U.S. federal income tax return with the IRS.

# Gain on Sale, Exchange or Other Disposition of Our Class A Common Stock

Subject to the discussion below on backup withholding and FATCA, a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized upon such holder's sale, exchange or other disposition of shares of our Class A common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed at the graduated U.S. federal income tax rates applicable to U.S. persons and, if the non-U.S. holder is a corporation (or an entity treated as a corporation for U.S. federal income tax purposes), it also may be subject to a U.S. federal branch profits tax at a rate of 30.0% (or such lower rate as may be specified by an applicable income tax treaty) on such effectively connected gain;
- the non-U.S. holder is a nonresident alien individual for U.S. federal income tax purposes who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30.0% tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any; or
- we are, or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a U.S. real property holding corporation for U.S. federal income tax purposes. Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50.0% of the sum of the fair market value of its worldwide real property interests plus the fair market value of any other of its assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. Even if we are or were to become a U.S. real property holding corporation, gains realized by a non-U.S. holder on a disposition of our Class A common stock will not be subject to U.S. federal income tax under this rule if our Class A common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5.0% of our outstanding Class A common stock, directly or indirectly, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our Class A common stock. No assurance can be provided that our Class A common stock will be regularly traded on an established securities market for purposes of the rules described above.

# **U.S. Federal Estate Tax**

Property having a U.S. situs generally is includible in the gross estate of an individual non-U.S. holder for U.S. federal estate tax purposes. Because we are a U.S. corporation, our Class A common stock will be U.S. situs property for U.S. federal estate tax purposes and, therefore, generally will be included in the gross estate of an individual who is a non-U.S. holder at the time of his or her death, unless an applicable estate tax treaty provides otherwise.

# **Backup Withholding and Information Reporting**

We must report annually to the IRS and to each non-U.S. holder payments of dividends on our Class A common stock to such holder and the tax withheld, if any, with respect to such dividends, along with certain other information. Non-U.S. holders may have to comply with specific certification procedures to establish that

the holder is not a U.S. person in order to avoid backup withholding with respect to dividends on our Class A common stock. Dividends paid to non-U.S. holders subject to the U.S. withholding tax, as described above in "—Distributions on our Class A common stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our Class A common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or non-U.S., unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or other agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

### Foreign Account Tax Compliance Act (FATCA)

Section 1471 through 1474 of the Code and related Treasury regulations and guidance (commonly referred to as "FATCA") generally imposes a U.S. federal withholding tax at a rate of 30.0% on dividends on, or gross proceeds from the sale or other disposition of, our Class A common stock that are paid to certain non-U.S. entities (including foreign financial institutions and non-financial foreign entities, both as specifically defined under FATCA), unless such non-U.S. entities establish that they are compliant with or exempt from FATCA. To comply with FATCA, a foreign financial institution generally is required to register with the IRS, collect and provide to tax authorities information regarding U.S. account holders of such institution (including certain equity and debt holders of such institution, as well as certain account holders that are non-U.S. entities with U.S. owners), and provide withholding agents with a certification that it is compliant with FATCA. A non-financial foreign entity generally is required to provide withholding agents with either a certification that it does not have any substantial direct or indirect U.S. owners or information regarding substantial direct and indirect U.S. owners of the entity, or otherwise establishes an exemption from FATCA. An intergovernmental agreement between the United States and an applicable foreign country may, however, modify these requirements and these requirements are different from and in addition to the certification requirements described elsewhere in this discussion. The FATCA withholding tax rules are in effect with respect to dividends on our Class A common stock. Pursuant to proposed regulations (which can be relied upon until final regulations are issued), withholding on payments of gross proceeds from the sale or other disposition of our Class A common stock would be eliminated. Amounts withheld under FATCA with respect to income that is also subject to the general U.S. federal withholding tax. Prospective investors should consult their tax advisor

### UNDERWRITING

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC and SVB Leerink LLC are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares indicated below:

Name	Number of Shares
Morgan Stanley & Co. LLC	
SVB Leerink LLC	
BTIG, LLC	
Oppenheimer & Co. Inc.	
Total	17,500,000

The underwriters and the representatives are collectively referred to as the "underwriters" and the "representatives," respectively. The underwriters are offering the shares of Class A common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of Class A common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of Class A common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' over-allotment option described below.

The underwriters initially propose to offer part of the shares of Class A common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of \$ per share under the public offering price. After the initial offering of the shares of Class A common stock, the offering price and other selling terms may from time to time be varied by the representative.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 2,625,000 additional shares of Class A common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of Class A common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of Class A common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of Class A common stock listed next to the names of all underwriters in the preceding table. In the event that affiliates of certain of our directors purchase shares of Class A common stock in this offering, the underwriters have agreed to reimburse us for the discounts and commissions payable with respect to such shares and we have agreed to pay such amounts to such affiliates.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us and the selling stockholders. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional 2,625,000 shares of Class A common stock.

		T	otal
	Per Share	No Exercise	Full Exercise
Public offering price	\$	\$	\$
Underwriting discounts and commissions to be paid by us	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$610,000. We have also agreed to reimburse the underwriters for expenses of up to \$50,000 related to the review of this offering by the Financial Industry Regulatory Authority, or FINRA, and in connection with the qualification of the shares for sale under the laws of certain jurisdictions.

Our Class A common stock is listed on The Nasdaq Capital Market under the symbol "ORGO."

We have agreed that we will not, without the prior written consent of the representatives, for a period of 90 days after the date of this prospectus, directly or indirectly, (i) offer, sell, issue, contract to sell, pledge or otherwise dispose of shares of Class A common stock, (ii) offer, sell, issue, contract to sell, contract to purchase or grant any option, right or warrant to purchase shares of Class A common stock, (iii) enter into any swap, hedge or any other agreement that transfers, in whole or in part, the economic consequences of ownership of shares of Class A common stock, (iv) establish or increase a put equivalent position or liquidate or decrease a call equivalent position in shares of Class A common stock within the meaning of Section 16 of the Exchange Act or (v) file with or confidentially submit to the Securities and Exchange Commission a registration statement under the Securities Act relating to shares of Class A common stock, or publicly disclose the intention to take any such action, except for (A) issuances pursuant to the conversion or exchange of convertible or exchangeable securities or the exercise of warrants or options, (B) grants of employee stock options pursuant to certain plans, (C) issuances pursuant to the exercise of such options, (D) issuances in connection with acquisitions by us, provided that the aggregate number of securities issued pursuant to such issuances does not exceed 5% of our outstanding shares and subject to certain lock-up requirements and (E) issuances pursuant to our dividend reinvestment plan.

Our officers, directors and certain security holders have agreed that, subject to certain exceptions, without the prior written consent of the representatives, they will not, and will not publicly disclose an intention to, for a period of 90 days after the date of this prospectus, (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of Class A common stock beneficially owned by such person or entity or any other securities so owned convertible into or exercisable or exchangeable for any shares of Class A common stock, (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the shares of Class A common stock, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of shares of Class A common stock or such other securities, in cash or otherwise, or (iii) make any demand for or exercise any right with respect to, the registration of any shares of Class A common stock or any security convertible into or exercisable or exchangeable for shares of Class A common stock.

In order to facilitate the offering of the Class A common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the Class A common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the Class A common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of Class A common stock in the open market to stabilize the price of the Class A common stock. These activities may raise or maintain the market price of the Class A common stock above independent market levels or prevent or retard a decline in the market price of the Class A common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

In addition, in connection with this offering certain of the underwriters (and selling group members) may engage in passive market making transactions in our Class A common stock on the Nasdaq Global Market prior to the pricing and completion of this offering. Passive market making consists of displaying bids on the Nasdaq Global Market no higher than the bid prices of independent market makers and making purchases at prices no higher than these independent bids and effected in response to order flow. Net purchases by a passive market maker on each day are generally limited to a specified percentage of the passive market maker's average daily trading volume in the Class A common stock during a specified period and must be discontinued when such limit is reached. Passive market making may cause the price of our Class A common stock to be higher than the price that otherwise would exist in the open market in the absence of these transactions. If passive market making is commenced, it may be discontinued at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representative may agree to allocate a number of shares of Class A common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representative to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory, lending and investment banking services for us, for which they received or will receive customary fees and expenses. For example, Silicon Valley Bank, a leader under our credit agreement, is an affiliate of SVB Leerink LLC, one of the underwriters in this offering.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

### **Selling Restrictions**

### European Economic Area

In relation to each Member State of the European Economic Area and the United Kingdom (each, a "Relevant State"), no securities have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the securities which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of securities may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives; or
  - (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any of our representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129 (as amended).

# **United Kingdom**

Each underwriter has represented and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 ("FSMA") received by it in connection with the issue or sale of the shares of our Class A common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- (b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our Class A common stock in, from or otherwise involving the United Kingdom.

#### Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

#### LEGAL MATTERS

The validity of the Class A common stock being offered hereby will be passed upon for us by Foley Hoag LLP, Boston, Massachusetts. William R. Kolb, Esq., a partner of Foley Hoag LLP, is our corporate secretary. The underwriters are represented by Ropes & Gray LLP, Boston, Massachusetts, in connection with certain legal matters related to this offering.

### **EXPERTS**

The consolidated financial statements of Organogenesis Holdings Inc. as of December 31, 2019 and 2018 and for each of the years in the three year period ended December 31, 2019 appearing in this Prospectus and Registration Statement have been audited by RSM US LLP, an independent registered public accounting firm, as stated in their report thereon appearing elsewhere herein, and are included in reliance upon such report and upon the authority of such firm as experts in accounting and auditing.

### WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of Class A common stock offered by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our Class A common stock you should refer to the registration statement and our exhibits. Statements contained in this prospectus concerning any of our contracts, agreements or other documents are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, we refer you to the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit.

We are subject to the informational requirements of the Exchange Act and file annual, quarterly and current reports and other information with the SEC. Our filings with the SEC are available to the public on the SEC's website at http://www.sec.gov. Those filings are also available to the public on, or accessible through, our website under the heading "Investors" at www.organogenesis.com. The information we file with the SEC or contained on or accessible through our corporate website or any other website that we may maintain is not part of this prospectus or the registration statement of which this prospectus is a part.

Notes to Consolidated Financial Statements

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# ORGANOGENESIS HOLDINGS INC. CONSOLIDATED BALANCE SHEETS

# (unaudited)

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

	Sep	otember 30, 2020	Dec	cember 31, 2019
Assets				
Current assets:				
Cash	\$	36,512	\$	60,174
Restricted cash		374		196
Accounts receivable, net		56,915		39,359
Inventory		29,882		22,918
Prepaid expenses and other current assets		5,327		2,953
Total current assets		129,010		125,600
Property and equipment, net		55,937	, <u> </u>	47,184
Notes receivable from related parties		_		556
Intangible assets, net		31,849		20,797
Goodwill		28,916		25,539
Deferred tax asset, net		16		127
Other assets		700		884
Total assets	\$	246,428	\$	220,687
Liabilities and Stockholders' Equity				
Current liabilities:				
Deferred acquisition consideration	\$	966	\$	5,000
Current portion of term loan		11,667		_
Current portion of capital lease obligations		3,473		3,057
Accounts payable		24,007		28,387
Accrued expenses and other current liabilities		26,132		23,450
Total current liabilities		66,245		59,894
Line of credit		39,353		33,484
Term loan, net of current portion		47,999		49,634
Deferred acquisition consideration, net of current portion		1,436		_
Earnout liability		3,782		_
Deferred rent		1,098		1,012
Capital lease obligations, net of current portion		12,239		14,431
Other liabilities		8,802		6,649
Total liabilities		180,954		165,104
Commitments and contingencies (Note 13)	_			
Stockholders' equity:				
Common stock, \$0.0001 par value; 400,000,000 shares authorized; 108,185,702 and 105,599,434 shares issued; 107,457,154 and 104,870,886 shares outstanding at September 30, 2020 and December 31, 2019,				
respectively.		11		10
Additional paid-in capital		237,015		226,580
Accumulated deficit		(171,552)		(171,007)
Total stockholders' equity		65,474		55,583
Total liabilities and stockholders' equity	\$	246,428	\$	220,687

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

# ORGANOGENESIS HOLDINGS INC. CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

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

		Three Months Ended September 30,			Nine Months Ende September 30,		ed	
		2020		2019		2020		2019
Net revenue	\$	100,799	\$	64,265	\$	231,491	\$	186,336
Cost of goods sold		22,964		19,131		61,799		55,557
Gross profit		77,835		45,134		169,692		130,779
Operating expenses:								
Selling, general and administrative		51,146		49,475		150,261		147,325
Research and development		3,709		3,924		13,787		11,159
Total operating expenses		54,855		53,399		164,048		158,484
Income (loss) from operations		22,980		(8,265)		5,644		(27,705)
Other expense, net:								
Interest expense, net		(2,969)		(2,427)		(8,391)		(6,392)
Loss on the extinguishment of debt		_		_		_		(1,862)
Gain on settlement of deferred acquisition consideration		951		_		2,246		
Other income (expense), net		44		(1)		90		11
Total other expense, net		(1,974)	_	(2,428)		(6,055)	_	(8,243)
Net income (loss) before income taxes		21,006		(10,693)		(411)		(35,948)
Income tax expense		(72)		(48)		(134)		(108)
Net income (loss)		20,934		(10,741)		(545)	_	(36,056)
Non-cash deemed dividend to warrant holders		_		(645)		_		(645)
Net income (loss) attributed to common shareholders	\$	20,934	\$	(11,386)	\$	(545)	\$	(36,701)
Net income (loss) attributed to common shareholders, per share:								
Basic	\$	0.20	\$	(0.12)	\$	(0.01)	\$	(0.40)
Diluted	\$	0.19	\$	(0.12)	\$	(0.01)	\$	(0.40)
Weighted-average common shares outstanding—basic and diluted								
Basic	10	05,040,035	9	2,276,858	10	04,748,297	9	1,182,233
Diluted	10	08,489,768	9	2,276,858	10	04,748,297	9	1,182,233

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

Exercise of common stock warrants

Stock-based compensation expense

Balance as of September 30, 2019

Common stock issued in warrant exchange

Redemption of redeemable common stock placed into treasury

Exercise of stock options

Net loss

# ORGANOGENESIS HOLDINGS INC. CONSOLIDATED STATEMENTS OF REDEEMABLE COMMON STOCK AND STOCKHOLDERS' EQUITY (unaudited)

(amounts in thousands, except share data)

Three and Nine Months Ended September 30, 2020

	Redeemable Common Stock		Common Stock		Additional Paid-in Accumulated		Total Stockholders'	
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity	
Balance as of June 30, 2020		<u>\$</u>	105,417,168	\$ 11	\$ 228,225	\$ (192,486)	\$ 35,750	
Exercise of stock options	_	_	92,033	_	318	_	318	
Stock-based compensation expense	_	_	_	_	486	_	486	
Issuance of common stock associated with business acquisition	_	_	1,947,953	_	7,986		7,986	
Net income						20,934	20,934	
Balance as of September 30, 2020		<u>\$</u>	107,457,154	\$ 11	\$ 237,015	\$ (171,552)	\$ 65,474	
Balance as of December 31, 2019		<u>\$</u>	104,870,886	\$ 10	\$ 226,580	\$ (171,007)	\$ 55,583	
Exercise of stock options	_	_	638,315	1	1,285	_	1,286	
Issuance of common stock associated with business acquisition			1,947,953	_	7,986		7,986	
Stock-based compensation expense	_	_	_	_	1,164	_	1,164	
Net loss						(545)	(545)	
Balance as of September 30, 2020		<u>\$</u>	107,457,154	\$ 11	\$ 237,015	\$ (171,552)	\$ 65,474	
	Three and Nine Months Ended September 30, 2019  Redeemable Additional					Total		
	Commo		Common		tock Paid-in Accumulated		Stockholders'	
Balance as of June 30, 2019	Shares	Amount \$ —	Shares 91,342,722	Amount \$ 9	Capital \$ 178,412	Deficit \$ (155,223)	<b>Equity</b> \$ 23,198	
Exercise of stock options	_	<b>5</b> —	64,362	\$ 9	109	\$ (133,223)	109	
Exercise of common stock warrants		_	19,426	_	109	_	109	
Common stock issued in warrant exchange			3,315,232		645	(645)	_	
Stock-based compensation expense			3,313,232		242	(043)	242	
Net loss	_	_	_	_		(10,741)	(10,741)	
Balance as of September 30, 2019		<u>s</u> —	94,741,742	\$ 9	\$ 179,408	\$ (166,609)	\$ 12,808	
Balance as of December 31, 2018	728,548	\$	91,261,413	\$ 9	\$ 177,272	\$ (130,240)	\$ 47,041	
Adoption of ASC 606	720,540	—	71,201,415	—	Ψ 1//,2/2	332	332	
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The accompanying notes are an integral part of these unaudited consolidated financial statements.

(728,548)

74,052

91,045

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94,741,742

628

163

645

700

\$ 179,408

(645)

(36,056)

(166,609)

628

163

700

(36,056)

12,808

# ORGANOGENESIS HOLDINGS INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

# (unaudited)

(amounts in thousands)

		ths Ended ber 30, 2019	
Cash flows from operating activities:	2020	0(26,056)	
Net loss Adjustments to reconcile net loss to net cash used in operating activities:	\$ (545)	\$(36,056)	
Depreciation	2,749	2,553	
Amortization of intangible assets	2,518	4,526	
Non-cash interest expense	160	196	
Deferred interest expense	1,577	974	
Deferred rent expense	33	606	
Gain on settlement of deferred acquisition consideration	(2,246)	_	
Recovery of certain notes receivable from related parties	(1,111)	_	
Provision (benefit) recorded for sales returns and doubtful accounts	2,559	(29)	
Loss on disposal of property and equipment	201		
Adjustment for excess and obsolete inventories	2,024	809	
Stock-based compensation	1,164	700	
Loss on extinguishment of debt	<u> </u>	1,862	
Changes in operating assets and liabilities:			
Accounts receivable	(19,160)	553	
Inventory	(7,757)	(7,840)	
Prepaid expenses and other current assets	(2,262)	(699)	
Accounts payable	(3,778)	5,348	
Accrued expenses and other current liabilities	3,521	85	
Other liabilities	878	(715)	
Net cash used in operating activities	(19,475)	(27,127)	
Cash flows from investing activities:			
Purchases of property and equipment	(12,260)	(2,526)	
Proceeds from the repayment of notes receivable from related parties	1,726	_	
Cash paid for business acquisition	(5,820)		
Acquisition of intangible asset		(250)	
Net cash used in investing activities	(16,354)	(2,776)	
Cash flows from financing activities:			
Line of credit borrowings	5,869	7,000	
Proceeds from term loan	10,000	50,000	
Repayment of notes payable	<del>-</del>	(17,585)	
Proceeds from the exercise of stock options	1,286	163	
Proceeds from the exercise of common stock warrants	_	628	
Redemption of redeemable common stock placed into treasury		(6,762)	
Principal repayments of capital lease obligations	(1,776)	(863)	
Payment of deferred acquisition consideration	(3,034)	(024)	
Payment of debt issuance costs		(924)	
Net cash provided by financing activities	12,345	31,657	
Change in cash and restricted cash	(23,484)	1,754	
Cash and restricted cash, beginning of period	60,370	21,405	
Cash and restricted cash, end of period	\$ 36,886	\$ 23,159	
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 7,130	\$ 5,922	
Cash paid for income taxes	\$ —	\$ 110	
Supplemental disclosure of non-cash investing and financing activities:			
Fair value of shares issued for business acquisition	\$ 7,986	\$ —	
Deferred acquisition consideration and earnout liability recorded for business acquisition	\$ 5,218	\$ —	
Debt and equity issuance costs included in accounts payable	\$ —	\$ 91	
Purchases of property and equipment included in accounts payable and accrued expenses	\$ 2,628	\$ 3,698	
Amounts due related to acquisition of intangible assets included in accrued expenses and other liabilities	<u> </u>	\$ 500	
Non-cash deemed dividend related to warrant exchange	\$ —	\$ 645	
Equipment acquired under capital lease	\$ —	\$ 973	

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

### ORGANOGENESIS HOLDINGS INC.

# NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS (amounts in thousands, except share and per share data)

## 1. Nature of the Business and Basis of Presentation

Organogenesis Holdings Inc. (formerly Avista Healthcare Public Acquisition Corp.) ("ORGO" or the "Company") is a leading regenerative medicine company focused on the development, manufacture, and commercialization of solutions for the Advanced Wound Care and Surgical & Sports Medicine markets. Many 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"). The Company's customers include hospitals, wound care centers, government facilities, ambulatory service centers ("ASCs") and physician offices. The Company has one operating and reportable segment.

# COVID-19 pandemic

The emergence of the coronavirus (COVID-19) around the world, and particularly in the United States, continues to present significant risks to the Company. While the COVID-19 pandemic has not materially adversely affected the Company's financial results and business operations through the third quarter ended September 30, 2020, the Company is unable to predict the impact that COVID-19 will have on its financial position and operating results because of the numerous uncertainties created by the unprecedented nature of the pandemic. The public health actions being undertaken to reduce the spread of the virus, and that may have to be undertaken again in the event of a resurgence of the virus, may create significant disruptions to the Company with respect to: (i) the demand for its products, (ii) the ability of its sales representatives to reach healthcare customers, (iii) its ability to maintain staffing levels to support its operations, (iv) its ability to continue to manufacture certain of its products, (v) the reliability of its supply chain and (vi) its ability to achieve the financial covenants required under the 2019 Credit Agreement (see Note "11. Long-Term Debt Obligations"). The extent to which the COVID-19 pandemic may impact the Company's business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, travel restrictions and social distancing in the U.S. and other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and other countries to contain and treat the disease.

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

# Merger with Avista Healthcare Public Acquisition Corp

On December 10, 2018, Avista Healthcare Public Acquisition Corp., our predecessor company ("AHPAC"), consummated the previously announced merger (the "Avista Merger") pursuant to an Agreement and Plan of Merger, dated as of August 17, 2018 (as amended, the "Avista Merger Agreement"), by and among AHPAC, Avista Healthcare Merger Sub, Inc., a 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. AHPAC changed its name to Organogenesis Holdings Inc. (ORGO).

The Avista Merger was accounted for as a reverse merger in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Under this method of accounting, AHPAC was treated as the "acquired" company for accounting purposes. 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 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.

# Liquidity and Financial Conditions

In accordance with ASC 205-40, *Going Concern* ("ASC 205-40"), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. While the Company has reported net income for the three months ended September 30, 2020, the Company has recurring losses from operations since its inception and has funded its operations primarily with cash flow from product sales and proceeds from loans from affiliates and entities controlled by its affiliates, sales of its common stock and third-party debt. As of September 30, 2020, the Company had an accumulated deficit of \$171,552 and working capital of \$62,765. During the nine months ended September 30, 2020, the Company incurred a net loss of \$545 and used \$19,475 of cash in operations. The Company may continue to incur negative cash flows from operations and operating losses in the future as the Company expends resources to grow the organization to support the planned expansion of the business. The Company expects that its cash of \$36,512 and working capital of \$62,765 as of September 30, 2020, plus net cash flows from product sales, will be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments for at least 12 months beyond the filing date of this quarterly report. The Company is closely monitoring ongoing developments in connection with the COVID-19 pandemic, which may negatively impact its commercial prospects, projected cash position and access to capital in the future. The Company will continue to assess its cash position and, if circumstances warrant, make appropriate adjustments to its operating plan.

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

### 2. Summary of Significant Accounting Policies

# Unaudited Interim Financial Information

The accompanying unaudited consolidated financial statements have been prepared by management in accordance with GAAP and in accordance with the rules and regulations of the Securities and Exchange Commission (the "SEC") regarding interim financial reporting. Accordingly, they do not include all the

information and footnotes required by generally accepted accounting principles for complete financial statements. While we believe that the disclosures presented are adequate in order to make the information not misleading, these unaudited quarterly financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (the "Annual Report").

The unaudited consolidated financial statements include the accounts and results of operations of Organogenesis Holdings Inc. and its wholly-owned or controlled subsidiaries of Organogenesis Inc., including Organogenesis GmbH (a Switzerland corporation) and Prime Merger Sub, LLC. All intercompany balances and transactions have been eliminated in consolidation. The Company considers events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. In the opinion of management, the unaudited consolidated financial statements reflect all adjustments of a normal recurring nature necessary for a fair presentation of the Company's financial position, results of operations and cash flows at the dates and for the periods indicated. The results for the nine months ended September 30, 2020 are not necessarily indicative of the results to be expected for the year ending December 31, 2020, any other interim periods, or any future years or periods.

# 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 the related disclosure as of the date of the consolidated financial statements and the reported results of operations during the reporting period. Actual results could differ from those estimates.

# Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note "2. Significant Accounting Policies" to the Consolidated Financial Statements included in the Annual Report. There have been no material changes to the significant accounting policies previously disclosed in the Annual Report.

### Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which applies to all leases and will require lessees to record most leases on the balance sheet but recognize expenses in a manner similar to the current standard. In July 2018, the FASB issued ASU 2018-10, *Codification Improvements to Topic 842, Leases*, which provides narrow amendments to clarify how to apply certain aspects of ASU 2016-02, and ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides adopters an additional transition method by allowing entities to initially apply ASU 2016-02, and subsequent related standards, at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Additionally, in March 2019, the FASB issued ASU 2019-01, *Leases (Topic 842): Codification Improvements*, which clarifies the transition guidance related to interim disclosures provided in the year of adoption. ASU 2016-02 and related amendments and improvements are effective for fiscal years beginning after December 15, 2018 for public business entities and interim periods within those years and for all other entities for years beginning after December 15, 2020. Entities are required to use a modified retrospective approach of adoption for leases that exist or are entered into after the beginning of the transition date. A full retrospective application is prohibited. The Company is a public entity but took advantage of the relief provided for emerging growth companies to allow them to follow the private company adoption timelines and the Company will adopt this standard and the related improvements on January 1, 2021 by recognizing a cumulative-effect adjustment for any impact. The Company continues to evaluate the impact of adopting this standard on its accounting policies, financial statements, business processes, systems and internal controls. Additionally, the Company has established a project management and implementation team consisting of inter

resources and external advisors. These evaluation and implementation processes are expected to continue through 2020. The Company expects to recognize all of its leases with terms over twelve months on the balance sheet by recording a right-of-use asset and a corresponding lease liability.

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

### 3. Acquisition

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

The aggregate consideration amounted to \$19,024 as of the Acquisition Date, subject to post-closing adjustments for working capital. Total consideration consisted of \$6,427 in cash, 2,151,438 shares of the Company's Class A common stock with a fair value of \$8,815, and contingent consideration (the "Earnout" or "Earnout Liability") with a fair value of \$3,782. On the Acquisition Date, the Company paid \$5,820 in cash and issued 1,947,953 shares of the Company's class A common stock. The remaining consideration of \$1,436 was held back (the "Holdback") and will be paid or issued, as applicable, eighteen months after the Acquisition Date, subject to any offsetting indemnification claims against CPN.

The Company is obligated to pay an Earnout to CPN's former shareholders if CPN's legacy product revenue in a twelve-month period, starting on January 1, 2021 (the "Earnout Period"), exceeds CPN's 2019 revenue. The amount of the Earnout, if any, will be equal to 70% of the excess and will be payable in March 2022. The Company recorded a non-current liability of \$3,782, for the fair value of the contingent consideration related to the expected Earnout. The Earnout Liability is classified as a Level 3 measurement for which fair value is derived from inputs that are unobservable and significant to the overall fair value measurement. The fair value of such Earnout Liability is estimated using a Monte Carlo simulation model that utilizes key assumptions including forecasted revenues and volatilities of the underlying financial metrics during the Earnout period.

This transaction was accounted for as a business combination using the acquisition method of accounting in accordance with ASC Topic 805, *Business Combinations*. Assets acquired and liabilities assumed have been recorded at their estimated fair values as of the Acquisition Date. The fair values of intangible assets were based on valuations using various income approaches and methods, such as the multiperiod excess earnings method,

relief from royalty method, etc., which require the use of significant estimates and assumptions, including estimating future cash flows and developing appropriate discount rates. The excess of the purchase price over the tangible assets, identifiable intangible assets and assumed liabilities was recorded as goodwill.

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

Assets acquired:	
Accounts receivable	\$ 1,048
Inventory	1,230
Prepaid expenses and other current assets	1
Property and equipment	85
Intangible assets	13,570
Other assets	4
Total assets acquired	15,938
Liabilities assumed:	
Accounts payable	51
Accrued expenses and other current liabilities	240
Total liabilities assumed	291
Total identifiable assets acquired, net	15,647
Total purchase price	19,024
Goodwill	\$ 3,377

The preliminary fair values recorded were based on a preliminary valuation and the estimates and assumptions used in such valuation are subject to change, which could be significant, within the measurement period (up to one year from the acquisition date). The Company is continuing to obtain information to determine the acquired assets and liabilities, including tax assts, liabilities and other attributes.

The preliminary purchase price allocation resulted in goodwill of \$3,377, which will be deductible for income tax purposes. The resulting amount of goodwill is primarily attributed to expected synergies from cross-sale opportunities and future growth. Intangible assets of \$13,570 include customer relationships of \$10,690, developed technologies of \$2,050, non-competition agreements of \$750, and trademarks of \$80, which are being amortized on a straight-line basis, over weighted-average useful lives of 10 years, 6 years, 5 years and 1 year, respectively.

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

# 4. Product and Geographic Sales

The Company generates revenue through the sale of Advanced Wound Care and Surgical & Sports Medicine products. There is a single performance obligation in all of the Company's contracts, which is the Company's promise to transfer the Company's products to customers based on specific payment and shipping terms in the arrangement. The entire transaction price reflects a single performance obligation. Product revenue is recognized when a customer obtains control of the Company's products which occurs at a point in time and may be upon shipment, procedure date, or delivery, based on the terms of the contract. Revenue is recorded net of a reserve for returns, discounts and Group Purchasing Organization ("GPO") rebates, which represent a direct reduction to the revenue recognized. These reductions are accrued at the time revenue is recognized, based upon historical experience and specific circumstances. For the three months ended September 30, 2020 and 2019, the

Company recorded GPO fees of \$1,013 and \$880, respectively, as a direct reduction of revenue. For the nine months ended September 30, 2020 and 2019, the Company recorded GPO fees of \$2,810 and \$1,991, respectively, as a direct reduction of revenue.

The following tables set forth revenue by product category:

	Three Months Ended September 30,
	2020 2019
Advanced Wound Care	\$ 89,990 \$ 54,310
Surgical & Sports Medicine	10,809 9,955
Total net revenue	\$ 100,799 \$ 64,265
	Nine Months Ended
	September 30,
	2020 2019
Advanced Wound Care	
Advanced Wound Care Surgical & Sports Medicine	2020 2019
	$\begin{array}{c cccc}  & & & & & & & & & \\ \hline  & 2020 & & & & & & & \\  & $201,009 & & $157,365 \\ \end{array}$

For the three months ended September 30, 2020 and 2019, net PuraPly revenue totaled \$40,945 and \$31,755, respectively. For the nine months ended September 30, 2020 and 2019, net PuraPly revenue totaled \$101,969 and \$86,893, respectively. For all periods presented, net revenue generated outside the United States represented less than 1% of total net revenue.

# 5. Fair Value of Financial Assets and Liabilities

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values as of September 30, 2020. There was no such assets or liabilities as of December 31, 2019.

	a	Fair Value Measurements as of September 30, 2020 Using:			
	Level 1	Level 2	Level 3	Total	
Liabilities:					
Earnout Liability	<u>\$</u>	<u>\$</u>	\$3,782	\$3,782	
	\$ —	\$ —	\$3,782	\$3,782	

### Earnout Liability

In connection with accounting for the CPN acquisition on September 17, 2020, the Company recorded the Earnout Liability representing the fair value of contingent consideration payable upon the achievement of a certain revenue target. The Earnout Liability was valued using the Monte Carlo simulation model based on inputs that are not observable in the market, which represents a level 3 measurement within the fair value hierarchy. Changes in the fair value of the Earnout Liability will be reflected in selling, general and administrative expenses until the liability is fully settled. For more information about the Earnout Liability, refer to Note "3. Acquisition".

The Company did not have any financial assets and liabilities measured at fair value on a non-recurring basis as of September 30, 2020 and December 31, 2019.

# 6. Accounts Receivable, Net

Accounts receivable consisted of the following:

		December 31,	
	 020	2019	
Accounts receivable	\$ 62,040	\$ 42,408	
Less — allowance for sales returns and doubtful accounts	 (5,125)	(3,049)	
	\$ 56,915	\$ 39,359	

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

	End	Three Months Ended September 30.		Nine Months Ended September 30,	
	2020	2019	2020	2019	
Balance at beginning of period	\$3,928	\$3,021	\$3,049	\$3,420	
Additions (reductions)	1,589	(56)	2,559	(29)	
Write-offs	(392)	(30)	(483)	(456)	
Balance at end of period	\$5,125	\$2,935	\$5,125	\$2,935	

# 7. Inventories

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

	September 30, 2020	December 31, 2019
Raw materials	\$ 9,676	\$ 9,178
Work in process	1,499	781
Finished goods	18,707	12,959
	\$ 29,882	\$ 22,918

Raw materials include various components used in the Company's manufacturing process. The Company's excess and obsolete inventory review process includes analysis of sales forecasts and historical sales as compared to inventory level, and working with operations to maximize recovery of excess inventory. During the three months ended September 30, 2020 and 2019, the Company charged \$315 and \$286, respectively, for inventory excess and obsolescence to cost of goods sold within the consolidated statements of operations. During the nine months ended September 30, 2020 and 2019, the Company charged \$2,024 and \$809, respectively, for inventory excess and obsolescence to cost of goods sold within the consolidated statements of operations.

# 8. Property and Equipment, Net

Property and equipment consisted of the following:

	September 30, 2020	December 31, 2019
Leasehold improvements	\$ 39,169	\$ 36,344
Furniture, computers and equipment	47,798	46,430
	86,967	82,774
Accumulated depreciation and amortization	(68,559)	(65,812)
Construction in progress	37,529	30,222
	\$ 55,937	\$ 47,184

Depreciation expense was \$956 and \$792 for the three months ended September 30, 2020 and 2019. Depreciation expense was \$2,749 and \$2,553 for the nine months ended September 30, 2020 and 2019. As of September 30, 2020 and December 31, 2019, the Company had \$21,689 of buildings under capital leases recorded within leasehold improvements. As of September 30, 2020 and December 31, 2019, the Company had \$14,675 and \$13,777 recorded within accumulated depreciation and amortization related to buildings under capital leases, respectively. Construction in progress primarily represents unfinished construction work on a building under a capital lease and, more recently, improvements at the Company's leased facilities in Canton and Norwood, Massachusetts.

# 9. Goodwill and Intangible Assets

On September 17, 2020, the Company acquired certain assets and assumed certain liabilities of CPN. This transaction was accounted for as a business combination in accordance with ASC Topic 805 *Business Combinations*. The Company recorded \$3,377 of goodwill and \$13,570 of intangible assets associated with this acquisition. Refer to Note "3. Acquisition" for detail.

Goodwill was \$28,916 as of September 30, 2020 and \$25,539 as of December 31, 2019. There were no impairments recorded against goodwill during the three and nine months ended September 30, 2020 and 2019.

In April 2019, the Company purchased \$750 of intangibles related to patent and know-how which were recorded within the developed technology category. The Company paid \$250 at the time of the transaction with the remaining purchase price being paid over two years after the transaction closed. As of September 30, 2020, \$250 was remaining and was recorded in accrued expenses and other current liabilities on the consolidated balance sheets.

Identifiable intangible assets consisted of the following as of September 30, 2020:

	Original <u>Cost</u>	Accumulated Amortization	Net Book Value
Developed technology	\$32,620	\$ (13,503)	\$19,117
Trade names and trademarks	2,080	(828)	1,252
Customer relationships	10,690	(45)	10,645
Non-compete agreements	1,010	(175)	835
Total	\$46,400	\$ (14,551)	\$31,849

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

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

Amortization of intangible assets, calculated on a straight-line basis or using an accelerated method, was \$885 and \$1,529 for the three months ended September 30, 2020 and 2019, respectively, and \$2,518 and \$4,526 for the nine months ended September 30, 2020 and 2019, respectively.

### 10. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	September 30, 2020	December 31, 2019
Accrued personnel costs	\$ 21,158	\$ 17,640
Other	4,974	5,810
	\$ 26,132	\$ 23,450

# 11. Long-Term Debt Obligations

Long-term debt obligations consisted of the following:

	September 30, 2020	December 31, 2019
Line of credit	\$ 39,353	\$ 33,484
Term loan	60,000	50,000
Less debt discount and debt issuance cost	(334)	(366)
Less current maturities	(11,667)	_
Term loan, net of debt discount, debt issuance cost and current maturities	\$ 47,999	\$ 49,634

# 2019 Credit Agreement

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

The Term Loan Facility is structured in three tranches, as follows: (i) the first tranche of \$40,000 was made available to the Company and fully funded on March 14, 2019; (ii) the second tranche of \$10,000 was made available to the Company and fully funded in September 2019 upon achievement of certain financial metrics; and (iii) the third tranche of \$10,000 was made available to the Company and fully funded in March 2020 upon achievement of a certain financial metric. The interest rate for the Term Loan Facility is a floating per annum interest rate equal to the greater of 3.75% above the Wall Street Journal Prime Rate and 9.25%. The interest rate as of September 30, 2020 was 9.25%. The 2019 Credit Agreement requires the Company to make monthly interest-only payments on outstanding balances under the Term Loan Facility through February 2021. Thereafter, each term loan advance will be repaid in thirty-six equal monthly installments of principal, plus accrued interest, with the Term Loan Facility maturing on March 1, 2024 (the "Term Loan Maturity Date").

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

The Revolving Facility is equal to the lesser of \$40,000 and the amount determined by the Borrowing Base, which is defined as a percentage of the Company's book value of qualifying finished goods inventory and eligible accounts receivable. The interest rate for advances under the Revolving Facility is a floating per annum interest rate equal to the greater of the Wall Street Journal Prime Rate and 5.50%. The interest rate as of September 30, 2020 was 5.50%. If the actual outstanding advances are less than 25% of the then-available Revolving Commitments, the Company must pay monthly interest equal to the interest that would have accrued if the average outstanding advances had been 25% of the then-available Revolving Commitments. The Company is also required to pay an unused line fee equal to 0.25% per annum, calculated based on the difference of \$40,000 minus the greater of (i) the average balance outstanding under the Revolving Facility for such period and (ii) 25% of the then-available Revolving Commitments. The maturity date for advances made under the Revolving Facility is March 1, 2024.

The Company may elect to reduce or terminate the Revolving Facility in its entirety at any time by repaying all outstanding principal, unpaid accrued interest and a reduction or termination fee equal to 3.00% of the aggregate Revolving Commitments so reduced or terminated if the reduction or termination occurs after the 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 Company is required to achieve certain financial covenants under the 2019 Credit Agreement, including Minimum Trailing Twelve Month Consolidated Revenue and Non-PuraPly Revenue, tested quarterly. The Minimum Trailing Twelve Month Consolidated Revenue thresholds for the year ending December 31, 2020 were agreed to and the covenant requiring Trailing Twelve Month Non-PuraPly Revenue beginning with the quarter ending September 30, 2020 was added in connection with the third amendment to the 2019 Credit Agreement entered into on March 26, 2020. In addition, the Company is required to maintain Minimum Liquidity equal to the greater of (i) 6 months Monthly Burn and (ii) \$10,000.

As of September 30, 2020, the Company was in compliance with the financial covenants under the 2019 Credit Agreement.

As of September 30, 2020, the Company had outstanding borrowings of \$60,000 under the Term Loan Facility and \$39,353 under the Revolving Facility with \$0 available for future revolving borrowings. The Company accrues for the Final Payment of \$3,900 over the term of the Term Loan Facility through a charge to the interest expense. The related liability of \$1,541 and \$681 as of September 30, 2020 and December 31, 2019, respectively, was included in other liabilities on the consolidated balance sheets. The Company incurred costs of \$554 in connection with the Term Loan Facility, which are recorded as a reduction of the carrying value of the term loan on the Company's consolidated balance sheets. In connection with the Revolving Facility, the Company incurred costs of \$370, which are recorded as other assets. Both of these costs are being amortized to interest expense through March 1, 2024.

Future payments of the 2019 Credit Agreement, as of September 30, 2020, are as follows for the calendar years ending December 31:

2020	\$ —
2021	16,667
2022	20,000
2023	20,000
2024	42,686
Total	\$ 99,353

### 2017 Credit Agreement

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

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

### Master Lease Agreement

On April 28, 2017, the Company entered into the Master Lease Agreement (the "ML Agreement") with Eastward Fund Management LLC that allowed the Company to borrow up to \$20,000 on or prior to June 30, 2018. If the Company elected to prepay the loan or terminated the loan early within the first 24 months, the Company was required to pay an additional 3% of the outstanding principal and any accrued and unpaid interest and fees. This prepayment fee decreased 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 was due upon the earlier to occur of the first day of the final payment term month or prepayment of all outstanding principal. In March 2019, upon entering into the 2019 Credit Agreement, the Company paid an aggregate amount of \$17,649 due under the ML Agreement, including unpaid principal, accrued interest, final payment, and early termination penalty, with proceeds from the 2019 Credit Agreement, and the ML Agreement was terminated. Upon termination of the ML Agreement, the Company recognized \$1,862 as loss on the extinguishment of the loan.

### 12. Stockholders' Equity

#### Common Stock

As of September 30, 2020, the Company was authorized to issue 400,000,000 shares of \$0.0001 par value Class A common stock and 1,000,000 shares of \$0.0001 par value preferred stock. 108,185,702 shares of Class A common stock were issued as of September 30, 2020, which included 728,548 shares of treasury stock. These treasury shares were initially issued in connection with the acquisition of Nutech Medical, Inc. ("NuTech Medical") in 2017 and included a put right. The holders of the shares exercised the right to put the shares back to the Company at an agreed-upon exercise price of \$9.28 per share on March 24, 2019.

As of September 30, 2020 and December 31, 2019, the Company reserved the following shares of Class A common stock for future issuance:

	September 30, 2020	December 31, 2019
Shares reserved for issuance for outstanding options	6,788,655	6,503,646
Shares reserved for issuance for outstanding restricted stock units	819,248	_
Shares reserved for issuance for future grants	6,819,449	9,008,996
Total shares of authorized common stock reserved for future issuance	14,427,352	15,512,642

# Warrant Exchange and Warrant Exercise

In the third quarter of 2019, the Company executed a series of transactions related to its then outstanding 30,890,748 public warrants and 4,100,000 private placement warrants. The Company issued an aggregate of

2,845,280 shares of Class A common stock for 29,950,150 public warrants at an exchange rate of 0.095. The Company issued an aggregate of 80,451 shares of Class A common stock for the remaining public warrants at an exchange rate of 0.0855. The Company issued an aggregate of 389,501 shares of Class A common stock for the private placement warrants at an exchange rate of 0.095.

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

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

As the fair value of the warrants exchanged in the warrant exchange transactions immediately prior to the exchanges was less than the fair value of the common stock issued, the Company recorded a non-cash deemed dividend of \$0.6 million for the incremental fair value provided to the warrant holders in the three months ended September 30, 2019.

### 13. Stock-Based Compensation

### Stock Incentive Plans-the 2018 Plan

On November 28, 2018, the Board of Directors of the Company adopted, and on December 10, 2018 the Company's stockholders approved, the Organogenesis 2018 Equity and Incentive Plan (the "2018 Plan"). The purposes of the 2018 Plan are to provide long-term incentives and rewards to the Company's employees, officers, directors and other key persons (including consultants), to attract and retain persons with the requisite experience and ability, and to more closely align the interests of such employees, officers, directors and other key persons with the interests of the Company's stockholders.

The 2018 Plan authorizes the Company's Board of Directors or a committee of not less than two independent directors (in either case, the "Administrator") to grant the following types of awards: non-statutory stock options; incentive stock options; restricted stock awards; restricted stock units; stock appreciation rights; unrestricted stock awards; performance share awards; and dividend equivalent rights. The 2018 Plan is administered by the Company's Board of Directors.

As of September 30, 2020, a total of 9,198,996 shares of Class A common stock have been authorized to be issued under the 2018 Plan (subject to adjustment in the case of any stock dividend, stock split, reverse stock split, or similar change in capitalization of the Company).

### Stock Incentive Plans-the 2003 Plan

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

Effective as of the closing of the Avista Merger on December 10, 2018, no additional awards may be made under the 2003 Plan and as a result (i) any shares in respect of stock options that are expired or terminated under the 2003 Plan without having been fully exercised will not be available for future awards; (ii) any shares in respect of restricted stock that are forfeited to, or otherwise repurchased by the Company, will not be available for future awards; and (iii) any shares of common stock that are tendered to the Company by a participant to exercise an award will not be available for future awards.

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

### Stock-Based Compensation Expense

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

Stock-based compensation expense was \$486 and \$242 for the three months ended September 30, 2020 and 2019, respectively, and was \$1,164 and \$700 for the nine months ended September 30, 2020 and 2019, respectively. The total amount of stock-based compensation expense was included within selling, general and administrative expenses on the consolidated statements of operations.

### Restricted Stock Units (RSUs)

In the nine months ended September 30, 2020, the Company granted 873,595 time-based restricted stock units to its employees, executives and the Board of Directors. Each restricted stock unit represents the contingent right to receive one share of the Company's common stock. A majority of the restricted stock units will vest in four equal annual installments in 2021, 2022, 2023 and 2024. The fair value of the restricted stock units was based on the fair market value of the Company's stock on the date of grant.

The activity of restricted stock units is set forth below:

Number of Shares	Weighted Average Grant Date Fair Value
	\$ —
873,595	3.81
_	_
(54,347)	3.69
819,248	\$ 3.82
	of Shares

As of September 30, 2020, the total unrecognized compensation cost related to unvested restricted stock units expected to vest was \$1,977 and the weighted average remaining recognition period for unvested awards was 3.21 years.

# Stock Option Valuation

The stock options granted during the nine months ended September 30, 2020 and 2019 were 1,553,723 and 100,000 respectively. The assumptions that the Company used to determine the grant-date fair value of stock options granted during these periods were as follows, presented on a weighted-average basis:

	September 30, 2020		mber 30, 2019
Risk-free interest rate	0.46%	<u>-</u>	2.24%
Expected term (in years)	6.22		6.50
Expected volatility	37.42%		42.7%
Expected dividend yield	0.0%		0.0%
Exercise price	\$ 4.04	\$	7.08
Underlying stock price	\$ 3.37	\$	7.08

These assumptions resulted in an estimated weighted-average grant-date fair value per share of stock options granted during the nine months ended September 30, 2020 and 2019 of \$1.05 and \$3.24, respectively.

# Stock Option Activity

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

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2019	7,179,636	\$ 1.98	5.06	\$ 20,799
Granted	1,553,723	4.04		
Exercised	(638,315)	2.02		1,623
Canceled / forfeited	(630,399)	3.64		
Outstanding as of September 30, 2020	7,464,645	2.27	5.53	12,855
Options exercisable as of September 30, 2020	5,512,393	1.60	4.20	12,701
Options vested or expected to vest as of September 30, 2020	7,062,928	\$ 2.16	5.30	\$ 12,835

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's Class A common stock for those stock options that have exercise prices lower than the fair value of the Company's Class A common stock.

The total fair value of options vested during the nine months ended September 30, 2020 and 2019 was \$387 and \$538, respectively.

As of September 30, 2020, the total unrecognized stock compensation expense related to unvested stock options expected to vest was \$1,598 and was expected to be recognized over a weighted-average period of 2.90 years.

As of September 30, 2020, partial recourse notes were outstanding totaling \$635. These notes were taken by a former executive to exercise his stock options between 2011 and 2013 and the notes were initially secured with the 675,990 shares held by the former executive. As the partial recourse notes are still outstanding, the options are not considered exercised and are included within the options outstanding. Accordingly, the 675,990 shares are not considered outstanding for accounting purposes and the additional paid-in capital associated with these shares were deducted from equity in prior periods. In the three months ended September 30, 2020, the former executive sold 25,096 of the 675,990 shares to pay back a portion of his nonrecourse notes. see Note "16. Related Parties Transactions".

# 14. Net Income (Loss) per Share (EPS)

Basic EPS is calculated by dividing net income (loss) by the weighted-average number of shares outstanding during the period. Diluted EPS is calculated by dividing net income (loss) by the weighted-average number of shares outstanding plus the dilutive effect, if any, of outstanding RSUs and options using the treasury stock method. The calculation of the dilutive effect of outstanding equity awards under the treasury stock method includes consideration of unrecognized compensation expenses as additional proceeds.

A reconciliation of the numerator and denominator used in the calculation of the basic and diluted net income (loss) attributable to the common stockholders of Organogenesis Holdings Inc. is as follows.

	Three Months Ended					Nine Months Ended				
	September 30,				er 30,					
Calculation of Basic and Diluted EPS	2020	0	2	2019	2	2020	2	2019		
Weighted-average common shares outstanding—basic	105,04	0,035	92,2	276,858	104,	,748,297	91,1	182,233		
Dilutive effect of restricted stock units	13	4,759		_		_		_		
Dilutive effect of options	3,31	4,974		—		_		_		
Weighted-average common shares outstanding—diluted	108,48	9,768	92,2	276,858	104,	,748,297	91,1	182,233		
Earnings (loss) per share—basic	\$	0.20	\$	(0.12)	\$	(0.01)	\$	(0.40)		
Earnings (loss) per share—diluted	\$	0.19	\$	(0.12)	\$	(0.01)	\$	(0.40)		

For the three months ended September 30, 2020, outstanding stock-based awards of 2,009,245 were excluded from the diluted EPS calculation. The Company had a net loss in the other periods presented. As such, the potentially dilutive securities have been excluded from the computation of diluted net loss per share as these securities have anti-dilutive effect and including them would reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same for these periods. For the three months ended September 30, 2019, the Company excluded 7,263,990 potential shares of Class A common stock, presented based on amount outstanding at this period end, from the computation of diluted net loss per share attributable to the common stockholders for this period. For the nine months ended September 30, 2020 and 2019, the Company excluded 8,283,893 and 7,263,990 potential shares of Class A common stock, respectively, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to the common stockholders for these periods.

# 15. Commitments and Contingencies

#### Capitalized Leases

On January 1, 2013, the Company entered into capital lease arrangements with 65 Dan Road SPE, LLC, 85 Dan Road Associates, LLC, Dan Road Equity I, LLC and 275 Dan Road SPE, LLC for office and laboratory space in Canton, Massachusetts. 65 Dan Road SPE, LLC, 85 Dan Road Associates, LLC, Dan Road Equity I, LLC and 275 Dan Road SPE, LLC are related parties as the owners of these entities are also stockholders of the Company. The leases terminate on December 31, 2022 and each contains a renewal option for a five-year period with the rental rate at the greater of (i) rent for the last year of the prior term, or (ii) the then fair market value. Notice of the exercise of this renewal option is due one year prior to the expiration of the initial term. Aggregate annual lease payments are approximately \$4,308 with future rent increases of 10% effective January 1, 2022.

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

As of September 30, 2020 and December 31, 2019, the Company owed an aggregate of \$10,336 of accrued but unpaid lease obligations, which are subordinated to the 2019 Credit Agreement and will not be paid until the debt under the 2019 Credit Agreement is paid off in 2024 even though the capital leases expire in December 2022. The accrued but unpaid lease obligations include rent in arrears and unpaid operating and common area maintenance costs under the aforementioned leases. The principal portion of rent in arrears on the capital leases totaled \$6,783 and \$6,321 as of September 30, 2020 and December 31, 2019, respectively, and is included in the long-term portion of capital lease obligations. The interest portion of rent in arrears totaled \$3,042 and \$3,512 as of September 30, 2020 and December 31, 2019, respectively, and is included in other liabilities on the consolidated balance sheets. The unpaid operating and common area maintenance costs totaled \$511 and \$503 as of September 30, 2020 and December 31, 2019, respectively, and are included in other liabilities on the consolidated balance sheets.

Effective April 1, 2019, the Company agreed to accrue interest on the accrued but unpaid lease obligations at an interest rate equal to the rate charged in the 2019 Credit Agreement (see Note "11. Long-Term Debt Obligations"). The accrued interest is also subordinated to the 2019 Credit Agreement and, as such, is included in other liabilities on the consolidated balance sheet. Interest accrual as of September 30, 2020 and December 31, 2019 totaled \$1,434 and \$717, respectively.

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

2020 (remaining 3 months)	\$ 1,198
2021	4,786
2022	4,945
2023	_
2024	9,825
	20,754
Less amount representing interest	(5,042)
Present value of minimum lease payments	15,712
Less current maturities	(3,473)
Long-term portion	\$12,239

#### **Operating Leases**

The Company leases vehicles for certain employees and has fleet services agreements for service on these vehicles. The minimum lease term for each newly leased vehicle is one year with three consecutive one-year renewal terms.

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

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

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

Operating lease expenses were \$1,620 and \$1,766 for the three months ended September 30, 2020 and 2019, respectively, and were \$4,971 and \$4,993 for the nine months ended September 30, 2020 and 2019, respectively.

Future minimum lease payments due under noncancelable operating lease agreements as of September 30, 2020 are as follows:

2020 (remaining 3 months)	\$ 1,250
2021	5,974
2022	3,471
2023	2,804
2024	1,224
Thereafter	$\frac{6,899}{$21,622}$
	\$ 21,622

#### Royalty Commitments

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 September 30, 2020 and December 31, 2019, respectively, and are classified as part of accrued expenses on the Company's consolidated balance sheets. There was no royalty expense incurred during the three and nine months ended September 30, 2020 or 2019 related to this agreement.

In October 2017, the Company entered into a license agreement with a third party. Under the license agreement, the Company is required to pay royalties based on a percentage of net sales of the licensed product that occur, after December 31, 2017, through the expiration of the underlying patent in October 2026, subject to minimum royalty payment provisions. The Company recorded royalty expense of \$1,201 and \$991 during the three months ended September 30, 2020 and 2019, respectively, and \$3,020 and \$2,695 during the nine months ended September 30, 2020 and 2019, respectively, within selling, general and administrative expenses on the consolidated statement of operations.

As part of the NuTech Medical acquisition, the Company inherited certain product development and consulting agreements for ongoing consulting services and royalty payments based on a percentage of net sales on certain products over a period of 15 years from the execution of the agreements. These product development and consulting agreements were cancelled in January 2020 for total consideration of \$1,950 that was paid on February 14, 2020. The \$1,950 cancellation fee was recorded within selling, general and administrative expenses on the consolidated statement of operations for the nine months ended September 30, 2020.

#### Ransomware Attack

In August 2020, the Company's information technology ("IT") systems were exposed to a ransomware attack, which partially impaired certain IT systems for a short period of time. The Company is investigating the incident, together with legal counsel and other incident response professionals. The Company does not believe it has experienced a material loss related to the ransomware attack, and substantially all costs incurred to date are expected to be reimbursed by insurance.

# Legal Proceedings

In conducting its activities, the Company, from time to time, is subject to various claims and also has claims against others. In management's opinion, the ultimate resolution of such claims would not have a material effect on the financial position, operating results or cash flows of the Company. The Company accrues for these claims when amounts due are probable and estimable.

The Company accrued \$158 and \$542 as of September 30, 2020 and December 31, 2019, respectively, in relation to certain pending lawsuits.

The purchase price for NuTech Medical acquired in 2017 included \$7,500 deferred acquisition consideration of which the Company paid \$2,500 in 2017. The remaining \$5,000 of deferred acquisition consideration plus accrued interest owed to the sellers of NuTech Medical was previously in dispute. The Company asserted certain claims for indemnification that would offset in whole or in part its payment obligation and the sellers of NuTech Medical filed a lawsuit alleging breach of contract and seeking specific performance of the alleged payment obligation and attorneys' fees. In February 2020, the Company entered into a settlement agreement with the sellers of NuTech Medical and settled the dispute for \$4,000, of which, \$2,000 was paid immediately on February 24, 2020 (the "Settlement Date") and the remaining \$2,000 is being paid in four quarterly installments of \$500 each with the first quarterly payment due and payable on the date that is 90 days from the Settlement Date. In addition, the Company assumed from the sellers of NuTech Medical the payment responsibilities related to a legacy lawsuit existing at the acquisition date of NuTech Medical. In connection with the settlement of this dispute, the Company recorded a gain of \$1,295 for the three months ended March 31, 2020. The assumed legacy lawsuit was settled in October 2020 and the Company recorded a gain of \$951 from the decrease in legal accrual for the three months ended September 30, 2020. Both of the gains were included as a component of other expense, net, on the consolidated statement of operations.

#### 16. Related Party Transactions

Capital lease obligations to affiliates, including unpaid lease obligations, and an operating lease with affiliates are further described in Note "15. Commitments and Contingencies".

During 2010, the Company's Board of Directors approved a loan program that permitted the Company to make loans to three executives of the Company (the "Employer Loans") to (i) provide them with liquidity ("Liquidity Loans") and (ii) fund the exercise of vested stock options ("Option Loans"). The Employer Loans mature with all principal and accrued interest due on the tenth anniversary of the issuance date of each subject loan. The borrower may prepay all or any portion of his Employer Loan at any time without premium or penalty. Interest on the Employer Loans accrues at various rates ranging from 2.30%—3.86% per annum, compounded annually. The Employer Loans are secured by shares of Company's Class A common stock. With respect to the Liquidity Loans, the Company has no personal recourse against the borrowers beyond the pledged shares.

As of September 30, 2020, Liquidity Loans and Option Loans to one former executive were outstanding with an aggregate principal balance of \$297 and \$635, respectively As of December 31, 2019, Liquidity Loans to two former executives were outstanding with an aggregate principal balance of \$2,350 and Option Loans to one former executive were outstanding with an aggregate principal balance of \$635. The principal and part of the interest receivable under the Employer Loans were fully reserved with net interest receivable of \$0 and \$556 as of September 30, 2020 and December 31, 2019, respectively, included in the notes receivable from related parties balance in the consolidated balance sheets. In the three months ended September 30, 2020, one of the former executives paid \$1,000 of the outstanding principal balance of his liquidity loans and the related interest receivable. The Company forgave \$1,000 of the remaining outstanding principal balance of his liquidity loans. The other former executive paid \$53 of the outstanding principal balance of his liquidity loans and \$58 of the related accrued interest. As a result, the Company recorded \$1,111 as a recovery of the previously reserved related party receivables within selling, general and administrative expenses on the consolidated statement of operations for the three months ended September 30, 2020.

# 17. Subsequent Events

The Company has evaluated subsequent events through November 9, 2020, the date on which these consolidated financial statements were issued.

On October 21, 2020, the Company committed to a plan to restructure the workforce and consolidate La Jolla facilities as part of the Company's long-term plan to consolidate manufacturing operations in Massachusetts in order to reduce the Company's cost structure. The restructuring is expected to result in a charge of approximately \$5.5 million, which is primarily attributable to the retention benefits associated with approximately 75 employees.

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

# **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Organogenesis Holdings Inc. and its subsidiaries (the Company) as of December 31, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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 9, 2020

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

		ber 31,
Assets	2019	2018
Current assets:		
Cash	\$ 60.174	\$ 21,291
Restricted cash	196	114
Accounts receivable, net	39,359	34,077
Inventory	22,918	13,321
Prepaid expenses and other current assets	2,953	2,328
Total current assets	125,600	71,131
Property and equipment, net	47,184	39,623
Notes receivable from related parties	556	477
Intangible assets, net	20,797	26,091
Goodwill	25,539	25,539
Deferred tax asset	127	238
Other assets	884	579
Total assets	\$ 220,687	\$ 163,678
Liabilities and Stockholders' Equity	<del></del>	
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	3,057	2,236
Accounts payable	28,387	19,165
Accrued expenses and other current liabilities	23,450	20,388
Total current liabilities	59,894	56,096
Line of credit	33,484	26,484
Notes payable, net of current portion	_	12,578
Term loan	49,634	_
Deferred rent	1,012	130
Capital lease obligations, net of current portion	14,431	15,418
Other liabilities	6,649	5,931
Total liabilities	165,104	116,637
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 400,000,000 shares authorized; 105,599,434 and 91,261,413 shares issued;		
104,870,886 and 91,261,413 shares outstanding at December 31, 2019 and 2018, respectively.	10	9
Additional paid-in capital	226,580	177,272
Accumulated deficit	(171,007)	(130,240)
Total stockholders' equity	55,583	47,041
Total liabilities and stockholders' equity	\$ 220,687	\$ 163,678

# ORGANOGENESIS HOLDINGS INC. CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	Year Ended December 31,				
		2019	2018	_	2017
Net revenue	\$	260,981	\$ 193,449	\$	198,508
Cost of goods sold		75,948	68,808		61,220
Gross profit		185,033	124,641		137,288
Operating expenses:					
Selling, general and administrative		199,693	161,961		133,717
Research and development		14,799	10,742		9,065
Write-off of deferred offering costs			3,494		
Total operating expenses		214,492	176,197		142,782
Loss from operations		(29,459)	(51,556)		(5,494)
Other expense, net:			·		
Interest expense, net		(8,996)	(10,789)		(8,010)
Change in fair value of warrants		_	(469)		(1,037)
Loss on the extinguishment of debt		(1,862)	(2,095)		_
Other income (expense), net		13	162		(9)
Total other expense, net		(10,845)	(13,191)		(9,056)
Net loss before income taxes		(40,304)	(64,747)		(14,550)
Income tax (expense) benefit		(150)	(84)		7,025
Net loss		(40,454)	(64,831)		(7,525)
Net income attributable to non-controlling interest in affiliates		_	<del>-</del>		863
Net loss attributable to Organogenesis Holdings Inc.		(40,454)	(64,831)		(8,388)
Accretion of redeemable common shares		_	_		(423)
Non-cash deemed dividend to warrant holders		(645)	_		_
Net loss attributed to Organogenesis Holdings Inc. common shareholders	\$	(41,099)	\$ (64,831)	\$	(8,811)
Net loss per share attributable to Organogenesis Holdings Inc. common shareholders—basic	-				
and diluted	\$	(0.44)	\$ (0.94)	\$	(0.14)
Weighted average common shares outstanding—basic and diluted	92	2,840,401	69,318,456	6	3,876,767
-	_			_	

# ORGANOGENESIS HOLDINGS INC. CONSOLIDATED STATEMENTS OF REDEEMABLE COMMON STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(in thousands, except share amounts)

	Redeer						Total Organogenesis	Non-	
	Common	Stock	Common St	ock	Additional Paid-in	Accumulated	Holdings Inc. Stockholders'	controlling Interest in	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)	Affiliates	Equity (Deficit)
Balances as of December 31, 2016		\$ —	63,872,058	\$ 6	\$ 33,563	\$ (55,647)	\$ (22,078)	\$ 6,099	\$ (15,979)
Shares issued in connection with NuTech Medical acquisition	728,548	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	728,548	\$ 6,762	66,983,139	\$ 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	728,548	\$ —	91,261,413	\$ 9	\$177,272	\$ (130,240)	\$ 47,041	\$ —	\$ 47,041
Adoption of ASC 606		_		_		332	332	_	332
Exercise of common stock warrants	_	_	74,052	_	628	_	628	_	628
Exercise of stock options	_	_	152,133	_	269	_	269	_	269
Common stock issued in warrant exchange	_	_	3,315,232	_	645	(645)	_	_	_
Stock-based compensation expense	_	_		_	936		936	_	936
Redemption of redeemable common stock placed into treasury	(728,548)	_		_	_	_	_	_	_
Stock issued in the Underwritten Public Offering, net of issuance costs of									
\$3,510			10,068,056	1	46,830	_	46,831	_	46,831
Net loss						(40,454)	(40,454)		(40,454)
Balance as of December 31, 2019		<u>\$</u>	104,870,886	\$ 10	\$226,580	\$ (171,007)	\$ 55,583	<u>\$</u>	\$ 55,583

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

		Year Ended December 31,		
	2019	2018	2017	
Cash flows from operating activities:	****	0.64.221	A (= ===	
Net loss	\$(40,454)	\$(64,831)	\$ (7,525)	
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	3,388	3,309	3,591	
Amortization of intangible assets	6,043	3,669	2,037	
Non-cash interest expense	243	845	410	
Deferred interest expense	1,446	249	233	
Deferred rent expense	882	56	70	
Deferred tax benefit (expense)	111	186	(7,301)	
Loss (gain) on disposal of property and equipment	146	1,209	(8)	
Impairment of notes receivable	_	_	113	
Write-off of deferred offering costs	_	3,494		
Provision recorded for sales returns and doubtful accounts	239	1,157	1,166	
Provision recorded for inventory reserve	1,297	2,473	3,170	
Stock-based compensation	936	1,075	919	
Change in fair value of warrant liability	_	469	1,037	
Loss of extinguishment of debt	1,862	2,095	_	
Change in fair value of interest rate swap	· —	_	6	
Changes in fair value of forfeiture rights	_	589	(212)	
Changes in operating assets and liabilities:				
Accounts receivable	(4,691)	(7,110)	(7,010)	
Inventory	(11,063)	(1,524)	(1,490	
Prepaid expenses and other current assets	(625)	(1,414)	(2,680	
Accounts payable	4,700	(60)	3,967	
Accrued expenses and other current liabilities	2,942	2,354	2,665	
Accrued interest—affiliate debt	_	(9,241)	3,190	
Other liabilities	(930)	316	159	
Net cash used in operating activities	(33,528)	(60,635)	(3,493)	
Cash flows from investing activities:	(55,526)	(00,033)	(3,773)	
Purchases of property and equipment	(5,984)	(1,857)	(2,426	
Acquisition of intangible asset	(250)	(1,037)	(2,720	
Proceeds from disposal of property and equipment	(250)	1	8	
Acquisition of NuTech Medical, net of cash acquired		<u> </u>	(11,790	
VIE deconsolidation	_	_	(666)	
	(6.224)	(1.05()		
Net cash used in investing activities	(6,234)	(1,856)	(14,874)	
Cash flows from financing activities:	7,000	0.066	10.740	
Line of credit borrowings, net	7,000	8,866	12,749	
Proceeds from term loan	50,000			
Proceeds from long-term debt—affiliates	<u> </u>	15,000	_	
Proceeds from notes payable—master lease			16,000	
Proceeds from equity financing	50,340	92,000	_	
Payment of equity issuance costs	(2,973)	(270)	_	
Payment of recapitalization costs	_	(11,206)	_	
Repayment of mortgage notes payables—Real Estate Entities, net			(1,335)	
Repayment of debt and debt issuance cost on affiliate debt	_	(22,680)	_	

	Year Ended December 31,					
Demonstrate and a function of the state of t		2019		2018	_	2017
Repayment of notes payable	,	17,585)		(10)		(6,325)
Principal repayments of capital lease obligations		(1,266)		(104)		(81)
Redemption of redeemable common stock placed into treasury		(6,762)		_		_
Proceeds from the exercise of stock options		269		119		221
Proceeds from the exercise of common stock warrants		628		_		_
Cash contributions from members of affiliates		_				1,000
Payments of deferred acquisition consideration		_		_		(2,500)
Payment of debt issuance costs		(924)		(177)	_	(862)
Net cash provided by financing activities		78,727	8	1,538		18,867
Change in cash and restricted cash		38,965	1	9,047		500
Cash and restricted cash, beginning of year		21,405		2,358		1,858
Cash and restricted cash, end of year	\$	60,370	\$2	1,405	\$	2,358
Supplemental disclosure of cash flow information:						
Cash paid for interest	\$	8,148	\$	5,423	\$	6,076
Cash paid for income taxes	\$	49	\$	8	\$	96
Supplemental disclosure of non-cash investing and financing activities:						
Fair value of shares issued in connection with investor debt settlement	\$	_	\$4	2,764	\$	_
Fair value of shares issued in connection with settlement of investor warrants	\$	_	\$	2,707	\$	
Common stock issued in exchange for APHAC shares	\$	_	\$	1	\$	_
Notice of put option exercise of redeemable common shares	\$	_	\$	6,762	\$	
Non-cash deemed dividend related to warrant exchange	\$	645	\$	_	\$	_
Equity issuance costs included in accounts payable	\$	537	\$	_	\$	
Purchases of property and equipment in accounts payable and accrued expenses	\$	4,014	\$	172	\$	764
Acquisition of intangible assets included in accrued expenses and other liabilities	\$	500	\$	_	\$	
Equipment acquired under capital lease	\$	1,099	\$	_	\$	_
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

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Amounts in thousands, except share and per share amounts)

#### 1. Nature of Business and Basis of Presentation

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

#### 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 and AHPAC changed its name to Organogenesis Holdings Inc. (ORGO).

The Avista Merger was accounted for as a reverse merger in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Under this method of accounting, AHPAC was treated as the "acquired" company for accounting purposes. 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 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.

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). 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.

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

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

Concurrently with the completion of the Avista Merger, the affiliate debt was discharged and terminated (See Note "10. Long-Term Debt—Affiliates").

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

# Acquisition of Nutech Medical, Inc.

On March 18, 2017, the Company purchased Nutech Medical, Inc. ("NuTech Medical") pursuant to an Agreement of Plan of Merger ("NuTech Merger Agreement") for an aggregate consideration of \$12,000 in cash at closing, \$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 728,548 shares were redeemable and 2,185,647 shares were subject to forfeiture in the event certain adverse FDA events occur during the one-year period following the acquisition. Upon the closing of the merger, NuTech Medical merged with and into Prime Merger Sub, LLC (a wholly-owned subsidiary organized for the purposes of this transaction), 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 since March 24, 2017, which was the closing date of the merger.

For the restricted shares of Class A common stock which were subject to forfeiture, 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 was remeasured at each balance sheet date with the change in the fair value being recorded within selling, general and administrative expenses in the consolidated statement of operations. The forfeiture rights expired in March 2018 because there was no adverse FDA event. The fair value of the contingent consideration forfeiture rights was determined to be \$0 and \$589 as of December 31, 2018 and 2017, respectively.

#### Liquidity and Financial Conditions

In accordance with ASC 205-40, Going Concern ("ASC 205-40"), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. The Company has incurred a recurring loss from operations since its inception and has funded its operations primarily with cash flow from product sales and proceeds from loans from affiliates and entities controlled by its affiliates, sales of its common stock and third-party debt. As of December 31, 2019, the Company had an accumulated deficit of \$171,007 and working capital of \$65,706. For the year ended December 31, 2019, the Company has incurred net losses of \$40,454, used \$33,528 of cash in operations and raised \$50,340 in gross proceeds in the Underwritten Public Offering (see Note "12. Stockholders' Equity"). The Company expects to continue to generate operating losses for the foreseeable future as the Company expends resources to grow the organization

to support the planned expansion of the business. The Company expects that its cash of \$60,174 as of December 31, 2019, plus cash flows from product sales and availability under the 2019 Credit Agreement (see Note "11. Line of Credit and Notes Payable"), will be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments for at least 12 months beyond the filing date of the Company's annual report on Form 10-K for the fiscal year ended December 31, 2019.

The Company expects to continue investing in product development, sales and marketing and customer support for its products. The Company may seek to raise additional funding through public and/or private equity financings, debt financings or other strategic transactions. There can be no assurance that the Company will be able to obtain additional debt or equity financing on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations, and financial condition. The 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 and outcomes may differ significantly from those estimates and assumptions.

#### **Principles of Consolidation**

The consolidated financial statements include the accounts and results of operations of Organogenesis Holdings Inc., and its wholly-owned subsidiaries, Organogenesis Inc. and the wholly-owned subsidiaries of Organogenesis Inc., including Organogenesis GmbH (a Switzerland corporation) and Prime Merger Sub, LLC. 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 Associates, LLC, 85 Dan Road Associates, LLC and Canton 65 Dan Road Associates, LLC (each a "Real Estate Entity," collectively the "Real Estate Entities") were variable interest entities requiring consolidation through the deconsolidation date of June 1, 2017. 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. The results of operations for the years ended December 31, 2017 include the operations for the years ended December 31, 2019 and 2018, and the results of operations for the years ended December 31, 2019 and 2018, do not include the accounts of the Real Estate Entities.

All intercompany balances and transactions have been eliminated in consolidation.

#### Segment Reporting

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

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

# Cash and Cash Equivalents

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

#### Restricted Cash

The Company had restricted cash of \$196 and \$114 as of December 31, 2019 and 2018, respectively. Restricted cash represents employee deposits in connection with the Company's health benefit plan.

#### Accounts Receivable

Accounts receivable are stated at invoice value less estimated allowances for sales returns and doubtful accounts. The Company estimates the allowance for sales returns based on a historical percentage of returns over a twelve-month trailing average of sales. The Company continually monitors customer payments and maintains a reserve for estimated losses resulting from its customers' inability to make required payments. The Company considers factors when estimating the allowance for doubtful accounts such as historical experience, credit quality, age of the accounts receivable balances, geography-related risks and economic conditions that may affect a customer's ability to pay. In cases where there are circumstances that may impair a specific customer's ability to meet its financial obligations, a specific allowance is recorded against amounts due, thereby reducing the net recognized receivable to the amount reasonably believed to be collectible. Accounts receivables are written off when deemed uncollectible. Recoveries of accounts receivables previously written off are recorded when received.

#### Inventories

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

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

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

# Property and Equipment, Net

Property and equipment are recorded at cost and depreciated over the estimated useful lives of the respective assets on a straight-line basis. As of December 31, 2019 and 2018, the Company's property and equipment

consisted of leasehold improvements, furniture and computers, and equipment. Property and equipment estimated useful lives are as follows:

Leasehold improvements Lesser of the life of the lease or the economic life

of the asset

Furniture and computers 3 - 5 years Equipment 5 - 10 years

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

#### Goodwill

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

In accordance with ASC Topic 350, *Intangibles—Goodwill and Other*, the Company first assesses qualitative factors to determine whether it is necessary to perform the quantitative goodwill impairment test. If after assessing the totality of events or circumstances, the Company determines that it is more likely than not (i.e. greater than 50% likelihood) that the fair value of the reporting unit is less than its carrying amount, then the quantitative test is required. Otherwise, no further testing is needed. Alternatively, the Company can bypass the qualitative test and proceed directly to the quantitative test. The quantitative goodwill impairment test requires the Company to estimate and compare the fair value of the reporting unit with its carrying value. If the fair value of the reporting unit exceeds the carrying value 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 recorded during the years ended December 31, 2019, 2018 or 2017.

#### 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 or accelerated method based on the following estimated useful lives:

Trade names and trademarks

Developed technology

Independent sales agency network

Non-compete agreements

10-12 years
10-12 years
3 years
5 years

#### Impairment of Long-Lived Assets

Long-lived assets consist primarily of property and equipment and intangible assets. The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. Factors that the Company considers in deciding when to perform an impairment review include, but not limited to, significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. When such an event occurs, the Company determines whether there has been impairment by comparing the anticipated undiscounted future net cash flows to the related asset group's carrying value. If an asset is determined to be impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised value, depending on the nature of the asset. The Company did not record any impairment of long-lived assets during the years ended December 31, 2019, 2018 or 2017.

# **Deferred Offering Costs**

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

The Company did not record any deferred offering costs in the consolidated balance sheets as of December 31, 2019 and 2018. During the year ended December 31, 2019, the Company recorded \$3,510 of equity issuance costs to the additional paid-in capital against proceeds received from the Underwritten Public Offering (see Note "12. Stockholders' Equity"). During the year ended December 31, 2018, the Company wrote off deferred offering costs of \$3,494 in connection with an abandoned public offering which was replaced with the Avista Merger transaction and recorded \$270 of equity issuance costs to the additional paid-in capital against proceeds received from the Initial Avista Investment equity financing transaction.

# Warrant Liability

In connection with the issuance of the 2016 Loans, the Company issued to the loan holders warrants to purchase shares of Class A common stock. The Company classified the warrants as a liability on its consolidated balance sheet because each warrant provided for down-round protection which would cause the exercise price of the warrants to be adjusted if future equity issuances were below the current exercise price of the warrants. The price of the warrant was also subject to adjustment any time the price of another equity-linked instrument

changed. The warrant liability was initially recorded at fair value upon issuance and was subsequently remeasured to fair value at each reporting date until the warrants were net exercised in December 2018 in connection with the Avista Merger. Changes in the fair value of the warrant liability were recognized as a component of other income (expense), net in the consolidated statements of operations. The Company had no warrant liability as of December 31, 2019 and 2018.

#### Revenue Recognition

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

The Company adopted ASC 606 on January 1, 2019, using the modified retrospective method for all contracts not completed as of the date of adoption. The reported results for the year ended December 31, 2019 reflect the application of ASC 606 guidance while the reported results for the years ended December 31, 2018 and 2017 were prepared under the guidance of ASC Topic 605, *Revenue Recognition* ("ASC 605"). The adoption of ASC 606 represents a change in accounting principle that more closely aligns revenue recognition with the transfer of control of the Company's products and provides enhanced disclosures to understand the nature, amount, timing, and uncertainty of revenues and cash flows arising from contracts with customers. In accordance with ASC 606, revenue is recognized when a customer obtains control of promised products. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these products.

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

#### Product Revenue

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

#### Reserves for Variable Consideration

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

#### Product Returns

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

#### Rebates and Allowances

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

#### GPO Fees

The Company pays fees to GPOs for administrative services that the GPOs perform in connection with the purchases of the product by the GPO members. These fees are based on a contractually-determined percentage of the Company's applicable sales. The Company classifies these GPO fees as a reduction of revenue based on the substance of the relationship of all parties involved in the transaction. For the years ended December 31, 2019, 2018 and 2017, the Company recorded GPO fees of \$3,096, \$1,923 and \$1,159, respectively, as a direct reduction of revenue.

#### Other Revenue Policies

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

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

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

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

# Disaggregation of Revenue

The following table sets forth revenue by product category:

	Ye	Year Ended December 31,			
	2019	2018	2017		
Advanced Wound Care revenue	\$ 220,744	\$ 164,332	\$ 178,896		
Surgical and Sports Medicine revenue	40,237	29,117	19,612		
Total revenue	\$ 260,981	\$ 193,449	\$ 198,508		

For the years ended December 31, 2019, 2018 and 2017, net PuraPly revenue totaled \$126,812, \$69,773 and \$109,085, respectively. For all periods presented, net revenue generated outside the US represented less than 1% of total net revenue.

# Stock-Based Compensation

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

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

### Advertising

Advertising costs are expensed as incurred and are included in selling, general and administrative expense in the consolidated statements of operations. Advertising costs were approximately \$1,059, \$773, and \$947 for the years ended December 31, 2019, 2018 and 2017, respectively.

# Research and Development Costs

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

#### Foreign Currency

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

#### 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.

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

#### Fair Value of Financial Instruments

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

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

The carrying values of accounts receivable, inventory, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. The fair value of the redeemable common stock liability was carried at fair value, determined according to Level 3 inputs in the fair value hierarchy described above (see Note "3. Fair Value Measurement of Financial Instruments"). The carrying values of outstanding borrowings under the Company's debt arrangements (see Notes "10. Long-Term Debt—Affiliates" and "11. Line of Credit and Notes Payable") approximate their fair values as determined based on a discounted cash flow model, which represents a Level 3 measurement.

# 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 income (loss) per share attributable to common stockholders is computed by dividing the net income (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.

# **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 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. For example, the Company will adopt ASU 2016-02, *Leases (Topic 842)* on January 1, 2021 and ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326) on* January 1, 2023. As a result, the Company's financial statements may not be comparable to other public companies. The Company may take advantage of these exemptions up until the last day of the fiscal year following October 14, 2021, the fifth anniversary of its IPO, or such earlier time that it is no longer an emerging growth company. It would cease to be an emerging growth company if the Company has more than \$1.07 billion in annual revenue, the Company has more than \$700.0 million in market value of its stock held by non-affiliates or the Company issues more than \$1.0 billion of non-convertible debt securities over a three-year period.

# 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 interest and principal on outstanding capital lease obligations and unpaid operating and common area maintenance costs as long-term liabilities on the consolidated balance sheets. The deferred interest and unpaid operating and common area maintenance costs were previously reported as accrued expenses on the consolidated balance sheets and the deferred principal on the capital lease obligations were recorded as part of the current portion of capital lease obligations on the consolidated balance sheet. These reclassifications have no effect on the reported net loss or equity for the years ended December 31, 2018 and 2017.

Reclassification has been made to prior period amounts reported in the cash flows from operating activities section of the consolidated cash flow statements to conform to the current year presentation. The provision recorded for inventory reserve has been reduced by amounts not related to excess and obsolete inventory and change in inventory has been increased by a corresponding amount. The reclassification has no effect on the reported balance sheet as of December 31, 2018 or net loss or equity or total operating, investing or financing cash flows for the years ended December 31, 2018 and 2017.

# Recently Adopted Accounting Pronouncements

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 and adopted this standard on January 1, 2019. The adoption of ASC 606 did not have a material impact on the Company's consolidated financial position, results of operations, equity or cash flows as of the adoption date or for the year ended December 31, 2019. In September 2018, the FASB issued ASU 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. This ASU expands the scope of Topic 718, Compensation—Stock Compensation to include share-based payments issued to nonemployees for goods or services. Under the new guidance, the existing employee guidance will apply to nonemployee share-based transactions (as long as the transaction is not effectively a form of financing), with the exception of specific guidance related to the attribution of compensation cost. The cost of nonemployee awards will continue to be recorded as if the grantor had paid cash for the goods or services. The accounting standards update is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The Company adopted this standard, beginning with its financial reporting for the quarter ended June 30, 2019 due to the option activity to nonemployees in this quarter. The adoption of this standard did not have any material effect on the Company's consolidated financial statements or any component of stockholders' equity.

#### Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which applies to all leases and will require lessees to record most leases on the balance sheet but recognize expenses in a manner similar to the current standard. In July 2018, the FASB issued ASU 2018-10, Codification Improvements to Topic 842, Leases, which provides narrow amendments to clarify how to apply certain aspects of ASU 2016-02, and ASU 2018-11, Leases (Topic 842): Targeted Improvements, which provides adopters an additional transition method by allowing entities to initially apply ASU 2016-02, and subsequent related standards, at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Additionally, in March 2019, the FASB issued ASU 2019-01, Leases (Topic 842): Codification Improvements, which clarifies the transition guidance related to interim disclosures provided in the year of adoption. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 for public business entities and interim periods within those years and for all other entities for years beginning after December 15, 2020. Entities are required to use a modified retrospective approach of adoption for leases that exist or are entered into after the beginning of the transition date. A full retrospective application is prohibited. The Company is a public entity but took advantage of the relief provided for emerging growth companies to allow them to follow the private company adoption timelines and the Company will adopt this standard and the related improvements on January 1, 2021 by recognizing a cumulative-effect adjustment for any impact. The Company continues to evaluate the impact of adopting this standard on its accounting policies, financial statements, business processes, systems and internal controls. The Company expects to recognize all of its leases with terms over twelve months on the balance sheet by recording a right-of-use asset and a correspondi

In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). Subsequent to the issuance of ASU 2016-13, the FASB has issued the following updates: ASU 2018-19, Codification Improvements to Topic 326, Financial Instruments—Credit Losses, ASU 2019-04, Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial

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

#### 3. Fair Value Measurement of Financial Instruments

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values as of December 31, 2018. The redeemable common stock liability was settled in March 2019 as described below.

	F	Fair Value Measurements as of December 31, 2018 Using:					
	Level 1	Level 2	Level 3	Total			
Liabilities:							
Redeemable common stock liability	<u>\$</u>	<u>\$</u>	\$6,762	\$6,762			
	<u>\$ —</u>	<u>\$ —</u>	\$6,762	\$6,762			

#### Redeemable Common Stock

On March 24, 2017, the Company issued 728,548 shares of Class A common stock in connection with the NuTech Medical acquisition (see Note "1. Nature of Business and Basis of Presentation"), which were recorded at their fair value of \$8.70 per share. These shares included 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 had 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 holder had the right to exercise the put right on March 24, 2019. These shares had 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 would be 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. The liability was settled in March 2019. As of December 31, 2019, the aforementioned 728,548 shares were held as treasury stock.

# 4. Accounts receivable, net

Accounts receivable consisted of the following:

	December 31,		
	2019	2018	
Accounts receivable	\$42,408	\$37,497	
Less—allowance for sales returns and doubtful accounts	(3,049)	(3,420)	
	\$39,359	\$34,077	

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

Balance as of December 31, 2017	\$3,225
Additions	1,157
Write-offs	(962)
Balance as of December 31, 2018	\$3,420
Additions	239
Write-offs	(610)
Balance as of December 31, 2019	\$3,049

# 5. Inventories

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

	December 31,	
	2019	2018
Raw materials	\$ 9,178	\$ 4,711
Work in process	781	1,759
Finished goods	12,959	6,851
	\$ 22,918	\$ 13,321

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, 2019, 2018 and 2017, the Company charged \$1,297, \$2,473, and \$3,170, respectively, for inventory excess and obsolescence to cost of goods sold within the consolidated statements of operations. As of December 31, 2019 and 2018, the Company recorded a reserve for excess and obsolete inventory of \$1,417 and \$1,206, respectively.

# 6. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	Decen	December 31,	
	2019	2018	
Prepaid subscriptions	\$1,041	\$ 594	
Prepaid inventory testing	291	116	
Prepaid conferences and marketing expenses	925	392	
Prepaid insurance	472	223	
Prepaid deposits	87	764	
Other	137	239	
	\$2,953	\$2,328	

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

#### 7. Property and Equipment, Net

Property and equipment consisted of the following:

	Decen	December 31,	
	2019	2018	
Leasehold improvements	\$ 36,344	\$ 34,345	
Furniture, computers and equipment	46,430	44,752	
	82,774	79,097	
Accumulated depreciation and amortization	(65,812)	(62,435)	
Construction in progress	30,222	22,961	
	\$ 47,184	\$ 39,623	

Depreciation expense was \$3,388, \$3,309, and \$3,591 for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019 and 2018, the Company had \$21,689 of buildings under capital leases recorded within leasehold improvements. As of December 31, 2019 and 2018, the Company had \$13,777 and \$12,579, recorded within accumulated depreciation and amortization related to buildings under capital leases, respectively. Construction in progress primarily represents unfinished construction work on a building under a capital lease and, more recently, improvements at the Company's leased facilities in Canton and Norwood, Massachusetts.

# 8. Goodwill and Intangible Assets

During 2017, the Company recorded \$19,446 of goodwill associated with the acquisition of NuTech Medical (see Note "1. Nature of Business and Basis of Presentation"). Goodwill was \$25,539 as of December 31, 2019 and 2018.

In April 2019, the Company purchased \$750 of intangible assets related to patent and know-how which were recorded within the developed technology category. The Company paid \$250 at the time of the transaction. The remaining \$500 is being paid over the eight quarters after the transaction closed and is recorded in accrued expenses and other current liabilities and other liabilities on the consolidated balance sheets.

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

	Original Cost	Accumulated Amortization	Net Book Value
Developed technology	\$30,570	\$ (11,266)	\$19,304
Trade names and trademarks	2,000	(650)	1,350
Independent sales agency network	4,500	(4,500)	_
Non-compete agreements	260	(117)	143
Total	\$37,330	\$ (16,533)	\$20,797

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

Original Cost	Accumulated Amortization	Net Book Value
\$29,820	\$ (8,454)	\$21,366
2,000	(413)	1,587
4,500	(1,569)	2,931
260	(53)	207
\$36,580	\$ (10,489)	\$26,091
	Cost \$29,820 2,000 4,500 260	Cost         Amortization           \$29,820         \$ (8,454)           2,000         (413)           4,500         (1,569)           260         (53)           \$36,580         \$ (10,489)

Amortization of intangible assets, calculated on a straight-line basis or using an accelerated method, which reflects the pattern in which the economic benefits of the intangible assets are consumed, was \$6,043, \$3,669 and \$2,037 for the years ended December 31, 2019, 2018 and 2017, respectively. Estimated future annual amortization expense related to these intangible assets is as follows:

2020	\$ 3,267
2021	3,332
2022	3,322
2023 2024	3,358
	1,842
Thereafter	$\frac{5,676}{$20,797}$
Total	\$ 20,797

# 9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	Decen	December 31,	
	2019	2018	
Accrued personnel costs	\$ 17,640	\$ 15,218	
Other	5,810	5,170	
	\$23,450	\$20,388	

# 10. Long-Term Debt—Affiliates

Historically, the Company has taken loans from its affiliates and entities controlled by its affiliates. More recent loans include the 2018 Loans of \$15,000 and the 2016 Loans of \$17,000. The loans from the Company's affiliates bore an annualized interest rate between 1.6% to 15% and were collateralized by substantially all assets of the Company and were subordinated to the Company's external indebtedness (see Note "11. Line of Credit

and Notes Payable"). These loans from affiliates had a balance of \$56,642 as of December 31, 2017. They were settled in conjunction with the Avista Merger in 2018 as described below. Interest expense for the affiliate debt totaled \$3,892 and \$3,189 for the years ended December 31, 2018 and 2017.

In 2017, the holders of the affiliate debt entered into new subordination agreements to subordinate all amounts due under the affiliate loans and all their security interests to the indebtedness and obligations under the 2017 Credit Agreement and Master Lease Agreement (see Note "11. Line of Credit and Notes Payable"). Due to the effective change in the maturity date of the affiliate loans resulting from these subordination agreements, the 2016 Loans were concluded to have been extinguished, and the resulting gain of \$4,577 was recorded to additional paid-in capital due to the controlling interest in the Company held by the investors.

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 these transactions, the affiliate debt is deemed fully paid and satisfied in full and discharged and terminated. As a result of the full satisfaction of the affiliate debt, the Company recorded a \$2,095 loss on the extinguishment of the 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 \$2,983 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 \$6.58.

#### 11. Line of Credit and Notes Payable

	Decem	
	2019	2018
Line of credit	\$33,484	\$26,484
Term loan	50,000	
Less debt discount and debt issuance cost	(366)	
Less current maturities		
Term loan, net of debt discount and debt issuance cost	\$49,634	\$ —
Notes payable		15,885
Less debt discount and debt issuance cost	_	(762)
Less current maturities		(2,545)
Notes payable, net of debt discount and debt issuance cost	<u>\$</u>	\$12,578

#### 2019 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 ("SVB"), as Administrative Agent, Issuing Lender and Swingline Lender, and the several other lenders thereto (the "Lenders") entered into a Credit Agreement, as amended (the "2019 Credit Agreement"), providing for a term loan (the "Term Loan Facility") and a revolving credit facility (the "Revolving Facility", 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 was made available to Borrower and fully funded in September 2019 upon: (a) Borrower's demonstrated compliance with the financial covenants in the 2019 Credit Agreement and (b) Borrower's achievement of trailing twelve month

Consolidated Revenue of not less than \$221,250 and a trailing three month Adjusted EBITDA (as defined in the 2019 Credit Agreement) loss not in excess of \$5,000; and (iii) the third tranche of \$10,000 is available to Borrower until March 31, 2020 subject to the Lenders' confirmation of Borrower's compliance with the financial covenants in the 2019 Credit Agreement through December 31, 2019 and Borrower's achievement of trailing twelve month Consolidated Revenue not less than \$231,500. 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 2019 Credit Agreement requires Borrower to make monthly interest-only payments on outstanding balances under the Term Loan Facility through February 2021. Thereafter, each term loan advance will be repaid in thirty-six equal monthly installments of principal, plus accrued interest, with the Term Loan Facility maturing on March 1, 2024 (the "Term Loan Maturity Date").

Borrower's final payment on the Term Loan Facility, due on the Term Loan Maturity Date, will include all outstanding principal and accrued and unpaid interest under the Term Loan Facility, plus a final payment (the "Final Payment") equal to the original aggregate principal amount of the Term Loan Facility multiplied by 6.25%. 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, which is defined as a percentage of the Company's book value of qualifying finished goods inventory and eligible accounts receivable. The interest rate for advances under the Revolving Facility is a floating per annum interest rate equal to the 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 2019 Credit Agreement) then Borrower must pay the Administrative Agent the Minimum Interest (as defined in the 2019 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 1, 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.

Under the 2019 Credit Agreement, Borrower is required to achieve Minimum Trailing Twelve Month Consolidated Revenue (as defined in the 2019 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 by March 31, 2020. In addition, Borrower is required to maintain Minimum Liquidity (as defined in the 2019 Credit Agreement) equal to the greater of (i) 6 months Monthly Burn (as defined in the 2019 Credit Agreement) and (ii) \$10,000.

As of December 31, 2019, the Company was in compliance with the financial covenants under the 2019 Credit Agreement and expects to draw the third tranche funding of \$10,000 in March 2020.

As of December 31, 2019, the Company had outstanding borrowings of \$50,000 under the Term Loan Facility and \$33,484 under the Revolving Facility with up to \$6,516 (subject to the Borrowing Base) available for future revolving borrowings. The Company accrues for the Final Payment over the term of the Term Loan Facility through a charge to the interest expense. The related liability of \$681 as of December 31, 2019, was included in the other liabilities in the consolidated balance sheets. The Company incurred costs of \$554 in connection with the Term Loan Facility, of which \$462 was recorded as a reduction of the carrying value of the term loan on the Company's consolidated balance sheet and is being amortized to interest expense through the Term Loan Maturity Date and \$92 related to the third tranche is recorded in other assets until the funding occurs. In connection with the Revolving Facility, the Company incurred costs of \$370, which are recorded as other assets and amortized to interest expense through March 1, 2024.

Future payments of Term Loan Facility, as of December 31, 2019, are as follows for the calendar years ended December 31:

2020	\$ —
2021	13,889
2022	16,666
2023 2024	16,667
2024	
Total	\$ 50,000

#### 2017 Credit Agreement

On March 21, 2017, the Company entered into a credit agreement (the "2017 Credit Agreement") with SVB whereby SVB agreed to extend to the Company a revolving credit facility in an aggregate amount not to exceed \$30,000 with a letter of credit sub-facility and a swing line sub-facility as a sublimit of the revolving loan facility. The amount available to borrow under both sub-facilities was dependent on a borrowing base, which was defined as a percentage of the Company's book value of qualifying finished goods and eligible accounts receivable. In April 2018, the Company further amended its 2017 Credit Agreement in order to receive additional funding of \$5,000 through a term loan. The amendment increased the commitment under the 2017 Credit Agreement to an aggregate amount not to exceed \$35,000, consisting of a term loan not to exceed \$5,000 and a revolving loan not to exceed \$30,000. In December 2018, the Company fully repaid and cancelled the term loan including the outstanding principal and accrued and unpaid interest. As of December 31, 2018, the Company had borrowed an aggregate of \$26,484 under the revolving credit facility and the total amount available for future revolving borrowings was \$3,516.

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

# Master Lease Agreement

On April 28, 2017, the Company entered into the Master Lease Agreement (the "ML Agreement") with Eastward Fund Management LLC that allowed the Company to borrow up to \$20,000 on or prior to June 30, 2018. Of the allowable amount, the Company borrowed a total of \$16,000. If the Company elected to prepay the

loan or terminated the loan early within the first 24 months, the Company was required to pay an additional 3% of the outstanding principal and any accrued and unpaid interest and fees. This prepayment fee decreased 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 was due upon the earlier to occur of the first day of the final payment term month or prepayment of all outstanding principal. In March 2019, upon entering into the 2019 Credit Agreement, the Company paid an aggregate amount of \$17,649 due under the ML Agreement, including unpaid principal, accrued interest, final payment, and early termination penalty, with proceeds from the 2019 Credit Agreement, and the ML Agreement was terminated. Upon termination of the ML Agreement, the Company recognized \$1,862 as loss on the extinguishment of the loan.

In connection with the ML Agreement, the Company issued a warrant to purchase 473,011 shares of Class A common stock at \$2.53 per share as a pre-condition for the agreement. The warrants became exercisable on April 27, 2017 and were recorded at the relative fair value of \$959 using a probability weighted Black Scholes option pricing model. 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 was 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.

#### 12. Stockholders' Equity

As of December 31, 2019, 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. 105,599,434 shares of Class A common stock were issued and 104,870,886 shares were outstanding as of December 31, 2019. The issued shares include 728,548 shares that were reacquired in connection with the redemption of redeemable shares in March 2019. See Note "3. Fair Value Measurement of Financial Instruments".

Each share of Class A common stock entitles the holder to one vote on all matters submitted to the stockholders for a vote. Class A common stockholders are entitled to receive dividends, as may be declared by the Board of Directors. Through December 31, 2019, no cash dividends have been declared or paid.

At December 31, 2019 and 2018, the Company has reserved the following shares of Class A common stock for future issuance:

	December 31, 2019	December 31, 2018
Shares reserved for issuance for outstanding options	6,503,646	6,590,195
Shares reserved for issuance for future option grant	9,008,996	9,108,996
Shares reserved for issuance under the warrants	_	17,732,700
Total shares of authorized common stock reserved for future issuance	15,512,642	33,431,891

# Avista Merger

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

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

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

# Warrant Exchange and Warrant Exercise

As of December 31, 2018, the outstanding warrants to purchase shares of Class A common stock consisted of the following:

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

On July 22, 2019, the Company made an exchange offer (the "Exchange Offer") to all holders of the Company's 30,890,748 outstanding warrants, that were issued in connection with the Company's initial public offering pursuant to a prospectus dated October 10, 2016 (the "Public Warrants"), to exchange 0.095 shares of Class A common stock for each Public Warrant tendered. On August 16, 2019, the expiration date of the Exchange Offer, a total of 29,950,150 warrants were tendered, resulting in the issuance of 2,845,280 shares of common stock.

On August 19, 2019, the Company executed an amendment to the warrant agreement, dated October 10, 2016, governing its outstanding Public Warrants to provide the Company with the right to require the Public Warrants holders to exchange one share of their Public Warrant for 0.0855 shares of the Company's Class A common stock. Pursuant to the amendment, the Company issued 80,451 additional shares in exchange for all remaining untendered Public Warrants.

Pursuant to the terms of the Company's previously announced Warrant Exchange Agreement dated July 12, 2019 with the PIPE Investors, the Company issued an aggregate of 389,501 shares of Class A common stock, to the PIPE Investors, at the same exchange ratio offered to the Public Warrant holders in the Exchange Offer, in exchange for an aggregate of 4,100,000 private placement warrants.

On August 13, 2019, the Company's prior lenders net exercised outstanding warrants to purchase an aggregate of 182,700 shares of the Company's Class A common stock at an exercise price of \$3.95 per share. The Company issued an aggregate of 19,426 shares of common stock in connection with this net exercise.

As a result of these transactions, the Company issued an aggregate of 3,334,658 shares of common stock, representing approximately 3% of the total Class A common stock outstanding after such issuances.

In addition, in the first quarter of 2019, the Company issued 54,626 shares of common stock in connection with some Public Warrant holders' exercise of Public Warrants and received cash proceeds of \$628. As of December 31, 2019, no warrants were outstanding.

As the fair value of the warrants exchanged in the warrant exchange transactions immediately prior to the exchanges was less than the fair value of the common stock issued, the Company recorded a non-cash deemed dividend of \$645 for the incremental fair value provided to the warrant holders in the year ended December 31, 2019.

# Underwritten Public Offering

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

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

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

#### 13. Equity Incentive Plan Share-Based Compensation

# 2018 Stock Incentive Plan

On November 28, 2018, the Board of Directors of the Company adopted, and on December 10, 2018, the Company's stockholders approved, the Organogenesis 2018 Equity and Incentive Plan (the "2018 Plan"). The purposes of the 2018 Plan are to provide long-term incentives and rewards to the Company's employees, officers, directors and other key persons (including consultants), to attract and retain persons with the requisite experience and ability, and to more closely align the interests of such employees, officers, directors and other key persons with the interests of the Company's stockholders.

The 2018 Plan authorizes the Company's Board of Directors or a committee of not less than two independent directors (in either case, the "Administrator") to grant the following types of awards: non-statutory stock options; incentive stock options; restricted stock awards; restricted stock units; stock appreciation rights; unrestricted stock awards; performance share awards; and dividend equivalent rights. The 2018 Plan is administered by the Company's Board of Directors.

As of December 31, 2019, 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, 2019, options to purchase 190,000 shares of Class A common stock were outstanding under the 2018 Plan.

#### 2003 Stock Incentive Plan

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

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 the Company, 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 Option

The Company measures the compensation cost of employee or consultant services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized over the period during which an employee or consultant is required to provide service in exchange for the award. During the years ended December 31, 2019, 2018 and 2017, the Company recorded stock-based compensation expense of \$936, \$1,075, and \$919, respectively, within selling, general and administrative expenses on the consolidated statements of operations.

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

The stock options granted during the years ended December 31, 2019 and 2018 were 100,000 and 248,567, respectively. The assumptions that the Company used to determine the grant-date fair value of stock options granted during these periods were as follows, presented on a weighted-average basis:

	Year Ended De	Year Ended December 31,	
	2019	2018	
Risk-free interest rate	2.24%	2.73%	
Expected term (in years)	6.50	5.89	
Expected volatility	42.7%	42.0%	
Expected dividend yield	0.0%	0.0%	
Exercise price	\$ 7.08	\$ 5.99	
Underlying stock price	\$ 7.08	\$ 5.82	

These assumptions resulted in an estimated weighted-average grant-date fair value per share of stock options granted during the years ended December 31, 2019 and 2018 of \$3.24 and \$2.39, respectively.

The following table summarizes the Company's stock option activity since December 31, 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2018	7,266,185	\$ 1.92	5.89	\$ 33,909
Granted	100,000	7.08		
Cancelled / forfeited	(34,416)	4.10		
Exercised	(152,133)	1.76		715
Outstanding as of December 31, 2019	7,179,636	1.98	5.06	20,799
Options exercisable as of December 31, 2019	6,195,889	1.64	4.60	19,767
Options vested or expected to vest as of December 31, 2019	6,984,130	\$ 1.92	4.98	\$ 20,603

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's Class A common stock for those stock options that have exercise prices lower than the fair value of the Company's Class A common stock.

The total fair value of options vested during the years ended December 31, 2019 and 2018 was \$1,079 and \$963, respectively.

As of December 31, 2019, the total unrecognized stock compensation expense was \$1,252 and is expected to be recognized over a weighted-average period of 2.34 years.

As of December 31, 2019, there were partial recourse notes outstanding totaling \$635. These notes were taken by a former executive to exercise his stock options (see Note "17. Related Parties Transactions") and the notes are secured with the 675,990 shares held by the former executive. As the loans are still outstanding, the options are not considered exercised and are included within the options outstanding. Accordingly, the 675,990 shares are not considered outstanding for accounting purposes and the additional paid-in capital associated with these shares were deducted from equity in prior periods.

#### 14. Income Taxes

The components of the income tax provision (benefit) consisted of the following for the years ended December 31, 2019, 2018 and 2017:

	Year l	Year Ended December 31,		
	2019	2018	2017	
(Benefit from) provision for income taxes:				
Current tax expense (benefit)				
Federal	\$(105)	\$(212)	\$ —	
State	116	101	214	
Foreign	28	9	62	
Total current tax expense (benefit)	39	(102)	276	
Deferred tax expense (benefit)				
Federal	105	212	(6,401)	
State	_	_	(900)	
Foreign	6	(26)		
Total deferred tax expense (benefit)	111	186	(7,301)	
Total income tax expense (benefit)	\$ 150	\$ 84	\$(7,025)	

As of December 31, 2019, the Company had available for the reduction of future years' federal taxable income, net operating loss carry-forwards of approximately \$173,843. Of these carry-forwards, \$114,467 will expire from the year ended December 31, 2020 through 2037 and \$59,376 can be carried forward indefinitely. The Company had state net operating loss carry-forwards of approximately \$73,278 expiring from the year ended December 31, 2020 through 2039. At December 31, 2019, the Company had available for the reduction of future years' federal taxable income, research and development credits of approximately \$919 expiring between December 31, 2020 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, 2019 and 2018 are as follows:

	Decen	December 31,	
	2019	2018	
Net operating loss carryforwards			
Federal	\$ 36,511	\$ 34,707	
State	4,075	3,208	
Foreign	21	26	
Other	11,858	12,219	
Stock-based compensation	633	29	
Fresh start and intangible assets acquired	1,280	(2,765)	
Net deferred tax assets before valuation allowance	54,378	47,424	
Valuation allowance	(54,251)	(47,186)	
Net deferred tax assets	\$ 127	\$ 238	

As of December 31, 2019 and 2018, the Company recorded a valuation allowance of \$54,251 and \$47,186, respectively. In 2019, the valuation allowance increased by \$7,065 primarily due to the federal and state net operating losses generated in 2019, which require a full valuation allowance. Realization of deferred tax assets is dependent upon sufficient future taxable income during the period that deductible temporary differences and carryforwards are expected to be available to reduce taxable income.

As of December 31, 2019, the Company recorded a net deferred tax asset of \$106 relating to AMT credits which are refundable under the Tax Act beginning with the 2018 tax return. This deferred tax asset will be realized, regardless of future taxable income, and thus no valuation allowance has been provided against this asset. As of December 31, 2019, fifty percent (50%) of the remaining AMT deferred tax asset was reclassified to prepaid expenses and other current assets, which represents the amount of refundable AMT credit the Company will claim with the 2019 tax return. Additionally, the Company's subsidiary in Switzerland is carrying a deferred tax asset of approximately \$21 relating to a net operating loss carryover that is expected to be benefited in the next couple of years.

The Company has not recorded withholding taxes on the undistributed earnings of its Swiss subsidiary because it is the Company's intent to reinvest such earnings indefinitely.

Ownership changes, as defined in the Internal Revenue Code, may limit the amount of net operating losses and research and development tax credit carryforwards that can be utilized annually to offset future taxable income. Subsequent ownership changes could further affect the limitation in future years.

The differences between income taxes expected at the U.S. federal statutory income tax rate of 21% and the reported consolidated income tax benefit (expense) are summarized as follows:

		December 31,	
	2019	2018	2017
U.S. federal statutory income tax rate	21.0%	21.0%	35.0%
Tax reform act	<u> </u>	<u> </u>	(134.4)%
Federal valuation allowance	(17.6)%	(18.4)%	147.5%
State valuation allowance	(3.9)%	(3.9)%	3.0%
State and local income taxes	3.5%	3.5%	2.3%
Nondeductible expenses	(1.4)%	(2.3)%	(6.8)%
Noncontrolling interest	<u> </u> %	<u> </u>	2.2%
Uncertain tax position reserves	(0.1)%	(0.1)%	(0.5)%
Research and development credits	(1.9)%	<u> </u>	<u> </u>
Effective income tax rate	(0.4)%	(0.2)%	48.3%

The Company recognizes the tax benefit from an uncertain tax position only if it is more-likely-than-not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The amount of unrecognized tax benefits is \$3,192, \$3,722 and \$3,801 as of December 31, 2019, 2018 and 2017, respectively, which have been subject to a full valuation allowance. The net decrease primarily relates to the expiration of the carryforward period for certain Federal R&D credits previously included as an unrecognized tax benefit.

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

	Year Ended December 31,		
	2019	2018	2017
Gross balance at beginning of year	\$3,286	\$3,486	\$3,663
Additions based on tax positions related to the current period	133	157	231
Reductions for tax positions of prior years	(801)	(357)	(408)
Gross balance at end of year	\$2,618	\$3,286	\$3,486

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, 2015. However, carryforward attributes that were generated prior to December 31, 2015 may still be adjusted upon examination by state or local tax authorities if they either have been or will be used in a future period.

The Company recognizes interest and penalty related expenses in tax expenses. There was \$269 and \$209 of interest recorded for uncertain tax positions for the years ended December 31, 2019 and 2018, respectively, which was classified in accrued expenses in the consolidated balance sheets. These amounts are not reflected in the reconciliation above.

#### 15. Net Loss Per Share

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

	Y	ear Ended December 31,	
	2019	2018	2017
Numerator:			
Net loss	\$ (40,454)	\$ (64,831)	\$ (7,525)
Less: Net income attributable to non-controlling interests	_	_	863
Less: Accretion of redeemable common shares	_	_	423
Less: Non-cash dividend to warrant holders	645	_	_
Net loss attributable to Organogenesis Holdings Inc. common shareholders \$ (41,099) \$ (64,831)		\$ (8,811)	
Denominator:			
Weighted average common shares outstanding—basic and diluted	92,840,401	69,318,456	63,876,767
Net loss per share—basic and diluted	\$ (0.44)	\$ (0.94)	\$ (0.14)

The Company's potentially dilutive securities, which include redeemable common stock and 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 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:

	Year Ended December 31,		
	2019	2018	2017
Options to purchase common stock	7,179,636	7,266,715	7,150,214
Redeemable common stock	_	728,548	728,548
Warrants to purchase common stock		17,732,700	1,561,485
	7,179,636	25,727,963	9,440,247

#### 16. Commitments and Contingencies

#### Capital Leases

On January 1, 2013, the Company entered into capital lease arrangements with 65 Dan Road SPE, LLC, 85 Dan Road Associates, LLC, Dan Road Equity I, LLC and 275 Dan Road SPE, LLC for office and laboratory space in Canton, Massachusetts. 65 Dan Road SPE, LLC, 85 Dan Road Associates, LLC, Dan Road Equity I, LLC and 275 Dan Road SPE, LLC are related parties as the owners of these entities are also stockholders of the Company. The leases terminate on December 31, 2022 and each contains a renewal option for a five-year period with the rental rate at the greater of (i) rent for the last year of the prior term, or (ii) the then fair market value. Notice of the exercise of this renewal option is due one year prior to the expiration of the initial term. Aggregate annual lease payments are approximately \$4,308 with future rent increases of 10% effective January 1, 2022.

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

As of December 31, 2019 and 2018, the Company owed an aggregate of \$10,336 and \$10,293, respectively, of accrued but unpaid lease obligations which include rent in arrears and unpaid operating and common area maintenance costs under the aforementioned leases. The principal portion of rent in arrears on the capital leases totaled \$6,321 and \$5,265 as of December 31, 2019 and 2018, respectively, and is included in the long-term portion of capital lease obligations. The interest portion of rent in arrears totaled \$3,512 and \$4,174 as of December 31, 2019 and 2018, respectively, and is included in other liabilities on the consolidated balance sheets. The unpaid operating and common area maintenance costs totaled \$503 and \$854 as of December 31, 2019 and 2018, respectively, and are included in other liabilities on the consolidated balance sheets. The unpaid lease obligations are subordinated to the 2019 Credit Agreement and will not be paid until the debt under the 2019 Credit Agreement is paid off in 2024 even though the capital leases expire in December 2022.

Effective April 1, 2019, the Company agreed to accrue interest on the accrued but unpaid lease obligations at an interest rate equal to the rate charged in the 2019 Credit Agreement (see Note "11. Line of Credit and Notes Payable"). The accrued interest is also subordinated to the 2019 Credit Agreement and, as such, is included in other liabilities on the consolidated balance sheet. Interest accrued as of December 31, 2019 totaled \$717.

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

2020	\$ 4,791
2021	4,780
2022	4,945
2023	_
2024	9,834
	$\frac{9,834}{24,350}$
Less amount representing interest	(6,862) 17,488
Present value of minimum lease payments	17,488
Less current maturities	(3,057)
Long-term portion	<u>\$14,431</u>

#### **Operating Lease**

The Company leases vehicles for certain employees and has fleet services agreements for service on these vehicles. The minimum lease term for each newly leased vehicle is one year with three consecutive one-year renewal terms.

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 sublease agreement calls for escalating monthly rental payments and expires in December 2021.

In conjunction with the acquisition of NuTech Medical in March 2017, the Company entered into an operating lease with Oxmoor Holdings, LLC, an entity that is affiliated with the former sole shareholder of NuTech Medical, related to the facility at NuTech Medical's headquarters in Birmingham, Alabama. Under the lease, the Company is required to make monthly rent payments of approximately \$21 through the lease termination date on December 31, 2020. The lease was extended in the first quarter of 2020 with the revised termination date on December 31, 2021.

In March 2019, the Company entered into an agreement to lease approximately 43,850 square feet of office and laboratory space in Norwood, Massachusetts. Pursuant to the lease agreement, the rent commencement date

is February 1, 2020. The initial lease term is ten years from the rent commencement date and includes an option for an early extension term of five years which is exercisable during the first two years after the rent commencement date. In addition to the early extension term, the lease provides the Company with an option to extend the lease term for a period of ten years, in addition to 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, an increase of \$44 during the first year of the early extension term and \$33 during year two through five of the early extension term. Upon execution of the agreement, the Company delivered a security deposit in the form of a letter of credit of \$526 to the landlord. Following 36 months from the rent commencement date, the security deposit may be reduced by \$263.

Operating lease expenses were \$6,231, \$4,628 and \$4,205 for the years ended December 31, 2019, 2018 and 2017.

Future minimum lease payments due under noncancellable operating lease agreements as of December 31, 2019 are as follows:

2020	\$ 5,661
2021	5,077
2022	2,677
2023	1,874
2024	1,224
Thereafter	$\frac{6,898}{\$23,411}$
	\$ 23,411

#### Royalties

The Company entered into a license agreement with a university for certain patent rights related to the development, use and production of one of its advanced wound care products. Under this agreement, the Company incurred a royalty based on a percentage of net product sales, for the use of these patents until the patents expired, which was in November 2006. Accrued royalties totaled \$1,187 as of December 31, 2019 and 2018 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, 2019, 2018 or 2017 related to this agreement.

In October 2017, the Company entered into a license agreement with a third party. Under the license agreement, the Company is required to pay royalties based on a percentage of net sales of the licensed product that occur, after December 31, 2017, through the expiration in October 2026 of the underlying patent, subject to minimum royalty payment provisions. The Company recorded royalty expense of \$3,778, \$2,059, and \$3,122 during the years ended December 31, 2019, 2018 and 2017, respectively, within selling, general and administrative expenses on the consolidated statements of operations.

As part of the NuTech Medical acquisition (see Note "1. Nature of Business and Basis of Presentation"), the Company inherited certain product development and consulting agreements for ongoing consulting services and royalty payments based on a percentage of net sales on certain products over a period of 15 years from the execution of the agreements. These product development and consulting agreements were cancelled in January 2020 for total consideration of \$1,950 which was paid on February 14, 2020.

### Legal Matters

In conducting its activities, the Company, from time to time, is subject to various claims and also has claims against others. In management's opinion, the ultimate resolution of such claims would not have a material effect on the financial position, operating results or cash flows of the Company. The Company accrues for these claims when amounts due are probable and estimable.

The Company accrued \$542 and \$1,000 as of December 31, 2019 and 2018 in relation to certain pending lawsuits.

As discussed in Note "1. Nature of Business and Basis of Presentation", the purchase price for NuTech Medical included \$7,500 of future payments issued as deferred acquisition consideration. As of December 31, 2019, the Company has paid \$2,500 in deferred acquisition consideration. The amount of the remaining \$5,000 of deferred acquisition consideration plus accrued interest owed to the sellers of NuTech Medical was previously in dispute. As of December 31, 2019, the Company recorded \$918 of accrued interest related to the deferred acquisition consideration which is recorded in accrued expenses and other current liabilities. The Company asserted certain claims for indemnification that would offset in whole or in part its payment obligation and the sellers of NuTech Medical filed a lawsuit alleging breach of contract and seeking specific performance of the alleged payment obligation and attorneys' fees. In February 2020, the Company entered into a settlement agreement with the sellers of NuTech Medical and settled the dispute for \$4,000, of which, \$2,000 was paid immediately on February 24, 2020 (the "Settlement Date") and the remaining \$2,000 is to be paid in four quarterly installments of \$500 each with the first quarterly payment due and payable on the date that is 90 days from the Settlement Date.

#### 17. Related Parties Transactions

Capital lease obligations to affiliates, including unpaid lease obligations, and an operating lease with affiliates are further described in Note "16 Commitments and Contingencies". Affiliate debts are described in Note "10. Long-Term Debt—Affiliates". Fee paid to the Avista Funds in connection with the Underwritten Public Offering is described in Note "12. Stockholders' Equity."

During 2010, the Company's Board of Directors approved a loan program that permitted the Company to make loans to three executives of the Company (the "Employer Loans") to (i) provide them with liquidity ("Liquidity Loans") and (ii) fund the exercise of vested stock options ("Option Loans"). 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. Interest on the Employer Loans accrues at various rates ranging from 2.30%—3.86% per annum, compounded annually. The Employer Loans are secured by 1,857,450 and 675,990 shares of the Company's Class A common stock held by two former executives, respectively. With respect to the Liquidity Loans, the Company has no personal recourse against the borrowers beyond the pledged shares. In connection with the Avista Merger (see Note "1. Nature of Business and Basis of Presentation"), the Company forgave the outstanding aggregate principal balance of \$997 and accrued interest of \$133 related to the current CEO's Liquidity Loans immediately prior to consummation of the Avista Merger.

As of December 31, 2019 and 2018, Liquidity Loans to two former executives were outstanding with an aggregate principal balance of \$2,350 and Option Loans to one former executive were outstanding with an aggregate principal balance of \$635. The principal and part of the interest receivable under the Employer Loans were fully reserved with net interest receivable of \$556 and \$477 as of December 31, 2019 and 2018, respectively, included in the notes receivable from related parties balance in the consolidated balance sheets. Interest income related to these notes was \$78, \$64, and \$111 for the years ended December 31, 2019, 2018 and 2017, respectively.

#### 18. Employee Benefit Plan

The Company maintains a 401(k) Savings Plan (the "Plan") for the U.S. employees. Under the Plan, eligible employees may contribute, subject to statutory limitations, a percentage of their salary to the Plan. Contributions made by the Company are made at the discretion of the Board of Directors and vest immediately. During the years ended December 31, 2019, 2018 and 2017, the Company made employer contributions of \$2,290, \$1,883 and \$1,006, respectively.

As part of the NuTech Medical acquisition (see Note "1. Nature of Business and Basis of Presentation"), 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.

### 19. Subsequent Events

The Company has performed an evaluation of subsequent events through March 9, 2020.

In January 2020, the Company cancelled certain product development and consulting agreements inherited from NuTech Medical for total consideration of \$1,950 which was paid on February 14, 2020. Refer to Note "16. Commitments and Contingencies".

In February 2020, the Company entered into a settlement agreement with the sellers of NuTech Medical and settled the dispute on the deferred acquisition consideration for \$4,000, of which, \$2,000 was paid immediately on February 24, 2020 (the "Settlement Date") and the remaining \$2,000 is to be paid in four quarterly installments of \$500 each with the first quarterly payment due and payable on the date that is 90 days from the Settlement Date. Refer to Note "16. Commitments and Contingencies".

On March 2, 2020, the Company's Board of Directors granted 596,000 of restricted stock units to our sales employees with an aggregated fair market value of \$2,408. These restricted stock units will vest over four years with the first tranche vesting on January 15, 2021.

# 17,500,000 Shares



Class A Common Stock

**PROSPECTUS** 

Morgan Stanley

SVB Leerink

BTIG

Oppenheimer & Co.

#### PART II

#### INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the SEC registration fee and the Financial Industry Regulatory Authority, or FINRA, filing fee.

	Amount
SEC registration fee	\$ 9,111.90
FINRA filing fee	\$ 13,028.00
Accountants' fees and expenses	\$ 75,000.00
Legal fees and expenses	\$ 470,000.00
Transfer agent's fees and expenses	\$ 10,000.00
Printing expenses	\$ 25,000.00
Miscellaneous	\$ 7,860.10
Total expenses	\$ 610,000.00

#### Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law (the "DGCL") provides that a corporation may indemnify directors and officers as well as other employees and individuals against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with any threatened, pending or completed actions, suits or proceedings in which such person is made a party by reason of such person being or having been a director, officer, employee or agent of the registrant. The DGCL provides that Section 145 is not exclusive of other rights to which those seeking indemnification may be entitled under any bylaws, agreement, vote of stockholders or disinterested directors or otherwise. Our Certificate of Incorporation and Bylaws provide for indemnification by us of our directors and officers to the fullest extent permitted by the DGCL.

Section 102(b)(7) of the DGCL permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (1) for any breach of the director's duty of loyalty to the corporation or its stockholders, (2) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (3) for unlawful payments of dividends or unlawful stock repurchases, redemptions or other distributions or (4) for any transaction from which the director derived an improper personal benefit. Our Certificate of Incorporation provides for such limitation of liability to the fullest extent permitted by the DGCL.

We maintain standard policies of insurance under which coverage is provided (1) to our directors and officers against loss arising from claims made by reason of breach of duty or other wrongful act, while acting in their capacity as our directors and officers, and (2) to us with respect to payments which we may make to such officers and directors pursuant to any indemnification provision contained in our Certificate of Incorporation and Bylaws or otherwise as a matter of law.

We have entered into indemnity agreements with each of our directors and executive officers providing for the indemnification described above. We believe that these limitations on liability are essential to attracting and retaining qualified persons as directors and executive officers.

Under agreements which may be entered into by us, certain of our directors and officers may be entitled to indemnification by underwriters and agents who participate in the distribution of securities covered by this registration statement against certain liabilities, including liabilities under the Securities Act.

#### Item 15. Recent Sales of Unregistered Securities.

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act:

#### (a) CPN Biosciences Acquisition

On September 17, 2020, the Company issued 1,947,953 shares of its Class A common stock to CPN Biosciences, LLC as partial consideration for the acquisition of substantially all of the assets of CPN Biosciences, LLC pursuant to an asset purchase agreement. For purposes of the acquisition, the agreed upon value of our Class A common stock was \$4.78 per share.

No underwriters were used in the foregoing transaction. This sale of securities was made in reliance upon the exemption from registration provided by Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder for transactions by an issuer not involving a public offering.

#### (b) NuTech Medical Acquisition

On March 24, 2017, Organogenesis Inc. issued 1,794,455 shares of its common stock in connection with the acquisition of Nutech Medical, Inc., pursuant to an agreement and plan of merger. For purposes of the acquisition of NuTech Medical, the agreed upon value of Organogenesis Inc. common stock was \$18.84 per share. The shares of Organogenesis Inc. common stock were issued to the sole shareholder of NuTech Medical.

No underwriters were used in the foregoing transaction. This sale of securities was made in reliance upon the exemption from registration provided by Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder for transactions by an issuer not involving a public offering.

#### (c) Grants and Exercises of Stock Options

At various times between January 1, 2017 and the filing of a registration statement on Form S-8 on February 11, 2019, we granted options to purchase an aggregate of 2,065,753 shares of Class A common stock to our employees, directors, and consultants at exercise prices ranging from \$3.46 per share to \$7.04 per share pursuant to the Organogenesis Inc. 2003 Stock Incentive Plan and the Organogenesis Holdings Inc. 2018 Equity Incentive Plan. Between January 1, 2017 and the filing of the S-8 registration statement on February 11, 2019, 273,550 shares of Class A common stock have been issued upon exercise of outstanding stock options for cash consideration of \$339,202, 112,498 options have been forfeited and, as of February 11, 2019, 6,587,975 options remained outstanding at a weighted average exercise price of \$2.02 per share. The issuances of these options and shares of Class A common stock were made in reliance on the exemptions from registration provided by Section 4(a)(2) of the Securities Act for transactions by an issuer not involving a public offering and by Rule 701 under the Securities Act for issuances of securities pursuant to a compensatory benefit plan.

#### (d) Grants of Warrants

2017 Warrant

On April 28, 2017, Organogenesis Inc. issued a warrant to purchase 233,010 shares of its common stock to an investor at an exercise price of \$5.15 per share.

No underwriters were used in the foregoing transaction. This sale of securities was made in reliance upon the exemption from registration provided by Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder for transactions by an issuer not involving a public offering.

#### (e) Private Placement

On August 17, 2018, the Company entered into a subscription agreement (the "Subscription Agreement") with Avista Capital Partners Fund IV L.P., a Delaware limited partnership and Avista Capital Partners Fund IV (Offshore), L.P., a limited partnership formed under the laws of Bermuda (collectively, the "PIPE Investor") for the purchase and sale of 9,022,741 shares of our Class A common stock and 4,100,000 warrants to purchase one-half of one share of our Class A common stock for an aggregate purchase price of \$46,000,000 through a private placement offered to a limited number of accredited investors (as defined by Rule 501 of Regulation D) pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the "private placement"). The PIPE Investor also purchased, concurrently with the execution and delivery of the merger agreement for the business combination, 3,221,050 shares of Organogenesis Inc. common stock for an aggregate purchase price of \$46,000,000 (such subscription, collectively with the private placement, the "equity financing").

On August 17, 2018, certain creditors of Organogenesis Inc. and the Company entered into an exchange agreement ("Exchange Agreement") whereby such creditors and the Company agreed that, concurrently with the consummation of the business combination, a portion of the outstanding obligations of Organogenesis Inc. owed to creditors who were insiders of Organogenesis Inc. ("Organogenesis Insider Debt") would be converted into Class A 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. Concurrently with the closing of the business combination on December 10, 2018, \$45.7 million of the indebtedness described below was converted into 6,502,679 shares of our Class A common stock based on a conversion price of \$7.035 per share, and we made a cash payment equal to \$35.6 million in satisfaction of the remaining portion of the indebtedness, including the accrued and unpaid interest and any fees on this indebtedness.

No underwriters were used in the foregoing transactions. The warrants and Class A common stock issued in connection with the Subscription Agreement and the Exchange Agreement were not registered under the Securities Act of 1933, as amended (the "Securities Act"), in reliance on the exemptions from registration provided by Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder.

#### (f) Warrant Exchange Offer

On August 19, 2019, the Company announced the final results of an offer to exchange ("Offer") 0.095 shares of the Company's Class A common stock for each outstanding warrant originally issued in connection with the Company's initial public offering pursuant to a prospectus dated October 10, 2016, exercisable for shares of the Company's Class A Common Stock, par value \$0.0001 per share (the "Shares"), which have an exercise price of \$5.75 per half share (the "Public Warrants"), upon the terms and subject to the conditions set forth in our Tender Offer Statement on Schedule TO originally filed by the Company with the SEC on July 12, 2019, as amended and supplemented by Amendment No. 1 filed by the Company with the SEC on July 22, 2019, Amendment No. 2 filed by the Company with SEC on August 9, 2019 and Amendment No. 3 filed by the Company with SEC on August 19, 2019, and the related Letter of Transmittal and Consent Solicitation. The Offer to Exchange expired at midnight, Eastern Time, on August 16, 2019. On August 21, 2019, the Company issued an aggregate of 2,845,280 Shares in exchange for the Public Warrants validly tendered and accepted for exchange in accordance with the Offer. As previously disclosed, the Company executed an amendment (the "Warrant Amendment") to the warrant agreement governing its outstanding Public Warrants on August 19, 2019, pursuant to which it exchanged all remaining untendered Public Warrants on September 3, 2019, in accordance with the terms of the Warrant Amendment (the "Redemption").

In addition, pursuant to the terms of the Company's previously announced Warrant Exchange Agreement with Avista Capital Partners IV L.P., and Avista Capital Partners IV (Offshore), L.P. (collectively, the "PIPE Investors"), on August 21, 2019, the Company issued an aggregate of 389,501 Shares (at the same exchange ratio offered to the Public Warrant holders in the Offer) to the PIPE Investors in exchange for an aggregate of 4,100,000 private placement warrants (the "Private Exchange").

On August 13, 2019, Massachusetts Capital Resource Company and Life Insurance Community Investment Initiative, LLC (the "Lender Warrant Holders") net exercised outstanding warrants to purchase an aggregate of 182,700 Shares at an exercise price of \$3.95 per Share (the "Net Exercise"). In connection with the Net Exercise, the Company issued an aggregate of 19,426 Shares.

In connection with the Offer, the Private Exchange and the Net Exercise, the Company issued an aggregate of 3,254,207 Shares, representing approximately 3.4% of the shares of Class A Common Stock outstanding after such issuances. On September 3, 2019, the Company issued approximately 80,422 additional Shares in connection with the Redemption.

No underwriters were used in the foregoing transactions. The issuance of Shares to the holders of Public Warrants in exchange for their Public Warrants and to the PIPE Investors in exchange for the private placement warrants were made by the Company pursuant to the exemption from the registration requirements of the Securities Act of 1933, as amended, contained in Section 3(a)(9) thereunder, on the basis that the Offer and the Private Exchange constituted an exchange with existing holders of the Company's securities and no commissions or other remuneration was paid or given, directly or indirectly, to any party for soliciting such exchanges. The issuance of Shares to the Lender Warrant Holders was made by the Company pursuant to the exemption from the registration requirements of the Securities Act provided by Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder for transactions by an issuer not involving a public offering.

# Item16. Exhibits and Financial Statement Schedules.

# EXHIBIT INDEX

Exhibit No.	Exhibit
1.1*	Form of Underwriting Agreement
2.1	Merger Agreement, dated August 17, 2018, by and among Avista Healthcare Public Acquisition Corp., Avista Healthcare Merger Sub, Inc. and Organogenesis Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on August 17, 2018)
2.2	Amendment No. 1 to Merger Agreement, dated October 5, 2018, by and among Avista Healthcare Public Acquisition Corp., Avista Healthcare Merger Sub, Inc. and Organogenesis Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on October 9, 2018)
2.3	Agreement and Plan of Merger dated as of March 18, 2017 by and among Organogenesis Inc., Prime Merger Sub, LLC, Nutech Medical, Inc., Howard P. Walthall, Jr., Gregory J. Yager, Kenneth L. Horton and Kenneth L. Horton, as representative (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
3.1	Certificate of Incorporation of ORGO (incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-3/A (File No. 333-233621) filed with the SEC on September 16, 2019)
3.2	Bylaws of ORGO (incorporated by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-3/A (File No. 333-233621) filed with the SEC on September 16, 2019)
5.1*	Opinion of Foley Hoag LLP
10.1	Amended and Restated Registration Rights Agreement dated as of December 10, 2018 among ORGO, Avista Acquisition Corp., Avista Capital Partners Fund IV L.P., Avista Capital Partners Fund IV (Offshore), L.P., and certain holders of Organogenesis Common Stock (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.2	Stockholders Agreement dated as of December 10, 2018 among ORGO, Avista Capital Partners Fund IV L.P., Avista Capital Partners Fund IV (Offshore), L.P., and certain holders of Organogenesis Common Stock (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.3†	License and Services Agreement, dated as of September 14, 2011, by and between Organogenesis Inc. and Net Health Systems, Inc., as amended by that certain First Amendment dated as of March 31, 2013, Second Amendment dated as of July 22, 2014, Third Amendment dated as of March 13, 2015 and Fourth Amendment dated as of August 17, 2017 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.4	<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	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)
	11.5

Exhibit No.	Exhibit
10.6	Lease dated as of January 1, 2013 by and between Organogenesis Inc. and Dan Road Equity I, LLC (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.7	Lease dated as of January 1, 2013 by and between Organogenesis Inc. and 275 Dan Road SPE, LLC (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.8	<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	Sublease Agreement dated as of March 18, 2014 by and between Organogenesis Inc. and Shire Holdings US AG, as amended by that certain First Amendment to Sublease dated as of January 13, 2017, as amended by that certain Second Amendment to Sublease dated as of January 25, 2017 (incorporated by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.10	Lease Agreement, dated as of June 5, 2012, by and between Organogenesis Switzerland GmbH and Stiftung Regionales Gründerzentrum Reinach, as amended by that certain Supplement No. 1 dated May 9, 2017 and that certain Supplement No. 2 dated May 9, 2017 (incorporated by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.11	<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	Standard Industrial/Commercial Multi-Tenant Lease—Net, dated as of March 7, 2011, by and among Liberty Industrial Park and Organogenesis Inc., as amended by that certain First Amendment dated as of April, 2013, Second Amendment dated as of April 19, 2015, and Third Amendment dated as of March 9, 2017 (incorporated by reference to Exhibit 10.12 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.13‡	Amended and Restated Key Employee Agreement dated as of February 1, 2007 by and between Organogenesis Inc. and Gary Gillheeney (incorporated by reference to Exhibit 10.13 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.14‡	Employee Letter Agreement dated as of February 14, 2017 by and between Organogenesis Inc. and Patrick Bilbo (incorporated by reference to Exhibit 10.14 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.15‡	Employee Letter Agreement dated as of 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)
10.16‡	Employee Letter Agreement dated as of February 14, 2017 by and between Organogenesis Inc. and Antonio Montecalvo (incorporated by reference to Exhibit 10.16 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.17‡	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)

Exhibit No.	Exhibit
10.18‡	Employee Letter Agreement dated as of January 19, 2018 by and between Organogenesis Inc. and Lori Freedman (incorporated by reference to Exhibit 10.18 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.19‡	Employee Letter Agreement dated as of May 9, 2017 by and between Organogenesis Inc. and Brian Grow (incorporated by reference to Exhibit 10.19 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.20	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)
10.21	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)
10.22	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)
10.23	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)
10.24	Credit Agreement dated March 14, 2019 between the Company, Organogenesis Inc. and Prime Merger Sub, LLC, collectively as borrower, and Silicon Valley Bank, in its capacity as Administrative Agent, and Silicon Valley Bank and the other lenders listed therein, collectively as lenders (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on March 14, 2019)
10.25	Amended and Restated Subordination Agreement dated as of August 6, 2019 by and among Dan Road Associates LLC, 85 Dan Road Associates LLC, 275 Dan Road SPE LLC, 65 Dan Road SPE LLC and Silicon Valley Bank (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on August 8, 2019)
10.26	Letter Agreement dated as of August 6, 2019 by and among Organogenesis Inc., Dan Road Associates LLC, 85 Dan Road Associates LLC, 275 Dan Road SPE LLC and 65 Dan Road SPE LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on August 8, 2019)
10.27‡	2003 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.27 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018).
10.28‡	Form of Incentive Stock Option Agreement under the 2003 Stock Incentive Plan (incorporated by reference to Exhibit 10.28 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018).
10.29‡	Form of Non-Statutory Stock Option Agreement under the 2003 Stock Incentive Plan (incorporated by reference to Exhibit 10.29 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.30‡	2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.30 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.31‡	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)

Exhibit No.	Exhibit
10.32‡	Form of Non-Statutory Stock Option Agreement under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.32 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018).
10.33‡	Form of Indemnification Agreement for Directors and Officers (incorporated by reference to Exhibit 10.33 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.34†	Settlement and License Agreement effective as of October 25, 2017 by and among Organogenesis Inc., RESORBA Medical GmbH, an Advanced Medical Solutions Group plc (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement in Form S-(File No. 333-227090) filed with the SEC on October 9, 2018)
10.35	Amended and Restated Code of Ethics and Conduct of ORGO adopted on December 10, 2018 (incorporated by reference to Exhibit 10.35 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11, 2018)
10.36	Controlling Stockholders Agreement dated as of December 10, 2018 by and among ORGO and the Controlling Entities (incorporated by reference to Exhibit 10.36 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on December 11 2018)
10.37	Exchange Agreement, dated August 17, 2018, by and among Avista Healthcare Public Acquisition Corp. and certain lenders listed on Schedule A therein (incorporated by reference to Exhibit 10.37 to the Company's Annual Report on Form 10-K (File No. 001-37906) filed with the SEC on March 18, 2019)
10.38	First Amendment to Credit Agreement dated November 12, 2019 among Organogenesis Holdings Inc., Organogenesis Inc. and Prime Merger Sub, LLC, collectively as borrower, and Silicon Valley Bank, in its capacity as the Issuing Lender and Swingline Lender, Silicon Valley Bank, as Administrative Agent, and Silicon Valley Bank and the other lenders listed therein, collectively as lenders (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on November 15, 2019).
10.39	Second Amendment to Credit Agreement entered into on February 14, 2020 and dated and effective as of February 13, 2020 among Organogenesis Holdings Inc., Organogenesis Inc. and Prime Merger Sub, LLC, collectively as borrower, and Silicon Valley Bank, in its capacity as the Issuing Lender and Swingline Lender, Silicon Valley Bank, as Administrative Agent, and Silicon Valley Bank and the other lenders listed therein, collectively as lenders (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on February 19, 2020)
10.40	Third Amendment to Credit Agreement dated March 26, 2020 among Organogenesis Holdings Inc., Organogenesis Inc. and Prime Merger Sub, LLC, collectively as borrower, and Silicon Valley Bank, in its capacity as the Issuing Lender and Swingline Lender, Silicon Valley Bank, as Administrative Agent, and Silicon Valley Bank and the other lenders listed therein, collectively as Lenders (incorporate by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on March 30, 2020)
10.41	Lease dated March 13, 2019 between Organogenesis Inc., as tenant, and Bobson Norwood Commercial, LLC, as landlord (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-37906) filed with the SEC on March 19, 2019)
10.42	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)

Exhibit No.	Exhibit
10.43	Fourth Amendment to Lease dated February 14, 2020 by and between Liberty Industrial Park and Organogenesis Inc. (incorporated by reference to Exhibit 10.41 of the Company's Annual Report on Form 10-K (File No. 001-37906) filed with the SEC on March 9, 2020)
10.44	Second Amendment to Lease dated February 7, 2020 by and between Oxmoor Holdings, LLC and Organogenesis Inc. (incorporated by reference to Exhibit 10.42 of the Company's Annual Report on Form 10-K (File No. 001-37906) filed with the SEC on March 9, 2020)
10.45‡	Summary of Severance Arrangement for Gary S. Gillheeney, Sr. (incorporated by reference to Exhibit 10.43 of the Company's Annual Report on Form 10-K/A (File No. 001-37906) filed with the SEC on April 29, 2020).
21.1	Subsidiaries of Organogenesis Holdings Inc. (incorporated by referenced to Exhibit 21.1 of the Company's Annual Report on Form 10-K (File No. 001-37906) filed with the SEC on March 9, 2020)
23.1*	Consent of Foley Hoag LLP (included in Exhibit 5.1)
23.2*	Consent of RSM US LLP
24.1	Power of Attorney (previously filed)
24.2*	Power of Attorney, relating to Robert Ades
24.3*	Power of Attorney, relating to David Erani
101.INS*	XBRL Instance Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

 <sup>\*</sup> Filed herewith.

#### Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

<sup>†</sup> 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.

The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

### **SIGNATURES**

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boston, The Commonwealth of Massachusetts, on the 10th day of November, 2020.

### ORGANOGENESIS HOLDINGS INC.

By: /s/ Gary S. Gillheeney, Sr.

Gary S. Gillheeney, Sr.
President and Chief Executive Officer

In accordance with the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Gary S. Gillheeney, Sr.	Chief Executive Officer, President and Director	November 10, 2020
Gary S. Gillheeney, Sr.	(Principal Executive Officer)	
/s/ Henry Hagopian	Interim Chief Financial Officer	November 10, 2020
Henry Hagopian	(Principal Financial and Accounting Officer)	,
*	Director	November 10, 2020
	Director	November 10, 2020
Alan A. Ades		
*	Director	November 10, 2020
Robert Ades	Billettor	110 (6111061 10, 2020
Robert Ades		
*	Director	November 10, 2020
David Erani		,
David Eldin		
*	Director	November 10, 2020
Arthur S. Leibowitz		•

Signature	Title	Date
* Wayne D. Mackie	Director	November 10, 2020
* Glenn H. Nussdorf	Director	November 10, 2020
* Joshua Tamaroff	Director	November 10, 2020
	*By: /s/ Gary S. Gillhe Gary S. Gillheene	

Attorney-in-fact

#### [•] Shares

#### Organogenesis Holdings Inc.

#### Class A Common Stock, \$0.0001 par value

#### **UNDERWRITING AGREEMENT**

[•], 2020

MORGAN STANLEY & CO. LLC SVB LEERINK LLC

As Representatives (the "Representatives") of the Several Underwriters

c/o Morgan Stanley & Co. LLC 1585 Broadway New York, N.Y. 10036

c/o SVB Leerink LLC 1301 Avenue of the Americas, 12th Floor New York, N.Y. 10019

#### Dear Sirs:

- 1. Introductory. Organogenesis Holdings Inc., a Delaware corporation ("Company"), agrees with the several Underwriters named in Schedule A hereto ("Underwriters") to issue and sell to the several Underwriters [•] shares ("Firm Securities") of its Class A common stock, par value \$0.0001 per share ("Common Stock"). The Company also agrees to sell to the Underwriters, at the option of the Underwriters, an aggregate of not more than [•] additional shares ("Optional Securities") of its Common Stock as set forth below. The Firm Securities and the Optional Securities are herein collectively called the "Offered Securities."
  - 2. Representations and Warranties of the Company. (a) The Company represents and warrants to, and agrees with, the several Underwriters that:
  - (i) Filing and Effectiveness of Registration Statement; Certain Defined Terms. The Company has filed with the Commission a registration statement on Form S-1 (No. 333-249531) covering the registration of the Offered Securities under the Act, including a related preliminary prospectus or prospectuses. At any particular time, this initial registration statement, in the form then on file with the Commission, including all information contained in the registration statement (if any) pursuant to Rule 462(b) and then deemed to be a part of the initial registration statement, and all 430A Information and 430C Information, that in any case has not then been superseded or modified, shall be referred to as the "Initial Registration Statement". The Company may also have filed, or may file with the Commission, a Rule 462(b) registration statement covering the registration of the Offered Securities. At any particular time, this Rule 462(b) registration statement, in the form then on file with the Commission, including the contents of the Initial Registration Statement incorporated by reference therein and including all 430A Information and all 430C Information, that in any case has not then been superseded or modified, shall be referred to as the "Additional Registration Statement".

As of the time of execution and delivery of this Agreement, the Initial Registration Statement has been declared effective under the Act and is not proposed to be amended. Any Additional Registration Statement has or will become effective upon filing with the Commission pursuant to Rule 462(b) and is not proposed to be amended. The Offered Securities all have been or will be duly registered under the Act pursuant to the Initial Registration Statement and, if applicable, the Additional Registration Statement.

For purposes of this Agreement:

- "430A Information", with respect to any registration statement, means information included in a prospectus and retroactively deemed to be a part of such registration statement pursuant to Rule 430A(b).
- "430C Information", with respect to any registration statement, means information included in a prospectus then deemed to be a part of such registration statement pursuant to Rule 430C.
  - "Act" means the Securities Act of 1933, as amended.
  - "Applicable Time" means [•] [a][p]m (Eastern time) on the date of this Agreement.
  - "Closing Date" has the meaning defined in Section 3 hereof.
  - "Commission" means the Securities and Exchange Commission.
- "Effective Time" with respect to the Initial Registration Statement or, if filed prior to the execution and delivery of this Agreement, the Additional Registration Statement means the date and time as of which such Registration Statement was declared effective by the Commission or has become effective upon filing pursuant to Rule 462(c). If an Additional Registration Statement has not been filed prior to the execution and delivery of this Agreement but the Company has advised the Representatives that it proposes to file one, "Effective Time" with respect to such Additional Registration Statement means the date and time as of which such Additional Registration Statement is filed and becomes effective pursuant to Rule 462(b).
  - "Exchange Act" means the Securities Exchange Act of 1934, as amended.
- "Final Prospectus" means the Statutory Prospectus that discloses the public offering price, other 430A Information and other final terms of the Offered Securities and otherwise satisfies Section 10(a) of the Act.

The Initial Registration Statement and any Additional Registration Statement, after the filing thereof, are referred to collectively as the "Registration Statements" and each is individually referred to as a "Registration Statement". A "Registration Statement" with reference to a particular time means the Initial Registration Statement and any Additional Registration Statement as of such time. A "Registration Statement" without reference to a time means such Registration Statement as of its Effective Time. For purposes of the foregoing definitions, 430A Information with respect to a Registration Statement shall be considered to be included in such Registration Statement as of the time specified in Rule 430A.

"Rules and Regulations" means the rules and regulations of the Commission.

"Securities Laws" means, collectively, the Sarbanes-Oxley Act of 2002, as amended, and all rules and regulations promulgated thereunder or implementing the provisions thereof ("Sarbanes-Oxley"), the Act, the Exchange Act, the Rules and Regulations, the auditing principles, rules, standards and practices applicable to auditors of "issuers" (as defined in Sarbanes-Oxley) promulgated or approved by the Public Company Accounting Oversight Board and, as applicable, the rules of The New York Stock Exchange and The Nasdaq Stock Market LLC ("Exchange Rules").

"Statutory Prospectus" with reference to a particular time means the prospectus included in a Registration Statement immediately prior to that time, including any 430A Information or 430C Information with respect to such Registration Statement. For purposes of the foregoing definition, 430A Information shall be considered to be included in the Statutory Prospectus as of the actual time that form of prospectus is filed with the Commission pursuant to Rule 424(b) or Rule 462(c) and not retroactively.

"Testing-the-Waters Communication" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Act.

"Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Act.

Unless otherwise specified, a reference to a "rule" is to the indicated rule under the Act.

- (ii) Compliance with Securities Act Requirements. (i) (A) At their respective Effective Times, (B) on the date of this Agreement and (C) on each Closing Date, each of the Initial Registration Statement and the Additional Registration Statement (if any) conformed and will conform in all respects to the requirements of the Act and the Rules and Regulations, and did not and will not include any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading, and (ii) on its date, at the time of filing of the Final Prospectus pursuant to Rule 424(b) or (if no such filing is required) at the Effective Time of the Additional Registration Statement in which the Final Prospectus is included, and on each Closing Date, the Final Prospectus will conform in all respects to the requirements of the Act and the Rules and Regulations and will not include any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading. The preceding sentence does not apply to statements in or omissions from any such document based upon written information furnished to the Company by any Underwriter through the Representatives specifically for use therein, it being understood and agreed that the only such information is that described as such in Section 8(b) hereof.
- (iii) *Emerging Growth Company Status*. From the time of the filing of the Initial Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly or through any person authorized to act on its behalf in any Testing-the-Waters Communication) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Act (an "Emerging Growth Company").
- (iv) General Disclosure Package. As of the Applicable Time, neither (i) the preliminary prospectus, dated [•], 2020 (which is the most recent Statutory Prospectus distributed to investors generally) and the other information, if any, stated in Schedule B to this Agreement to be included in the General Disclosure Package, all considered together (collectively, the "General Disclosure Package") nor (ii) any individual Written Testing-the-Waters Communication, when considered together with the General Disclosure Package, included any untrue statement of a material fact or omitted to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The preceding sentence does not apply to statements in or omissions from any Statutory Prospectus or any Written Testing-the-Waters Communication in reliance upon and in conformity with written information furnished to the Company by any Underwriter through the Representatives specifically for use therein, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 8(b) hereof.
- (v) No Free Writing Prospectus. The Company has not, directly or indirectly, prepared, used or referred to, and will not, directly or indirectly, prepare, use or refer to, any free writing prospectus, as such term is defined in Rule 405 under the Act, in connection with the offer and sale of the Offered Securities; the preliminary prospectus dated [•], 2020 is a prospectus that satisfies the requirements of Section 10 of the Act, including a price range where required by rule; the Company was and is an "ineligible issuer" (as defined in Rule 405 under the Act) as of the time of filing the Registration Statement and as of the Applicable Time; the parties hereto agree and understand that the content of any and all road shows (as defined in Rule 433(h) under the Act) (a "road show"), any Testing-the-Waters Communication or Written Testing-the-Waters Communication related to the offering of the Offered Securities contemplated hereby are solely the property of the Company.
- (vi) Testing-the-Waters Communication. The Company (a) has not alone engaged in any Testing-the-Waters Communication and (b) has not authorized anyone other than the Representatives and Oppenheimer & Co. Inc. ("Oppenheimer") to engage in Testing-the-Waters Communications. The Company reconfirms that the Representatives and Oppenheimer have been authorized to act on the Company's behalf in undertaking any Testing-the-Waters Communication. The Company has not presented to any potential investors or otherwise distributed any Written Testing-the-Waters Communication.
- (vii) *Good Standing of the Company*. The Company has been duly incorporated and is validly existing as a corporation and in good standing under the laws of the State of Delaware, with power and authority (corporate and other) to own, lease and operate its properties and to conduct its business as

described in the Registration Statement, the General Disclosure Package and the Final Prospectus and to enter into and perform its obligations under this Agreement; and the Company is duly qualified to do business as a foreign corporation in good standing in all other jurisdictions in which its ownership or lease of property or the conduct of its business requires such qualification, except where the failure to so qualify or to be in good standing would not result in a material adverse effect on the condition (financial or otherwise), results of operations, business or properties of the Company and its subsidiaries taken as a whole ("Material Adverse Effect").

- (viii) Subsidiaries. Each "significant subsidiary" of the Company (as such term is defined in Rule 1-02 of Regulation S-X) (each a "Subsidiary" and, collectively, the "Subsidiaries") has been duly incorporated or organized and is validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization, with power and authority (corporate and other) to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the General Disclosure Package and the Final Prospectus; and each Subsidiary of the Company is duly qualified to do business as a foreign corporation in good standing in all other jurisdictions in which its ownership or lease of property or the conduct of its business requires such qualification, except where the failure to so qualify or to be in good standing would not result in a Material Adverse Effect; all of the issued and outstanding capital stock of each subsidiary of the Company has been duly authorized and validly issued and is fully paid and nonassessable; and the capital stock of each subsidiary owned by the Company, directly or through subsidiaries, is owned free from liens, encumbrances and defects.
- (ix) Offered Securities. The Offered Securities and all other outstanding shares of capital stock of the Company have been duly authorized; the authorized equity capitalization of the Company is as set forth in the Registration Statement, the General Disclosure Package and the Final Prospectus; all outstanding shares of capital stock of the Company are, and, when the Offered Securities have been delivered and paid for in accordance with this Agreement on each Closing Date, such Offered Securities will have been, validly issued, fully paid and nonassessable, will conform to the information in the General Disclosure Package and to the description of such Offered Securities contained in the Final Prospectus; the stockholders of the Company have no preemptive rights with respect to the Offered Securities; and none of the outstanding shares of capital stock of the Company have been issued in violation of any preemptive or similar rights of any security holder of the Company. Except as disclosed in the Registration Statement, the General Disclosure Package and the Final Prospectus, there are no outstanding (A) securities or obligations of the Company convertible into or exchangeable for any capital stock of the Company, (B) warrants, rights or options to subscribe for or purchase from the Company any such capital stock or any such convertible or exchangeable securities or obligations or (C) obligations of the Company to issue or sell any shares of capital stock, any such convertible or exchangeable securities or obligations or any such warrants, rights or options. The Company has not, directly or indirectly, offered or sold any of the Offered Securities by means of any "prospectus" (within the meaning of the Act and the Rules and Regulations) or used any "prospectus" or made any offer (within the meaning of the Act and the Rules and Regulations) in connection with the offer or sale of the Offered Securities, in each case other than the preliminary prospectus referred to in Section 2(a)(v) hereof, the General Disclosu
- (x) No Finder's Fee. Except as disclosed in the Registration Statement, the General Disclosure Package, the Final Prospectus and as contemplated by this Agreement, there are no contracts, agreements or understandings between the Company and any person that would give rise to a valid claim against the Company or any Underwriter for a brokerage commission, finder's fee or other like payment in connection with this offering.
- (xi) Registration Rights. Except as disclosed in the Registration Statement, the General Disclosure Package and the Final Prospectus, there are no contracts, agreements or understandings between the Company and any person granting such person the right to require the Company to file a registration statement under the Act with respect to any securities of the Company owned or to be owned by such person or to require the Company to include such securities in the securities registered pursuant to a Registration Statement or in any securities being registered pursuant to any other registration statement filed by the Company under the Act. (collectively, "registration rights"), and any person to whom the Company has granted registration rights has agreed not to exercise such rights until after the expiration of the Lock-Up Period referred to in Section 5(l) hereof.

- (xii) Listing. The Company is subject to and in compliance in all material respects with the reporting requirements of Section 13 or Section 15(d) of the Exchange Act. The Common Stock is registered pursuant to Section 12(b) or 12(g) of the Exchange Act and is listed on the Nasdaq Capital Market, and the Company has taken no action designed to, or reasonably likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the Nasdaq Capital Market, nor has the Company received any notification that the Commission or the Exchange is contemplating terminating such registration or listing.
- (xiii) Absence of Further Requirements. No consent, approval, authorization, or order of, or filing or registration with, any person (including any governmental agency or body or any court) is required to be obtained or made by the Company for the consummation of the transactions contemplated by this Agreement in connection with the offering, issuance and sale of the Offered Securities, except such as have been obtained, or made and such as may be required under state securities laws or by the Financial Industry Regulatory Authority ("FINRA").
- (xiv) *Title to Property*. Except as disclosed in the Registration Statement, the General Disclosure Package and the Final Prospectus, the Company and its subsidiaries have good and marketable title to all real properties and all other properties and assets owned by them, in each case free from all liens, charges, mortgages, pledges, security interests, claims, restrictions or encumbrances of any kind and defects that would materially affect the value thereof or materially interfere with the use made or to be made thereof by them and, except as disclosed in the Registration Statement, the General Disclosure Package and the Final Prospectus, the Company and its subsidiaries hold any leased real or personal property under valid and enforceable leases with no terms or provisions that would materially interfere with the use made or to be made thereof by them.
- (xv) Absence of Defaults and Conflicts Resulting from Transaction. The execution, delivery and performance of this Agreement, and the issuance and sale of the Offered Securities will not result in a breach or violation of any of the terms and provisions of, or constitute a default or a Debt Repayment Triggering Event (as defined below) under, or result in the imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, the charter or by-laws or similar organizational documents of the Company or any of its subsidiaries, any statute, rule, regulation or order of any governmental agency or body or any court, domestic or foreign, having jurisdiction over the Company or any of its subsidiaries or any of their properties, or any agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any of the properties of the Company or any of its subsidiaries is subject (except for such conflicts, breaches, violations, defaults or Debt Repayment Triggering Events, or liens, charges or encumbrances that would not, singly, or in the aggregate, result in a Material Adverse Effect); a "Debt Repayment Triggering Event" means any event or condition that gives, or with the giving of notice or lapse of time would give, the holder of any note, debenture, or other evidence of indebtedness (or any person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or any of its subsidiaries.
- (xvi) Absence of Existing Defaults and Conflicts. Neither the Company nor any of its subsidiaries is (i) in violation of its respective charter or by-laws or similar organizational documents; (ii) in default (or with the giving of notice or lapse of time would be in default) under any existing obligation, agreement, covenant or condition contained in any indenture, loan agreement, mortgage, lease or other agreement or instrument to which any of them is a party or by which any of them is bound or to which any of the properties of any of them is subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority, except in the case of clauses (ii) and (iii) above, for any such defaults or violation that would not, individually or in the aggregate, result in a Material Adverse Effect.

(xvii) Authorization of Agreement. This Agreement has been duly authorized, executed and delivered by the Company.

(xviii) Possession of Licenses and Permits. Except as disclosed in the Registration Statement, the General Disclosure Package and the Final Prospectus, the Company and its subsidiaries possess, and are in compliance with the terms of, all adequate certificates, authorizations, franchises, licenses and permits issued by appropriate federal, state, local or foreign regulatory bodies (collectively, "Licenses") necessary or material to the conduct of the business now conducted or proposed in the Registration Statement, the General Disclosure Package and the Final Prospectus to be conducted by them, except where the failure to so possess would not, singly or in the aggregate, result in a Material Adverse Effect. The Company and each of its subsidiaries are in compliance with the terms and conditions of all such Licenses, except where the failure to so comply would not, singly or in the aggregate, result in a Material Adverse Effect, and have not received any notice of proceedings relating to the revocation or modification of any Licenses that, in each case, if determined adversely to the Company or any of its subsidiaries, would individually or in the aggregate have a Material Adverse Effect.

(xvix) Absence of Labor Dispute. No labor dispute with the employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company or any of its subsidiaries, is imminent and the Company and its subsidiaries are not aware of any existing or imminent labor disturbance by the employees of any of its or any subsidiary's principal suppliers, manufacturers, customers or contractors that would reasonably be expected to have a Material Adverse Effect.

(xx) Possession of Intellectual Property. The Company and its subsidiaries own or have existing licenses under all patents, patent applications, patent rights, licenses, inventions, copyrights, know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures), trademarks, service marks, trade names and other intellectual property used in or necessary for the conduct of the business of the Company and its subsidiaries, in the manner described in the Registration Statement, the General Disclosure Package or the Final Prospectus (collectively, the "Intellectual Property"), and such licenses are enforceable against the Company and, to the Company's knowledge, enforceable against the counterparties to the license agreements under which such licenses were granted to the Company, except as certain rights under any licenses may be limited by bankruptcy and other similar laws affecting the rights of creditors generally and general principles of equity; to the knowledge of the Company, the patents, trademarks, and copyrights, if any, included within the Intellectual Property are valid, enforceable, and subsisting; other than as disclosed in the Registration Statement, the General Disclosure Package or the Final Prospectus: (i) neither the Company nor any of its subsidiaries is obligated to pay a material royalty, grant a license to, or provide other material consideration to any third party in connection with the Intellectual Property, (ii) neither the Company nor any of its subsidiaries has received any written notice or is otherwise aware of any claim of infringement, misappropriation of or conflict with asserted rights of others with respect to any of the Company's or its subsidiaries' products, product candidates, processes or Intellectual Property or of any facts or circumstances which would render any Intellectual Property invalid or inadequate to protect the interest of the Company or any of its subsidiaries therein, and which infringement or conflict (if the subject of any unfavorable decision, ruling or finding) or invalidity or inadequacy, singly or in the aggregate, would result in a Material Adverse Effect, (iii) with the exception of the review of pending applications in the United States Patent and Trademark Office ("USPTO") or corresponding foreign patent offices, no action, suit, claim or other proceeding is pending or, to the knowledge of the Company, is threatened, challenging the Company's or any of its subsidiaries' rights in or to any Intellectual Property, or challenging the validity, enforceability, inventorship, priority or scope of any Intellectual Property, (iv) to the knowledge of the Company, none of the development, manufacture, sale or use of any of the discoveries, inventions, products, product candidates or processes of the Company or its subsidiaries in the manner presently practiced and referred to in the Registration Statement, the General Disclosure Package or the Final Prospectus infringe, or violate any right or issued patent claim of any third party, (v) to the knowledge of the Company, no third party has any ownership right in or to any Intellectual Property that is owned by the Company, other than any co-owner of any patent constituting Intellectual Property who is listed on the records of the

USPTO and any co-owner of any patent application constituting Intellectual Property who is named in such patent application, (vi) the Intellectual Property owned by the Company and its subsidiaries is free and clear of all liens or encumbrances, (vii) to the knowledge of the Company, none of the Intellectual Property employed by the Company or its subsidiaries in the conduct of the business in the manner described in the Registration Statement, the General Disclosure Package or the Final Prospectus has been obtained or is being used by the Company or its subsidiaries in material violation of any contractual obligation binding on the Company or, to the knowledge of the Company, upon any of its officers, consultants, directors or employees, and (viii) the Company has taken reasonable measures to protect its confidential information and trade secrets and to maintain and safeguard the Intellectual Property. All patents and patent applications owned by or licensed to the Company or any of its subsidiaries and included within the Intellectual Property, to the knowledge of the Company, have been duly and properly filed, prosecuted and maintained

(xxi) Company IT Systems. The Company and its subsidiaries own or have a valid right to access and use all computer systems, networks, hardware, software, databases, websites, and equipment used to process, store, maintain and operate data, information, and functions used in connection with the business of the Company and its subsidiaries (the "Company IT Systems"), except as would not, individually or in the aggregate, have a Material Adverse Effect. The Company IT Systems are adequate for, and operate and perform in all material respects as required in connection with, the operation of the business of the Company and its subsidiaries as currently conducted, except as would not, individually or in the aggregate, have a Material Adverse Effect. The Company and its subsidiaries have implemented commercially reasonable backup, security and disaster recovery technology consistent in all material respects with applicable regulatory standards and customary industry practices.

(xxii) Environmental Laws. Except as disclosed in the Registration Statement, the General Disclosure Package and the Final Prospectus and except for such matters as would not individually or in the aggregate have a Material Adverse Effect: (a) neither the Company nor any of its subsidiaries (i) is or has been in violation of any foreign, federal, state or local statute, law, rule, regulation, judgment, order, decree, decision, ordinance, code or other legally binding requirement (including common law) relating to the pollution, protection or restoration of the environment, wildlife or natural resources; human health or safety; or the generation, use, handling, transportation, treatment, storage, discharge, disposal or release of, or exposure to, any Hazardous Substance (as defined below) (collectively, "Environmental Laws"), (ii) is conducting or funding, in whole or in part, any investigation, remediation, monitoring or other corrective action pursuant to any Environmental Law, including to address any actual or suspected Hazardous Substance, (iii) has received notice of, or is subject to any action, suit, claim or proceeding alleging, any actual or potential liability under, or violation of, any Environmental Law, including with respect to any Hazardous Substance, (iv) is party to any order, decree or agreement that imposes any obligation or liability under any Environmental Law, or (v) is or has been in violation of, or has failed to obtain and maintain, any permit, license, authorization, identification number or other approval required under applicable Environmental Laws; (b) to the knowledge of the Company and its subsidiaries, there are no facts or circumstances that would reasonably be expected to result in any violation of or liability under any Environmental Law, including with respect to any Hazardous Substance; and (c) neither the Company nor any of its subsidiaries (i) is subject to any pending or threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigations or proceedings relating to any Environmental Law against the Company or any of its subsidiaries, nor does the Company or any of its subsidiaries know any such proceeding is contemplated, (ii) is aware of any material effect on the capital expenditures, earnings or competitive position of the Company and its subsidiaries resulting from compliance with Environmental Laws, or (iii) anticipates any material capital expenditures relating to any Environmental Laws. For purposes of this subsection, "Hazardous Substance" means (A) any pollutant, contaminant, petroleum and petroleum products, by-products or breakdown products, radioactive materials, asbestos, asbestos-containing materials, polychlorinated biphenyls or toxic mold, and (B) any other toxic, radioactive, ignitable, corrosive, reactive or otherwise hazardous chemical, material, waste or substance.

(xxiii) Absence of Manipulation. Neither the Company nor any affiliate of the Company has taken, nor will the Company or any affiliate take, directly or indirectly, any action that is designed, or would be expected, to cause or result in, or which constitutes, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Offered Securities or to result in a violation of Regulation M under the Exchange Act.

(xxiv) Statistical and Market-Related Data. Any third-party statistical and market-related data included in a Registration Statement, a Statutory Prospectus, the General Disclosure Package, the Final Prospectus or any Written Testing-the-Waters Communication is based on or derived from sources that the Company believes to be reliable and accurate.

(xxv) Compliance with the Sarbanes-Oxley Act. The Company has taken all necessary actions to ensure that it is in compliance with the provisions of Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith (the "Sarbanes-Oxley Act") that are currently in effect and with which the Company is required to comply. There is and has been no material failure on the part of the Company or, to the knowledge of the Company, any of the Company's directors or officers, in their capacities as such, to comply with any applicable provision of the Sarbanes-Oxley Act, including Section 402 related to loans and Sections 302 and 906 related to certifications.

(xxvi) Internal Controls. The Company maintains a system of internal controls, including, but not limited to, disclosure controls and procedures, internal controls over accounting matters and financial reporting and legal and regulatory compliance controls (collectively, "Internal Controls") that comply with applicable Securities Laws and are sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with U.S. Generally Accepted Accounting Principles ("GAAP") and to maintain accountability for assets, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Internal Controls are overseen by the Audit Committee (the "Audit Committee") of the Company's Board of Directors (the "Board") in accordance with Exchange Rules. Except as described in the Registration Statement, the General Disclosure Package and the Final Prospectus, the Company has not publicly disclosed or reported to the Audit Committee or the Board, and within the next 90 days the Company does not reasonably expect to publicly disclose or report to the Audit Committee or the Board, a "significant deficiency" or "material weakness" (each, as defined in Rule 12b-2 of the Exchange Act), a change in Internal Controls or fraud involving management or other employees who have a significant role in Internal Controls (each, an "Internal Control Event"), any violation of, or failure to comply with, the U.S. federal securities laws and the Exchange Rules, or any matter which, if determined adversely, would have a Material Adverse Effect.

(xxvii) Litigation. Except as disclosed in the Registration Statement, the General Disclosure Package and the Final Prospectus, there are no pending actions, suits or proceedings (including any inquiries or investigations by any court or governmental agency or body, domestic or foreign) against or affecting the Company, any of its subsidiaries or any of their respective properties that, if determined adversely to the Company or any of its subsidiaries, would individually or in the aggregate have a Material Adverse Effect, or would materially and adversely affect their respective properties or assets or the ability of the Company to perform its obligations under this Agreement, or which are otherwise material in the context of the sale of the Offered Securities; and no such actions, suits or proceedings (including any inquiries or investigations by any court or governmental agency or body, domestic or foreign) are threatened or, to the knowledge of the Company or any of its subsidiaries, contemplated. The aggregate of all pending legal or governmental proceedings to which the Company or any such subsidiary is a party or of which any of their respective properties or assets is the subject that are not described in the Registration Statement, the General Disclosure Package and the Final Prospectus, including ordinary routine litigation incidental to the business, would not reasonably be expected to result in a Material Adverse Effect.

(xxiii) *Financial Statements*. The financial statements included in the Registration Statement, the General Disclosure Package and the Final Prospectus, together with the related schedules and notes, present fairly, in all material respects, the financial position of the Company and its consolidated subsidiaries as of the dates shown and their results of operations, stockholders' equity and cash flows for the periods shown, and, except as otherwise disclosed in the Registration Statement, the General Disclosure Package and the Final Prospectus, such financial statements have been prepared in conformity with GAAP applied on a consistent basis.

(xxix) No Material Adverse Change in Business. Except as disclosed in the Registration Statement, the General Disclosure Package and the Final Prospectus, since the end of the period covered by the latest audited financial statements included in the Registration Statement, the General Disclosure Package and the Final Prospectus: (i) there has been no change, nor any development or event involving a prospective change, in the condition (financial or otherwise), results of operations, business, properties or prospects of the Company and its subsidiaries, taken as a whole, that is material and adverse, (ii) except as disclosed in or contemplated by the Registration Statement, the General Disclosure Package and the Final Prospectus, there has been no dividend or distribution of any kind declared, paid or made by the Company on any class of its capital stock, (iii) except as disclosed in or contemplated by the General Disclosure Package and the Final Prospectus, there has been no material adverse change in the capital stock, short-term indebtedness, long-term indebtedness, net current assets or net assets of the Company or any of its subsidiaries, (iv) there has been no material transaction entered into and there is no material transaction that is probable of being entered into by the Company or any of its subsidiaries other than transactions in the ordinary course of business, (v) there has been no obligation, direct or contingent, that is material to the Company or any of its subsidiaries taken as a whole, incurred by the Company or any of its subsidiaries, except obligations incurred in the ordinary course of business and (vi) neither the Company nor any of its subsidiaries has sustained any material loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor disturbance or dispute or any action, order or decree of any court or arbitrator or governmental or regulatory authority.

(xxx) *Investment Company Act*. The Company is not and, after giving effect to the offering and sale of the Offered Securities and the application of the proceeds thereof as described in the Registration Statement, the General Disclosure Package and the Final Prospectus, will not be required to register as an "investment company" as defined in the Investment Company Act of 1940, as amended (the "Investment Company Act").

(xxxi) *Ratings*. Neither the Company nor its subsidiaries have any debt securities or preferred stock that are rated by any "nationally recognized statistical rating agency" (as defined in Section 3(a)(62) of the Exchange Act).

(xxxii) *PFIC Status*. The Company was not a "passive foreign investment company" ("**PFIC**") as defined in Section 1297 of the United States Internal Revenue Code of 1986, as amended (the "**Code**"), for its most recently completed taxable year and, based on the Company's current projected income, assets and activities, the Company does not expect to be classified as a PFIC for any subsequent taxable year.

(xxxiii) *Taxes*. The Company and each of its subsidiaries has filed all federal, state, local and foreign tax returns required to be filed through the date of this Agreement and have paid all taxes required to be paid thereon (except as currently being contested in good faith and for which reserves required by GAAP have been created in the financial statements of the Company and with respect to foreign tax returns, except insofar as the failure to file such returns would not result in a Material Adverse Effect), and no material tax deficiency has been, or would reasonably be expected to be, asserted against the Company or any of its subsidiaries. The United States federal income tax returns of the Company through the fiscal year ended December 31, 2019 have been settled and no assessment in connection therewith has been made against the Company. The charges, accruals and reserves on the books of the Company in respect of any income and corporation tax liability for any years not finally determined are adequate to meet any assessments or re-assessments for additional income tax for any years not finally determined, except to the extent of any inadequacy that would not result in a Material Adverse Effect.

(xxxiv) *Insurance*. The Company and its subsidiaries are insured by insurers with appropriately rated claims paying abilities against such losses and risks and in such amounts as are prudent and customary for the businesses in which they are engaged; all policies of insurance and fidelity or surety bonds insuring the Company or any of its subsidiaries or their respective businesses, assets, employees, officers and directors are in full force and effect; the Company and its subsidiaries are in compliance with the terms of such policies and instruments in all material respects; and there are no claims by the Company or any of its subsidiaries under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause; neither the Company nor any such subsidiary has been refused any insurance coverage sought or applied for; neither the Company nor any such subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a Material Adverse Effect, except as set forth in or contemplated in the Registration Statement, the General Disclosure Package and the Final Prospectus.

(xxxv) No Unlawful Payments. None of the Company or any of its subsidiaries, or any director or officer thereof, or, to the knowledge of the Company, any employee, affiliate or any agent or other person acting on behalf of the Company or of any of its subsidiaries or affiliates, has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) taken or will take any action in furtherance of an offer, payment, promise to pay, or authorization or approval of the payment or giving or receipt of money, property, gifts or anything else of value, directly or indirectly, to any government official, including any officer or employee of a government or government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office ("Governmental Official") to influence official action or secure an improper advantage, or to any person in violation of any applicable anti-corruption laws; (iii) violated or is in violation of any provision of the Foreign Corrupt Practices Act of 1977, as amended, or any applicable law or regulation implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or committed an offence under the Bribery Act 2010 of the United Kingdom or any other applicable anti-bribery or anti-corruption law; or (iv) made, offered, agreed, requested or taken an act in furtherance of any unlawful bribe or other unlawful benefit, including, without limitation, any rebate, payoff, influence payment, kickback or other unlawful or improper payment or benefit, to any Government Official or other person or entity. The Company and its subsidiaries and, to the knowledge of the Company, its affiliates have conducted their businesses in compliance with applicable anti-corruption laws and have instituted and maintain and will continue to maintain policies and procedures designed to promote and achieve compliance with all applicable anti-bribery and anti-corruption laws and with the representations and warranties contained herein. Neither the Company nor any of its subsidiaries will use, directly or indirectly, the proceeds of the Offering in furtherance of an offer, payment, promise to pay, or authorization of the payment or giving of money, or anything else of value, to any person in violation of any applicable anti-corruption laws.

(xxxvi) Compliance with Anti-Money Laundering Laws. The operations of the Company and each of its subsidiaries are and have been conducted at all times in compliance with all applicable financial recordkeeping and reporting requirements, including those of the Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), and the applicable anti-money laundering statutes of all jurisdictions where the Company and each of its subsidiaries conduct business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental or regulatory agency (collectively, the "Anti-Money Laundering Laws"), and no action, suit or proceeding by or before any court or governmental or regulatory agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of the Company and its subsidiaries, threatened.

(xxxvii) Economic Sanctions. Neither the Company nor any of its subsidiaries, nor any director, or officer thereof, nor, to the knowledge of the Company or any of its subsidiaries, any agent, employee, affiliate or representative of the Company or any of its subsidiaries, is an individual or entity ("Person") that is, or is owned or controlled by one or more Persons that are: (A) the subject or target of any U.S. sanctions administered or enforced by the U.S. government (including, without limitation, the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State and including, without limitation, the designation as a "specially designated national" or "blocked person"), the United Nations Security Council, the European Union, Her Majesty's Treasury, the Swiss Secretariat of Economic Affairs, the Hong Kong Monetary Authority, the Monetary Authority of Singapore, or other relevant sanctions authority (collectively, "Sanctions"), or (B) located, organized or resident in a country or territory that is the subject or target of Sanctions including, without limitation, Crimea, Cuba, Iran, North Korea and Syria (each a "Sanctioned Country"); and the Company will not, directly or indirectly, use the proceeds of the Offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other Person: (i) to fund or facilitate any activities or business of or with any Person or in any country or territory that, at the time of such funding or facilitation, is the subject or target of any Sanctions; (ii) to fund or facilitate any activities of or business in any Sanctioned Country or (iii) in any other manner that will result in a violation of Sanctions by any Person (including any Person participating in the offering, whether as underwriter, advisor, investor or otherwise). For the past five years, the Company and each of its subsidiaries have not knowingly engaged in, are not now knowingly engaged in, and will not engage in, any dealings or transactions with any Person, or in any country or territory, that at the time of the dealing or transaction is or was the subject or target of Sanctions.

(xxxiii) Clinical Data and Regulatory Compliance. The clinical trials, and other studies (collectively, "studies") that are described in, or the results of which are referred to in the Registration Statement, the General Disclosure Package or the Prospectus were and, if still pending, are being conducted in all material respects in accordance with (i) the protocols, procedures and controls designed and approved for such studies, (ii) standard medical and scientific research procedures, and (iii) applicable laws and regulations; each description of the results of such studies is accurate and complete in all material respects and fairly presents the data derived from such studies in all material respects, and the Company and its subsidiaries have no knowledge of any other studies the results of which are materially inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement, the General Disclosure Package or the Prospectus; except as disclosed in the Registration Statement, the General Disclosure Package and the Final Prospectus, the Company and its subsidiaries have made all such filings and obtained all such approvals as may be required by any Governmental Entity, including the U.S. Food and Drug Administration ("FDA"), the Centers for Medicare & Medicaid Services, and the Department of Health and Human Services Office of Inspector General, Department of Justice, or any committee thereof or from any other U.S. or foreign government or drug or medical device regulatory agency, or by any Institutional Review Board; neither the Company nor any of its subsidiaries has received any written notice of, or correspondence from, any Governmental Entity requiring the termination, suspension or modification of any clinical trials that are described or referred to in the Registration Statement, the General Disclosure Package or the Prospectus; and, except as disclosed in the Registration Statement, the General Disclosure Package and the Final Prospectus, the Company and its subsidiaries have each operated and currently are in compliance in all material respects with all applicable rules, regulations and policies of the Governmental Entities.

(xxxix) *Regulatory Matters*. Except as described in the Registration Statement, the General Disclosure Package and the Final Prospectus: (i) neither the Company nor any of its subsidiaries has received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the FDA or any other Governmental Entity alleging or asserting any material noncompliance with any Applicable Laws (as defined in clause (ii) below) or Authorizations (as defined in clause (iii) below); (ii) to the knowledge of the Company, it and each of its subsidiaries is and has been in material compliance with statutes, laws, ordinances, rules and regulations applicable to the Company and its subsidiaries and their respective activities, including for the ownership, testing, development, manufacture, packaging, processing, use, distribution,

marketing, labeling, advertising, promotion, sale, offer for sale, storage, import, export or disposal of any product developed, manufactured or distributed by the Company, including without limitation, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., similar laws of other Governmental Entities and the regulations promulgated pursuant to such laws (collectively, "Applicable Laws"); (iii) except as disclosed in the Registration Statement, the General Disclosure Package and the Final Prospectus, the Company and each of its subsidiaries possess all material licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws and/or to carry on its businesses as now conducted ("Authorizations") and such Authorizations are valid and in full force and effect, and the Company and its subsidiaries are not in violation of any term of any such Authorizations; (iv) neither the Company nor any of its subsidiaries has received notice of any ongoing claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Entity or third party alleging that any product, operation or activity is in violation of any Applicable Laws or Authorizations or has any knowledge that any such Governmental Entity or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding, nor, to the best of the Company's knowledge, has there been any noncompliance with or violation of any Applicable Laws by the Company or any of its subsidiaries that could reasonably be expected to result in a Material Adverse Effect; (v) neither the Company nor any of its subsidiaries has received notice that any Governmental Entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations or has any knowledge that any such Governmental Entity has threatened or is considering such action; and (vi) the Company and each of its subsidiaries has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and, to the Company's knowledge, all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete, correct and not misleading on the date filed (or were corrected or supplemented by a subsequent submission). Neither the Company, any subsidiary nor, to the Company's knowledge, any of their respective directors, officers, employees or agents has been convicted of any crime under any Applicable Laws or has been the subject of an FDA debarment proceeding. Neither the Company nor any subsidiary has been nor is now subject to FDA's Application Integrity Policy. To the Company's knowledge, neither the Company, any subsidiary nor any of its directors, officers, employees or agents, has made, or caused the making of, any material false statements on, or material omissions from, any other records or documentation prepared or maintained to comply with the requirements of the FDA or any other Governmental Entity.

(xl) *Healthcare Law Compliance*. Except to the extent disclosed in each of the Registration Statement, the General Disclosure Package or the Final Prospectus, (i) each of the Company and its subsidiaries is and has been, since January 1, 2014, in material compliance with all applicable healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a), the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)), the federal Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h), all criminal laws relating to health care fraud and abuse, including 18 U.S.C. Sections 286 and 287, the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.) including the Standards for Privacy of Individually Identifiable Health Information (45 CFR Part 160 and Part 164, Subparts A, D and E), the Transactions and Code Set Standards (45 CFR Part 162), and Security Standards for the Protection of Electronic Protected Health Information (45 CFR Part 164, Subparts A and C), and all other implementing regulations in effect, and the Health Information Technology for Economic and Clinical Health Act provisions of the American Recovery and Reinvestment Act of 2009 set forth at 42 USC § 17931 et seq., and all implementing regulations thereof (collectively "HIPAA"), state laws governing the privacy, security and/or data breach notification requirements of personally identifiable information or any information that constitutes personal data under such laws, the exclusion laws (42 U.S.C. § 1320a-7), the Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.), Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act), state laws restricting interactions between pharmaceutical manufacturers or related entities and healthcare providers or other individuals and entities associated with the healthcare industr

administrative guidance promulgated or issued pursuant to any such laws; all federal or state laws regarding the collection, reporting and/or processing of any applicable prices, rebate, chargeback and/or adjustment under the Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8) and any state supplemental rebate program, Medicare average sales price reporting (42 U.S.C. § 1395w-3a), the Public Health Service Act 340B discount drug program (42 U.S.C. § 256b), the VA Federal Supply Schedule (38 U.S.C. § 8126) or under any state pharmaceutical assistance program, and the regulations promulgated pursuant to such laws and programs (collectively, the "Health Care Laws") as well as the Pharmaceutical Research and Manufacturers of America Code of Interactions with Healthcare Professions ("PhRMA Code") and Advanced Medical Technology Associate Code of Ethics on Interactions with Healthcare Professionals ("AdvaMed Code"); (ii) neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, employee, agent, employee or affiliate of the Company or any of its subsidiaries have committed any act, made any statement or failed to make any statement that would reasonably be expected to provide a basis for the FDA or any other governmental or regulatory authority to invoke its policy with respect to "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," or similar policies, set forth in any Health Care Law; (iii) neither the Company nor any of its subsidiaries, nor any director, officer, employee, or to the knowledge of the Company, agent of the Company or any of its subsidiaries: (a) is or has been suspended, excluded, debarred, or otherwise ineligible to participate in any government health care program; (b) has been charged with or convicted of any criminal offense relating to the delivery of an item or service under Medicare, Medicaid or any other government health care program, or relating to the unlawful distribution, prescription, dispensing or delivery of a controlled substance, or (c) to the knowledge of the Company, is the target or subject of any current or potential investigation relating to any Medicare, Medicaid or any other government health care program related offense; (iv) neither the Company nor any of its subsidiaries has received any notification, correspondence or any other written or oral communication of any pending or threatened claim, suit, proceeding, hearing, enforcement, audit, investigation, arbitration or other action from any Governmental Entity or any third party, including employees, former employees or competitors alleging that any operation or activity of the Company or any of its subsidiaries is, or potentially is, in violation of any Health Care Law; (v) neither the Company nor any of its subsidiaries have knowledge that it engaged in activities that are, as applicable, criminal or cause for false claims liability, civil penalties or mandatory or permissive exclusion from Medicare, Medicaid or any other government healthcare program; (vi) neither the Company nor any of its subsidiaries is a party to any corporate integrity agreements, monitoring agreements, deferred prosecution agreements, consent decrees, settlement orders, or similar agreements with or imposed by any Governmental Entity and no such agreement, decree or order is pending; (vii) neither the Company nor any of its subsidiaries nor any of their respective officers, directors or any of its employees has, directly or indirectly, provided any remuneration or made any bribe, payoff, influence payment, kickback, or other illegal or improper inducement in violation of any Health Care Law, in cash or in kind, to any Person, private or public, regardless of form, whether in money, property, or services to: (a) induce such Person to order any item or service for which payment may be made in whole or in part under any government health care program; (b) to obtain favorable treatment in securing business; (c) to pay for favorable treatment for business secured; or (d) to obtain special concessions or for special concessions already obtained, for or in respect of the Company or any of its subsidiaries; (viii) the Company and each of its subsidiaries has, and operates in material compliance with, an operational healthcare compliance program that: (a) governs all employees and sales representatives; (b) is consistent with the current U.S. Federal Sentencing Guidelines standards for effective compliance programs, the Department of Health and Human Services Office of Inspector General identified seven elements of an effective compliance program and, to the extent applicable, the Department of Health and Human Services Office of Inspector General Voluntary Compliance Guidance for Pharmaceutical Manufacturers; (c) materially complies with the PhRMA Code and AdvaMed Code; and (d) addresses compliance with state laws regulating, or requiring the disclosure to a state agency of, interactions between pharmaceutical manufacturers or related entities and healthcare providers or other individuals and entities associated with the healthcare industry, as well as with the so-called federal "sunshine" law or Open Payments program (42 U.S.C. § 1320a-7h), which compliance includes, without limitation, current registration and filings with appropriate state agencies, as applicable; (ix) to the extent that Company or any of its subsidiaries provides reimbursement coding or billing advice regarding products offered for sale

by Company or any of its subsidiaries and procedures related thereto, such advice is: (a) true and complete, (b) in compliance with all Health Care Laws, (c) conforms to the applicable American Medical Association's Current Procedural Terminology (CPT), the International Classification of Disease, Tenth Revision, Clinical Modification (ICD 10 CM) and other applicable coding systems, (d) includes a disclaimer advising customers to contact individual payers to confirm coding and billing guidelines, (e) has been independently verified and supports accurate claims for reimbursement by federal, state and commercial payors, and (f) provided only with respect to approved indications of such products, and (x) Company is unaware of any proposed or passed, but not yet implemented, federal or state legislation or proposed or adopted, but not yet implemented, policy or contractual change involving a federal health care program (as defined in 42 U.S.C. §1320a-7b(f)) state healthcare program or private third party payor that would materially and adversely affect the reimbursement rates for Company's products or services under such healthcare programs or with respect to such payors.

(xli) ERISA Compliance. Each "employee benefit plan" (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations thereunder (collectively, "ERISA")) established or maintained by the Company, its subsidiaries or their "ERISA Affiliates" (as defined below) is in compliance in all material respects with ERISA. "ERISA Affiliate" means, with respect to the Company or any of its subsidiaries, any member of any group of organizations described in Sections 414(b), (c), (m) or (o) of the Internal Revenue Code of 1986, as amended, and the regulations and published interpretations thereunder (the "Code") of which the Company or such subsidiary is a member. No "reportable event" (as defined under ERISA) has occurred or is reasonably expected to occur with respect to any "employee benefit plan" established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates that either has resulted, or would reasonably be expected to result, in material liability to the Company. No "employee benefit plan" established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates has incurred or reasonably expects to incur any liability under (i) Title IV of ERISA with respect to termination of, or withdrawal from, any "employee benefit plan" or (ii) Sections 412, 4971, 4975 or 4980B of the Code. Each employee benefit plan established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates that is intended to be qualified under Section 401(a) of the Code is so qualified and, to the knowledge of the Company, nothing has occurred, whether by action or failure to act, that would cause the loss of such qualification.

(xlii) Affiliated Transactions or Relationships. No transaction has occurred or relationship exists between or among the Company or any of its subsidiaries, on the one hand, and its affiliates, officers or directors, on the other hand, that is required to be described in the Registration Statement, the General Disclosure Package or the Final Prospectus that is not so described therein.

(xliii) Forward-Looking Statements. No forward-looking statement (within the meaning of Section 27A of the Act and Section 21E of the Exchange Act) contained in the Registration Statement, the General Disclosure Package or the Final Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.

(xliv) Other Offerings. Except as disclosed in the Registration Statement, the General Disclosure Package and the Final Prospectus, the Company has not sold, issued or distributed any Securities during the six-month period preceding the date hereof, including any sales pursuant to Rule 144A under, or Regulation D or Regulation S of, the Act, other than Securities issued pursuant to employee benefit plans, qualified stock option plans or other employee compensation plans or pursuant to outstanding options, rights or warrants.

(xlv) Accuracy of Exhibits. There are no contracts or documents which are required to be described in the Registration Statement, the General Disclosure Package or the Final Prospectus or to be filed as exhibits to the Registration Statement which have not been so described in all material respects and filed as required.

(xlvi) Lending Relationship. Except as disclosed in the Registration Statement, the General Disclosure Package and the Final Prospectus, the Company and its subsidiaries (i) do not have any material lending or other relationship with any bank or lending affiliate of any Underwriter and (ii) does not intend to use any of the proceeds from the sale of the Offered Securities to repay any outstanding debt owed to any affiliate of any Underwriter.

(xlvii) *Margin Rules*. The application of the proceeds received by the Company from the issuance, sale and delivery of the Offered Securities as described in the Registration Statement, the General Disclosure Package and the Final Prospectus will not violate Regulation T, U or X of the Board of Governors of the Federal Reserve System or any other regulation of such Board of Governors.

(xliii) Data Security. (i) The Company and its subsidiaries have materially complied and are presently in material compliance with all of their internal and external privacy policies, contractual obligations, applicable laws, statutes, judgments, orders, rules and regulations of any court or arbitrator or other governmental or regulatory authority and any other legal obligations, in each case, relating to the collection, use, transfer, import, export, storage, protection, disposal and disclosure by the Company and its subsidiaries of personal data, "Protected Health Information" as defined under HIPAA or personally identifiable information ("Data Security Obligations", and such data, "Data"); (ii) neither the Company nor any of its subsidiaries have received any written notification of or complaint regarding and, to the Company's knowledge, there are no other facts that, individually or in the aggregate, would reasonably indicate non-compliance with any Data Security Obligation; and (iii) there is no action, suit or proceeding by or before any court or governmental agency, authority or body pending or threatened alleging in writing non-compliance with any Data Security Obligation.

(xlix) *GDPR*. The Company and its subsidiaries have taken all reasonably necessary actions to comply in all material respects with the European Union General Data Protection Regulation (and are taking all reasonably necessary actions to be in material compliance as of the effective date of any applicable laws and regulations with respect to personal data that have been announced as of the date hereof as becoming effective within 12 months after the date hereof, and for which any non-compliance with same would be reasonably expected to have a Material Adverse Effect).

- (l) Data Breach. The Company and its subsidiaries have taken all commercially reasonable technical and organizational measures necessary to protect the information technology systems and Data used in connection with the operation of their business. Without limiting the foregoing, the Company and its subsidiaries have used commercially reasonable efforts to establish and maintain, and have established, maintained, implemented and complied with, commercially reasonable information technology, information security, cyber security and data protection controls, policies and procedures, including oversight, access controls, encryption, technological and physical safeguards and business continuity/disaster recovery and security plans that are designed to protect against and prevent unauthorized access to or acquisition of Data used in connection with the operation of their business ("Breach") and comply with all Applicable Laws in all material respects. Except as described in the Registration Statement, the General Disclosure Package and the Final Prospectus, to the Company's knowledge, there has been no such Breach, and neither the Company nor any of its subsidiaries have been notified in writing of and has no knowledge of any event or condition that would reasonably be expected to result in any such Breach.
- (li) eXtensible Business Reporting Language. The interactive data in eXtensible Business Reporting Language included in the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.
- 3. Purchase, Sale and Delivery of Offered Securities. On the basis of the representations, warranties and agreements and subject to the terms and conditions set forth herein, the Company agrees to sell to the several Underwriters, and each of the Underwriters agrees, severally and not jointly, to purchase from the Company, at a purchase price of \$[•] per share, the number of Firm Securities set forth opposite the name of such Underwriter in Schedule A hereto.

The Company will deliver the Firm Securities to or as instructed by the Representatives for the accounts of the several Underwriters in a form reasonably acceptable to the Representatives, against payment of the purchase price by the Underwriters in Federal (same day) funds by wire transfer to an account at a bank acceptable to the Representatives drawn to the order of Organogenesis Holdings Inc. at the office of Ropes & Gray LLP, 800 Boylston Street, Boston, MA, 02199-3600, at 10:00 A.M., New York time, on [•], 2020, or at such other time not later than seven full business days thereafter as the Representatives and the Company determine, such time being herein referred to as the "First Closing Date". For purposes of Rule 15c6-1 under the Exchange Act, the First Closing Date (if later than the otherwise applicable settlement date) shall be the settlement date for payment of funds and delivery of securities for all the Offered Securities sold pursuant to the offering. The Firm Securities so to be delivered or evidence of their issuance will be made available for checking at the above office of Ropes & Gray LLP at least 24 hours prior to the First Closing Date.

In addition, upon written notice from the Representatives given to the Company from time to time not more than 30 days subsequent to the date of the Final Prospectus, the Underwriters may purchase all or less than all of the Optional Securities at a purchase price of \$[•] per share; provided, however, that the purchase price paid by the Underwriters for any Optional Securities shall be reduced by an amount per share equal to any dividends declared by the Company and payable on the Firm Securities but not payable on such Optional Securities. The Company agrees to sell to the Underwriters the number of Optional Securities specified in such notice and the Underwriters agree, severally and not jointly, to purchase such Optional Securities. Such Optional Securities shall be purchased from the Company for the account of each Underwriter in the same proportion as the number of shares of Firm Securities set forth opposite such Underwriter's name bears to the total number of shares of Firm Securities (subject to adjustment by the Representatives to eliminate fractions) and may be purchased by the Underwriters only for the purpose of covering over-allotments made in connection with the sale of the Firm Securities. No Optional Securities shall be sold or delivered unless the Firm Securities previously have been, or simultaneously are, sold and delivered. The right to purchase the Optional Securities or any portion thereof may be exercised from time to time and to the extent not previously exercised may be surrendered and terminated at any time upon notice by the Representatives to the Company.

Each time for the delivery of and payment for the Optional Securities, being herein referred to as an "Optional Closing Date", which may be the First Closing Date (the First Closing Date and each Optional Closing Date, if any, being sometimes referred to as a "Closing Date"), shall be determined by the Representatives but shall be not later than five full business days after written notice of election to purchase Optional Securities is given. The Company will deliver the Optional Securities being purchased on each Optional Closing Date to or as instructed by the Representatives for the accounts of the several Underwriters, in a form reasonably acceptable to the Representatives against payment of the purchase price therefore in Federal (same day) funds by wire transfer to an account at a bank acceptable to the Representatives drawn to the order of Organogenesis Holdings Inc., at the above office of Ropes & Gray LLP. The certificates for the Optional Securities being purchased on each Optional Closing Date or evidence of their issuance will be made available for checking at the above office of Ropes & Gray LLP at a reasonable time in advance of such Optional Closing Date.

- 4. Offering by Underwriters. It is understood that the several Underwriters propose to offer the Offered Securities for sale to the public as set forth in the Final Prospectus.
  - 5. Certain Agreements of the Company. The Company agrees with the several Underwriters that:
  - (a) Additional Filings. Unless filed pursuant to Rule 462(c) as part of the Additional Registration Statement in accordance with the next sentence, the Company will file the Final Prospectus, in a form approved by the Representatives, with the Commission pursuant to and in accordance with subparagraph (1) (or, if applicable and if consented to by the Representatives, subparagraph (4)) of Rule 424(b) (such consent not to be unreasonably withheld) not later than the earlier of (A) the second business day following the execution and delivery of this Agreement or (B) the fifteenth business day after the Effective Time of the Initial Registration Statement.. The Company will advise the Representatives promptly of any such filing pursuant to Rule 424(b) and provide satisfactory evidence

to the Representatives of such timely filing. If an Additional Registration Statement is necessary to register a portion of the Offered Securities under the Act but the Effective Time thereof has not occurred as of the execution and delivery of this Agreement, the Company will file the Additional Registration Statement or, if filed, will file a post-effective amendment thereto with the Commission pursuant to and in accordance with Rule 462(b) on or prior to 10:00 P.M., New York time, on the date of this Agreement or, if earlier, on or prior to the time the Final Prospectus is finalized and distributed to any Underwriter, or will make such filing at such later date as shall have been consented to by the Representatives.

- (b) Filing of Amendments: Response to Commission Requests. The Company will promptly advise the Representatives of any proposal to amend or supplement at any time the Initial Registration Statement, any Additional Registration Statement or any Statutory Prospectus and will not effect such amendment or supplementation without the Representatives' consent (such consent not to be unreasonably withheld); and the Company will also advise the Representatives promptly of (i) the effectiveness of any Additional Registration Statement (if its Effective Time is subsequent to the execution and delivery of this Agreement), (ii) any amendment or supplementation of a Registration Statement or any Statutory Prospectus, (iii) any request by the Commission or its staff for any amendment to any Registration Statement, for any supplement to any Statutory Prospectus or for any additional information, (iv) the institution by the Commission of any stop order proceedings in respect of a Registration Statement or the threatening of any proceeding for that purpose, and (v) the receipt by the Company of any notification with respect to the suspension of the qualification of the Offered Securities in any jurisdiction or the institution or threatening of any proceedings for such purpose. The Company will use its best efforts to prevent the issuance of any such stop order or the suspension of any such qualification and, if issued, to obtain as soon as possible the withdrawal thereof.
- (c) Continued Compliance with Securities Laws. If, at any time when a prospectus relating to the Offered Securities is (or but for the exemption in Rule 172 would be) required to be delivered under the Act by any Underwriter or dealer, any event occurs as a result of which the Final Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state any material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, or if it is necessary at any time to amend the Registration Statement or supplement the Final Prospectus to comply with the Act, the Company will promptly notify the Representatives of such event and will promptly prepare and file with the Commission and furnish, at its own expense, to the Underwriters and the dealers and any other dealers upon request of the Representatives, an amendment or supplement which will correct such statement or omission or an amendment which will effect such compliance. Neither the Representatives' consent to, nor the Underwriters' delivery of, any such amendment or supplement shall constitute a waiver of any of the conditions set forth in Section 7 hereof.
- (d) Testing-the-Waters Communication. If at any time following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such statement or omission.
- (e) Rule 158. As soon as practicable, but not later than the Availability Date (as defined below), the Company will make generally available to its security holders an earnings statement covering a period of at least 12 months beginning after the Effective Time of the Initial Registration Statement (or, if later, the Effective Time of the Additional Registration Statement) which will satisfy the provisions of Section 11(a) of the Act and Rule 158 under the Act. For the purpose of the preceding sentence, "Availability Date" means the day after the end of the fourth fiscal quarter following the fiscal quarter that includes such Effective Time on which the Company is required to file its Form 10-Q for such fiscal quarter except that, if such fourth fiscal quarter is the last quarter of the Company's fiscal year, "Availability Date" means the day after the end of such fourth fiscal quarter on which the Company is required to file its Form 10-K.

- (f) Furnishing of Prospectuses. The Company will furnish to the Representatives copies of the Registration Statement and each amendment thereto (each of which will be signed and will include all exhibits), each related Statutory Prospectus, and, so long as a prospectus relating to the Offered Securities is (or but for the exemption in Rule 172 would be) required to be delivered under the Act, the Final Prospectus and all amendments and supplements to such documents, in each case in such quantities as the Representatives request. The Final Prospectus shall be so furnished on the date it was filed with the Commission pursuant to Section 5(a) hereof. All other such documents shall be so furnished as soon as available. The Company will pay the expenses of printing and distributing to the Underwriters all such documents.
- (g) *Blue Sky Qualifications*. The Company will use commercially reasonable efforts to arrange for the qualification of the Offered Securities for sale under the laws of such jurisdictions as the Representatives designate and will continue such qualifications in effect so long as required for the distribution; provided, however, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject.
- (h) *Reporting Requirements*. During the period when the Final Prospectus is required to be delivered under the Act, the Company will furnish to the Representatives and, upon request, to each of the other Underwriters, as soon as practicable after the end of each fiscal year, a copy of its annual report to stockholders for such year; and the Company will furnish to the Representatives (i) as soon as available, a copy of each report and any definitive proxy statement of the Company filed with the Commission under the Exchange Act or mailed to stockholders, and (ii) from time to time, such other information concerning the Company as the Representatives may reasonably request. However, so long as the Company is subject to the reporting requirements of either Section 13 or Section 15(d) of the Exchange Act and is timely filing reports with the Commission on its Electronic Data Gathering, Analysis and Retrieval system (or any successor system) ("EDGAR"), it is not required to furnish such reports or statements to the Underwriters.
- (i) Payment of Expenses. Except as otherwise provided in Section 10, the Company agrees with the several Underwriters that the Company will pay all expenses incident to the performance of the obligations of the Company under this Agreement, including but not limited to (A) any filing fees and other expenses (including fees and disbursements of counsel to the Underwriters) incurred in connection with qualification of the Offered Securities for sale under the laws of such jurisdictions as the Representatives designate and the preparation and printing of memoranda relating thereto, (B) costs and expenses related to the review by FINRA of the Offered Securities (including filing fees and the fees and expenses of counsel for the Underwriters relating to such review) (with such fees, costs and expenses described in (A) and (B) not to exceed \$50,000 in the aggregate), (C) costs and expenses relating to investor presentations or any road show in connection with the offering and sale of the Offered Securities including, without limitation, any travel expenses of the Company's officers and employees and any other expenses of the Company including the cost of transportation in connection with the road show; provided, that 50% of the cost of any aircraft chartered in connection with the road show shall be the responsibility of the Underwriters (it being understood that 50% shall be the responsibility of the Company), (D) fees and expenses incident to listing the Offered Securities on the Nasdaq Stock Market LLC and other national and foreign exchanges, (E) fees and expenses in connection with the registration of the Offered Securities under the Exchange Act, (F) any transfer taxes payable in connection with the delivery of the Offered Securities to the Underwriters and (G) expenses incurred in distributing preliminary prospectuses and the Final Prospectus (including any amendments and supplements thereto) to the Underwriters. Except as provided in this Section 5(i) and in Section 10, the Underwriters shall pay their own co

- (j) Use of Proceeds. The Company will use the net proceeds received by it in connection with this offering in the manner described in the "Use of Proceeds" section of the General Disclosure Package and, except as disclosed in the General Disclosure Package and the Final Prospectus, the Company does not intend to use any of the proceeds from the sale of the Offered Securities hereunder to repay any outstanding debt owed to any Underwriter or affiliate of any Underwriter.
- (k) Absence of Manipulation. The Company will not take, directly or indirectly, any action designed to or that would constitute or that might reasonably be expected to cause or result in, stabilization or manipulation of the price of any securities of the Company to facilitate the sale or resale of the Offered Securities.
- (1) Restriction on Sale of Securities by Company. For the period specified below (the "Lock-Up Period"), the Company will not, and will not publicly disclose an intention to, directly or indirectly, take any of the following actions with respect to its shares of Common Stock or any securities convertible into or exchangeable or exercisable for any of its shares of Common Stock ("Lock-Up Securities"): (i) offer, sell, issue, contract to sell, pledge or otherwise dispose of Lock-Up Securities, (ii) offer, sell, issue, contract to sell, contract to purchase or grant any option, right or warrant to purchase Lock-Up Securities, (iii) enter into any swap, hedge or any other agreement that transfers, in whole or in part, the economic consequences of ownership of Lock-Up Securities, (iv) establish or increase a put equivalent position or liquidate or decrease a call equivalent position in Lock-Up Securities within the meaning of Section 16 of the Exchange Act or (v) file with or confidentially submit to the Commission a registration statement under the Act relating to Lock-Up Securities, in each case without the prior written consent of the Representatives, except: (A) issuances of Lock-Up Securities pursuant to the conversion or exchange of convertible or exchangeable securities or the exercise of warrants or options, in each case outstanding on the date hereof as described in each of the General Disclosure Package and the Final Prospectus, (B) grants of employee stock options pursuant to the terms of a plan in effect on the date hereof as described in each of the General Disclosure Package and the Final Prospectus, (C) issuances of Lock-Up Securities pursuant to the exercise of such options as described in each of the General Disclosure Package and the Final Prospectus, (D) issuances of Lock-Up Securities in connection with acquisitions by the Company provided that (1) the aggregate number of Lock-Up Securities issued pursuant to this clause (D) shall not exceed 5% of the total number of outstanding shares of Common Stock immediately following the issuance and sale of the Offered Securities pursuant hereto and (2) the holder of such Lock-Up Securities shall sign a lock-up agreement in the form attached hereto as Exhibit A if the issuance of Lock-Up Securities occurs during the Lock-Up Period, or (E) issuances of Lock-Up Securities pursuant to the Company's dividend reinvestment plan as described in each of the General Disclosure Package and the Final Prospectus. The Lock-Up Period will commence on the date hereof and continue for 90 days after the date hereof or such earlier date that the Representatives consent to in writing.
- (m) *Emerging Growth Company Status*. The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) completion of the distribution of the Offered Securities within the meaning of the Act and (ii) completion of the Lock-Up Period.
- 7. Conditions of the Obligations of the Underwriters. The obligations of the several Underwriters to purchase and pay for the Firm Securities on the First Closing Date and the Optional Securities to be purchased on each Optional Closing Date will be subject to the accuracy of the representations and warranties of the Company herein (as though made on such Closing Date), to the accuracy of the statements of Company officers made pursuant to the provisions hereof, to the performance by the Company of its obligations hereunder and to the following additional conditions precedent:
  - (a) Accountants' Comfort Letter. The Representatives shall have received letters, dated, respectively, the date hereof and each Closing Date, of RSM US LLP, confirming that they are a registered public accounting firm and independent public accountants within the meaning of the Securities Laws and in the form and substance satisfactory to the Representatives (except that, in any letter dated a Closing Date, the specified date referred to in the comfort letters shall be a date no more than three days prior to such Closing Date).

- (b) Effectiveness of Registration Statement. If the Effective Time of the Additional Registration Statement (if any) is not prior to the execution and delivery of this Agreement, such Effective Time shall have occurred not later than 10:00 P.M., New York time, on the date of this Agreement or, if earlier, the time the Final Prospectus is finalized and distributed to any Underwriter, or shall have occurred at such later time as shall have been consented to by the Representatives. The Final Prospectus shall have been filed with the Commission in accordance with the Rules and Regulations and Section 5(a) hereof. Prior to such Closing Date, no stop order suspending the effectiveness of a Registration Statement shall have been issued and no proceedings for that purpose or under Section 8A of the Securities Act shall have been instituted or, to the knowledge of the Company or the Representatives, shall be contemplated by the Commission.
- (c) No Material Adverse Change. Subsequent to the execution and delivery of this Agreement, there shall not have occurred (i) any change, or any development or event involving a prospective change, in the condition (financial or otherwise), results of operations, business, properties or prospects of the Company and its subsidiaries taken as a whole which, in the judgment of the Representatives, is material and adverse and makes it impractical or inadvisable to market the Offered Securities; (ii) any downgrading in the rating of any debt securities of the Company by any "nationally recognized statistical rating organization" (as defined in Section 3(a)(62) of the Exchange Act), or any public announcement that any such organization has under surveillance or review its rating of any debt securities of the Company (other than an announcement with positive implications of a possible upgrading, and no implication of a possible downgrading, of such rating); (iii) any change in U.S. or international financial, political or economic conditions or currency exchange rates or exchange controls the effect of which is such as to make it, in the judgment of the Representatives, impractical to market or to enforce contracts for the sale of the Offered Securities, whether in the primary market or in respect of dealings in the secondary market; (iv) any suspension or material limitation of trading in securities generally on the New York Stock Exchange or the Nasdaq Stock Market, or any setting of minimum or maximum prices for trading on such exchange; (v) or any suspension of trading of any securities of the Company on any exchange or in the over-the-counter market; (vi) any banking moratorium declared by any U.S. federal or New York authorities; (vii) any major disruption of settlements of securities, payment or clearance services in the United States or any other country where such securities are listed or (viii) any attack on, outbreak or escalation of hostilities or act of terrorism involving the United States, any declaration of war by Congress or any other national or international calamity or emergency if, in the judgment of the Representatives, the effect of any such attack, outbreak, escalation, act, declaration, calamity or emergency is such as to make it impractical or inadvisable to market the Offered Securities or to enforce contracts for the sale of the Offered Securities.
- (d) Opinion and 10b-5 Statement of Counsel for the Company. The Representatives shall have received an opinion and 10b-5 statement, dated such Closing Date, of Foley Hoag LLP, counsel for the Company, in form and substance reasonably satisfactory to the Representatives.
- (e) *Opinion of Intellectual Property Counsel for the Company*. The Representatives shall have received the favorable opinion, dated such Closing Date, of each of Foley Hoag LLP and Maynard, Cooper & Gale, P.C., counsel for the Company with respect to intellectual property matters, in form and substance satisfactory to counsel for the Underwriters.
- (f) Opinion of Regulatory Counsel for the Company. The Representatives shall have received the favorable opinion, dated such Closing Date, of Wilson Sonsini Goodrich & Rosati LLP, counsel for the Company with respect to regulatory matters, in form and substance satisfactory to counsel for the Underwriters.
- (g) Opinion and 10b-5 Statement of Counsel for Underwriters. The Representatives shall have received from Ropes & Gray LLP, counsel for the Underwriters, such opinion or opinions and 10b-5 statement, dated such Closing Date, with respect to such matters as the Representatives may require, and the Company shall have furnished to such counsel such documents as they request for the purpose of enabling them to pass upon such matters.

- (h) Officers' Certificate. The Representatives shall have received a certificate, dated such Closing Date, of an executive officer of the Company and a principal financial or accounting officer of the Company in which such officers shall state that: the representations and warranties of the Company in this Agreement are true and correct; the Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied hereunder at or prior to such Closing Date; no stop order suspending the effectiveness of any Registration Statement has been issued and no proceedings for that purpose or under Section 8A of the Securities Act have been instituted or, to the best of their knowledge and after reasonable investigation, are contemplated by the Commission; the Additional Registration Statement (if any) satisfying the requirements of subparagraphs (1) and (3) of Rule 462(b) was timely filed pursuant to Rule 462(b), including payment of the applicable filing fee in accordance with Rule 456(a) or (b); and, subsequent to the date of the most recent financial statements in the General Disclosure Package and the Final Prospectus, there has been no material adverse change, nor any development or event involving a prospective material adverse change, in the condition (financial or otherwise), results of operations, business, properties or prospects of the Company and its subsidiaries taken as a whole except as set forth in the General Disclosure Package and the Final Prospectus or as described in such certificate.
- (i) *Lock-Up Agreements*. On or prior to the date hereof, the Representatives shall have received lockup agreements in the form set forth on Exhibit A hereto from each executive officer, director, stockholder and other equity holder of the Company specified in Schedule C to this Agreement.
- (j) FinCEN Certificate. On or before the date of this Agreement, the Representatives shall have received a certificate satisfying the beneficial ownership due diligence requirements of the Financial Crimes Enforcement Network ("FinCEN") from the Company in form and substance reasonably satisfactory to the Representatives, along with such additional supporting documentation as the Representatives have requested in connection with the verification of the foregoing certificate.
- (k) CFO Certificate. The Representatives shall have received certificates, dated, respectively, the date hereof and each Closing Date, of the chief financial officer of the Company, which shall contain statements and information of the type ordinarily included in a "CFO certificate," providing "management comfort" with request to certain financial information contained in the General Disclosure Package and the Final Prospectus, in form and substance reasonably satisfactory to counsel for the Underwriters.
- (l) Additional Documents. On the Closing Date, counsel for the Underwriters shall have been furnished with such documents and opinions as they may reasonably require for the purpose of enabling them to pass upon the issuance and sale of the Offered Securities as herein contemplated, or in order to evidence the accuracy of any of the representations or warranties, or the fulfillment of any of the conditions herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Offered Securities as herein contemplated shall be reasonably satisfactory in form and substance to the Representatives and counsel for the Underwriters.

The Company will furnish the Representatives with such conformed copies of such opinions, certificates, letters and documents as the Representatives reasonably request. The Representatives may in their sole discretion waive on behalf of the Underwriters compliance with any conditions to the obligations of the Underwriters hereunder, whether in respect of an Optional Closing Date or otherwise.

8. Indemnification and Contribution. (a) Indemnification of Underwriters by Company. The Company will indemnify and hold harmless each Underwriter, its partners, members, directors, officers, employees, agents, affiliates and each person, if any, who controls such Underwriter within the meaning of Section 15 of the Act or Section 20 of the Exchange Act (each an "Indemnified Party"), against any and all losses, claims, damages or liabilities, joint or several, to which such Indemnified Party may become subject, under the Act, the Exchange Act, other Federal or state statutory law or regulation or otherwise, insofar as such

losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of any material fact contained in any part of any Registration Statement at any time, any Statutory Prospectus as of any time, the General Disclosure Package, the Final Prospectus, any road show or any Written Testing-the-Waters Communication, or arise out of or are based upon the omission or alleged omission of a material fact required to be stated therein or necessary to make the statements therein not misleading, and will reimburse each Indemnified Party for any legal or other expenses reasonably incurred by such Indemnified Party in connection with investigating or defending against any loss, claim, damage, liability, action, litigation, investigation or proceeding whatsoever (whether or not such Indemnified Party is a party thereto), whether threatened or commenced, and in connection with the enforcement of this provision with respect to any of the above as such expenses are incurred; provided, however, that the Company will not be liable in any such case to the extent that any such loss, claim, damage or liability arises out of or is based upon an untrue statement or alleged untrue statement in or omission or alleged omission from any of such documents in reliance upon and in conformity with written information furnished to the Company by any Underwriter through the Representatives specifically for use therein, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in subsection (b) below.

(b) Indemnification of Company. Each Underwriter will severally and not jointly indemnify and hold harmless the Company, each of its directors and each of its officers who signs a Registration Statement and each person, if any, who controls the Company within the meaning of Section 15 of the Act or Section 20 of the Exchange Act (each, an "Underwriter Indemnified Party") against any losses, claims, damages or liabilities to which such Underwriter Indemnified Party may become subject, under the Act, the Exchange Act, or other Federal or state statutory law or regulation or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any untrue statement or alleged untrue statement of any material fact contained in any part of any Registration Statement at any time, any Statutory Prospectus as of any time, the Final Prospectus or any Written Testing-the-Waters Communication, or arise out of or are based upon the omission or the alleged omission of a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in reliance upon and in conformity with written information furnished to the Company by such Underwriter through the Representatives specifically for use therein, and will reimburse any legal or other expenses reasonably incurred by such Underwriter Indemnified Party in connection with investigating or defending against any such loss, claim, damage, liability, action, litigation, investigation or proceeding whatsoever (whether or not such Underwriter Indemnified Party is a party thereto), whether threatened or commenced, based upon any such untrue statement or omission, or any such alleged untrue statement or omission as such expenses are incurred, it being understood and agreed that the only such information furnished by any Underwriter consists of the following information in the Final Prospectus furnished on behalf of each Underwriter: the concession and reallowance figures appearing in the third paragraph under the caption "Underwriting" and the information relating to stabilizing transactions and passive market making contained in the tenth paragraph under the caption "Underwriting".

(c) Actions against Parties; Notification. Promptly after receipt by an indemnified party under this Section of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against an indemnifying party under subsection (a) or (b) above, notify the indemnifying party of the commencement thereof; but the failure to notify the indemnifying party shall not relieve it from any liability that it may have under subsection (a) or (b) above except to the extent that it has been materially prejudiced (through the forfeiture of substantive rights or defenses) by such failure; and provided further that the failure to notify the indemnifying party shall not relieve it from any liability that it may have to an indemnified party otherwise than under subsection (a) or (b) above. In case any such action is brought against any indemnified party and it notifies an indemnifying party of the commencement thereof, the indemnifying party will be entitled to participate therein and, to the extent that it may wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel satisfactory to such indemnified party (who shall not, except with the consent of the indemnified party, be counsel to the indemnifying party), and after notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof, the indemnifying party will not be liable to such indemnified party under this Section for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof other than reasonable costs of investigation. The indemnifying party shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the

plaintiff, the indemnifying party agrees to indemnify the indemnified party from and against any loss or liability by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (A) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request and (B) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement of any pending or threatened action in respect of which any indemnified party is or could have been a party and indemnity could have been sought hereunder by such indemnified party unless such settlement (i) includes an unconditional release of such indemnified party from all liability on any claims that are the subject matter of such action and (ii) does not include a statement as to, or an admission of, fault, culpability or a failure to act by or on behalf of an indemnified party.

(d) Contribution. If the indemnification provided for in this Section is unavailable or insufficient to hold harmless an indemnified party under subsection (a) or (b) above, then each indemnifying party shall contribute to the amount paid or payable by such indemnified party as a result of the losses, claims, damages or liabilities referred to in subsection (a) or (b) above (i) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other from the offering of the Offered Securities or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company on the one hand and the Underwriters on the other in connection with the statements or omissions which resulted in such losses, claims, damages or liabilities as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Underwriters on the other shall be deemed to be in the same proportion as the total net proceeds from the offering (before deducting expenses) received by the Company bear to the total underwriting discounts and commissions received by the Underwriters. The relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or the Underwriters and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such untrue statement or omission. The amount paid by an indemnified party as a result of the losses, claims, damages or liabilities referred to in the first sentence of this subsection (d) shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any action or claim which is the subject of this subsection (d). Notwithstanding the provisions of this subsection (d), no Underwriter shall be required to contribute any amount in excess of the amount by which the total price at which the Offered Securities underwritten by it and distributed to the public were offered to the public exceeds the amount of any damages which such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligations in this subsection (d) to contribute are several in proportion to their respective underwriting obligations and not joint. The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this Section 8(d) were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to in this Section 8(d).

9. Default of Underwriters. If any Underwriter or Underwriters default in their obligations to purchase Offered Securities hereunder on either the First Closing Date or any Optional Closing Date and the aggregate number of Offered Securities that such defaulting Underwriter or Underwriters agreed but failed to purchase does not exceed 10% of the total number of Offered Securities that the Underwriters are obligated to purchase on such Closing Date, the Representatives may make arrangements satisfactory to the Company for the purchase of such Offered Securities by other persons, including any of the Underwriters, but if no such arrangements are made by such Closing Date, the non-defaulting Underwriters shall be obligated severally, in proportion to their respective commitments hereunder, to purchase the Offered Securities that such defaulting Underwriters agreed but failed to purchase on such Closing Date. If any Underwriter or Underwriters so default and the aggregate number of Offered Securities with respect to which such defaults occur exceeds 10% of the total number of Offered Securities that the Underwriters are obligated to purchase on such Closing Date and arrangements satisfactory to the Representatives and the Company for the purchase of such Offered Securities

by other persons are not made within 36 hours after such default, this Agreement will terminate without liability on the part of any non-defaulting Underwriter or the Company, except as provided in Section 10 (provided that if such default occurs with respect to Optional Securities after the First Closing Date, this Agreement will not terminate as to the Firm Securities or any Optional Securities purchased prior to such termination). As used in this Agreement, the term "Underwriter" includes any person substituted for an Underwriter under this Section. Nothing herein will relieve a defaulting Underwriter from liability for its default.

- 10. Termination. The Underwriters may terminate this Agreement by notice given by the Representatives to the Company, if after the execution and delivery of this Agreement and prior to or on the Closing Date or any Optional Closing Date (i) trading generally shall have been suspended or materially limited on, or by, as the case may be, any of the New York Stock Exchange or The Nasdaq Global Market, (ii) trading of any securities of the Company shall have been suspended on any exchange or in any over-the-counter market, (iii) a material disruption in securities settlement, payment or clearance services in the United States shall have occurred, (iv) any moratorium on commercial banking activities shall have been declared by Federal or New York State authorities or (v) there shall have occurred any outbreak or escalation of hostilities, or any change in financial markets or any calamity or crisis that, in the judgment of the Representatives, is material and adverse and which, singly or together with any other event specified in this clause (v), makes it, in the judgment of the Representatives, impracticable or inadvisable to proceed with the offer, sale or delivery of the Offered Securities on the terms and in the manner contemplated in the Registration Statement, the General Disclosure Package or the Final Prospectus.
- 11. Survival of Certain Representations and Obligations. The respective indemnities, agreements, representations, warranties and other statements of the Company or its officers and of the several Underwriters set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation, or statement as to the results thereof, made by or on behalf of any Underwriter, the Company or any of their respective representatives, officers or directors or any controlling person, and will survive delivery of and payment for the Offered Securities. If the purchase of the Offered Securities by the Underwriters is not consummated for any reason other than because of the termination of this Agreement pursuant to Section 9 hereof, the Company will reimburse the Underwriters for all documented out-of-pocket expenses (including fees and disbursements of counsel) reasonably incurred by them in connection with the offering of the Offered Securities, and the respective obligations of the Company and the Underwriters pursuant to Section 8 hereof shall remain in effect. In addition, if any Offered Securities have been purchased hereunder, the representations and warranties in Section 2 and all obligations under Section 5 shall also remain in effect. For the avoidance of doubt, if the purchase of the Offered Securities by the Underwriters is not consummated due to the termination of this Agreement pursuant to Section 9 hereof, the Company will have no obligation to reimburse the Underwriters for any expenses incurred by them in connection with the offering of the Offered Securities.
- 12. Notices. All communications hereunder will be in writing and, if sent to the Underwriters, will be mailed, delivered or telegraphed and confirmed to the Representatives, c/o Morgan Stanley & Co. LLC, 1585 Broadway, New York, New York 10036, Attention: Equity Syndicate Desk, with a copy to the Legal Department; and c/o SVB Leerink, 1301 Avenue of the Americas, 12th Floor, New York, New York 10019 Attention: Stuart Nayman, or, if sent to the Company, will be mailed, delivered or telegraphed and confirmed to it at Organogenesis Holdings Inc., 85 Dan Road, Canton, MA 02021, Attention: General Counsel, with a copy to Foley Hoag LLP, 155 Seaport Boulevard, Boston, Massachusetts 02210, attention of William R. Kolb, provided, however, that any notice to an Underwriter pursuant to Section 8 will be mailed, delivered or telegraphed and confirmed to such Underwriter.
- 13. *Successors*. This Agreement will inure to the benefit of and be binding upon the parties hereto and their respective successors and the officers and directors and controlling persons referred to in Section 7, and no other person will have any right or obligation hereunder.
- 14. *Representation of Underwriters*. The Representatives will act for the several Underwriters in connection with the transactions contemplated by this Agreement, and any action under this Agreement taken by the Representatives jointly will be binding upon all the Underwriters.

- 15. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, but all such counterparts shall together constitute one and the same Agreement. Delivery of this Agreement by one party to the other may be made by facsimile, electronic mail (including any electronic signature complying with the New York Electronic Signatures and Records Act (N.Y. State Tech. §§ 301-309), as amended from time to time, or other applicable law) or other transmission method, and the parties hereto agree that any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.
  - 16. Absence of Fiduciary Relationship. The Company acknowledges and agrees that:
- (a) No Other Relationship. The Representatives have been retained solely to act as underwriters in connection with the sale of the Offered Securities and that no fiduciary, advisory or agency relationship between the Company, on the one hand, and the Representatives, on the other, has been created in respect of any of the transactions contemplated by this Agreement or the Final Prospectus, irrespective of whether the Representatives have advised or are advising the Company on other matters;
- (b) Arms' Length Negotiations. The price of the Offered Securities set forth in this Agreement was established by the Company following discussions and arms-length negotiations with the Representatives and the Company is capable of evaluating and understanding and understand and accept the terms, risks and conditions of the transactions contemplated by this Agreement;
- (c) Regulation BI. None of the activities of the Underwriters in connection with the transactions contemplated herein constitutes a recommendation, investment advice, or solicitation of any action by the Underwriters with respect to any entity or natural person;
- (d) Absence of Obligation to Disclose. The Company has been advised that the Representatives and their affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that the Representatives have no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; and
- (e) Waiver. The Company waives, to the fullest extent permitted by law, any claims it may have against the Representatives for breach of fiduciary duty or alleged breach of fiduciary duty and agree that the Representatives shall have no liability (whether direct or indirect) to the Company in respect of such a fiduciary duty claim or to any person asserting a fiduciary duty claim on behalf of or in right of the Company, including stockholders, employees or creditors of the Company.
- 17. Applicable Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York. The Company hereby submits to the non-exclusive jurisdiction of the Federal and state courts in the Borough of Manhattan in The City of New York in any suit or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby. The Company irrevocably and unconditionally waives any objection to the laying of venue of any suit or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby in Federal and state courts in the Borough of Manhattan in the City of New York and irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such suit or proceeding in any such court has been brought in an inconvenient forum.
- 18. Waiver of Jury Trial. The Company hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.
  - 19. Recognition of the U.S. Special Resolution Regimes.
  - (i) In the event that any Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

(ii) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

As used in this Section 19:

- "BHC Act Affiliate" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k). "Covered Entity" means any of the following:
  - (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b);
  - (ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or
  - (iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b).
- "Default Right" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable.
- "U.S. Special Resolution Regime" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

[Remainder of page intentionally left blank]

If the foregoing is in accordance with the Representatives' understanding of our agreement, kindly sign and return to the Company one of the counterparts hereof, whereupon it will become a binding agreement among the Company and the several Underwriters in accordance with its terms.	
	Very truly yours,
	ORGANOGENESIS HOLDINGS INC.
	By:
	Name: Title:
The foregoing Underwriting Agreement is hereby confirmed and accepted as of the date first above written.	
MORGAN STANLEY & CO. LLC	
By: Name: Title:	
SVB LEERINK LLC	
Ву:	
Name: Title:	

Acting on behalf of themselves and as the Representatives of

the several Underwriters.

# SCHEDULE A

	Number of
	Firm Securities
<u>Underwriter</u>	to be Purchased
Morgan Stanley & Co. LLC	[•]
SVB Leerink LLC	[•]
BTIG, LLC	[•]
Oppenheimer & Co. Inc.	
Total	[•]

### SCHEDULE B

## 1. Other Information Included in the General Disclosure Package

The following information is also included in the General Disclosure Package:

- 1. Price per Offered Security to the public: \$[•]
- 2. Number of Offered Securities: [•] (including [•] Firm Securities)

# SCHEDULE C

Organo Investors LLC		
Avista Acquisition Corp.		
Avista Capital Partners IV, L.P.		
Avista Capital Managing Member IV, LLC		
Avista Capital Partners (Offshore) IV, L.P.		
Avista Capital Partners IV GP, L.P.		
Alan A. Ades		
Robert Ades		
David Erani		
Arthur Leibowitz		
Wayne Mackie		
Glenn H. Nussdorf		
Michael Katz		
Joshua Tamaroff		
Gary S. Gillheeney, Sr		
Henry Hagopian		
Patrick Bilbo		
Lori Freedman		
Brian Grow		
Antonio S. Montecalvo		
Starr Wisdom		
Dennis Erani		
Albert Erani Family Trust Dated 12/29/2012		
Dennis Erani 2012 Issue Trust Dated 12/20/2012		
Alan Ades 2014 GRAT		
GN 2016 Family Trust U/A/D August 12, 2016		
GN 2016 Organo 10-Year GRAT U/A/D September 30, 2016		

Organo PFG LLC



Seaport West 155 Seaport Boulevard Boston, MA 02210-2600

617 832 1000 main 617 832 7000 fax

November 10, 2020

Organogenesis Holdings Inc. 85 Dan Road Canton, Massachusetts 02021

Re: Registration Statement on Form S-1

#### Ladies and Gentlemen:

We are acting as counsel to Organogenesis Holdings Inc., a Delaware corporation (the "Company") in connection with the registration statement on Form S-1, as amended (File No. 333-249531) (the "Registration Statement"), filed by the Company with the Securities and Exchange Commission (the "Commission") pursuant to the Securities Act of 1933, as amended (the "Securities Act"). The Registration Statement relates to the proposed public offering by the Company of up to 20,125,000 shares (the "Shares") of the Company's Class A common stock, par value \$0.0001 per share. The foregoing number of Shares assumes the exercise in full of the over-allotment option described in the Registration Statement. This opinion is furnished to you at your request in accordance with the requirements of Item 16 of the Commission's Form S-1 and Item 601(b)(5) of Regulation S-K promulgated under the Securities Act.

The Shares are to be sold by the Company pursuant to an underwriting agreement (the "Underwriting Agreement") to be entered into by and among the Company, Morgan Stanley & Co. LLC and SVB Leerink LLC, as representatives of the underwriters, a form of which is being filed as Exhibit 1.1 to the Registration Statement.

We have examined the Certificate of Incorporation and Bylaws of the Company, records of meetings and consents of the Board of Directors of the Company or committees thereof, and records of proceedings of the stockholders, deemed by us to be relevant to this opinion letter and each as provided to us by the Company, and the Registration Statement and the exhibits thereto. We have also made such further legal and factual examinations and investigations as we deemed necessary for purposes of expressing the opinion set forth herein.

As to certain factual matters relevant to this opinion letter, we have relied conclusively upon originals or copies, certified or otherwise identified to our satisfaction, of such records, agreements, documents and instruments, including certificates or other comparable documents of officers of the Company and of public officials, as we have deemed appropriate as a basis for the opinion hereinafter set forth. Except to the extent

Organogenesis Holdings Inc. November 10, 2020 Page 2

expressly set forth herein, we have made no independent investigations with regard to matters of fact and, accordingly, we do not express any opinion as to matters that might have been disclosed by independent verification.

In rendering the opinion set forth below, we have assumed that (i) all information contained in all documents reviewed by us is true and correct; (ii) all signatures on all documents examined by us are genuine; (iii) all documents submitted to us as originals are authentic, and all documents submitted to us as copies conform to the originals of those documents; (iv) each natural person signing any document reviewed by us had the legal capacity to do so; and (v) the certificates or other documents representing the Shares will be duly executed and delivered.

Based upon the foregoing and subject to the limitations, qualifications, exceptions and assumptions set forth herein, we are of the opinion that the Shares, when sold and issued against payment therefor as provided in the Underwriting Agreement and described in the Registration Statement and the prospectus forming a part thereof, will be validly issued, fully paid and non-assessable.

This opinion is to be used only in connection with the offer and sale of the Shares while the Registration Statement is effective.

Our opinion set forth herein is limited to the General Corporation Law of the State of Delaware, and we do not express any opinion herein concerning any other laws.

This opinion is being delivered solely for the benefit of the Company and such other persons as are entitled to rely upon it pursuant to the applicable provisions of the Securities Act. This opinion may not be used, quoted, relied upon or referred to for any other purpose, nor may it be used, quoted, relied upon or referred to by any other person, for any purpose, without our prior written consent. No opinion may be implied or inferred beyond the opinion expressly stated above. Our opinion expressed herein is as of the date hereof, and we undertake no obligation to advise you of any changes in applicable law or any other matters that may come to our attention after the date hereof that may affect our opinion expressed herein.

We consent to the filing of this opinion letter with the Commission as an exhibit to the Registration Statement and the use of our name therein and in the related prospectus under the heading "Legal Matters" in the prospectus included in the Registration Statement. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder.

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This opinion letter shall be interpreted in accordance with the Core Opinion Principles jointly issued by the Committee on Legal Opinions of the American Bar Association's Business Law Section and the Working Group on Legal Opinions Foundation as published in 74 Business Lawyer 815 (2019).

Very truly yours,

FOLEY HOAG LLP

By: /s/ Stacie S. Aarestad

A Partner

### **Consent of Independent Registered Public Accounting Firm**

We consent to the use in this Amendment No. 1 to the Registration Statement (No. 333-249531) on Form S-1 of Organogenesis Holdings Inc. of our report dated March 9, 2020, relating to the consolidated financial statements of Organogenesis Holdings Inc., appearing in the Prospectus, which is part of this Registration Statement.

We also consent to the reference to our firm under the heading "Experts" in such Prospectus.

/s/ RSM US LLP

Boston, Massachusetts November 10, 2020

#### **POWER OF ATTORNEY**

KNOW ALL BY THESE PRESENTS that the individual whose signature appears below constitutes and appoints each of Gary S. Gillheeney, Sr. and Henry Hagopian as such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to the Organogenesis Holdings Inc. registration statement on Form S-1 (File No. 333-249531) filed with the Securities and Exchange Commission (the "SEC") on October 16, 2020 (or any registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act), and to file the same, with all exhibits thereto, and all documents in connection therewith, with the SEC, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Date: November 10, 2020 By: /s/ Robert Ades

Robert Ades Director Organogenesis Holdings Inc.

#### **POWER OF ATTORNEY**

KNOW ALL BY THESE PRESENTS that the individual whose signature appears below constitutes and appoints each of Gary S. Gillheeney, Sr. and Henry Hagopian as such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to the Organogenesis Holdings Inc. registration statement on Form S-1 (File No. 333-249531) filed with the Securities and Exchange Commission (the "SEC") on October 16, 2020 (or any registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act), and to file the same, with all exhibits thereto, and all documents in connection therewith, with the SEC, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Date: November 10, 2020 By: \_/s/ David Erani

David Erani Director

Organogenesis Holdings Inc.