

PROSPECTUS

# ORGANOGENESIS HOLDINGS INC.

## 46,853,325 Shares of Class A Common Stock

The Selling Stockholders named in this prospectus or their permitted transferees may offer and sell from time to time up to 46,853,325 shares of our Class A common stock (as defined below) covered by this prospectus, which includes: up to (i) 1,390,993 shares of Class A common stock, originally issued as Founder Shares (as defined below) and initially purchased by the sponsor (as defined below) and certain other accredited investors, which are subject to certain transfer restrictions as described herein; (ii) 9,022,741 shares of Class A common stock issued immediately following the domestication through the equity financing pursuant to the Subscription Agreement, dated as of August 17, 2018, by and among the PIPE Investors (as defined below); (iii) 6,538,732 shares of Class A common stock issued to the PIPE Investors in connection with the merger; (iv) 6,502,679 shares of Class A common stock issued in connection with the conversion of a portion of the outstanding obligations of Organogenesis owed to creditors who are insiders of Organogenesis; (v) 131,744 shares of Class A common stock issued to the executive officers of Organogenesis in connection with the merger; (vi) 378,281 shares of Class A common stock issued to Organogenesis PFG LLC in connection with the merger; (vii) 15,500,000 shares of Class A common stock, issuable upon the exercise of redeemable warrants that were issued as part of the units in our initial public offering, where two warrants must be exercised for one whole share at an exercise price of \$11.50 per share of Class A common stock; (viii) 2,050,000 shares of Class A common stock issuable upon the exercise of redeemable warrants that we issued immediately following the domestication through the equity financing pursuant to the Subscription Agreement, dated as of August 17, 2018, by and among the PIPE Investors, where two warrants must be exercised for one whole share at an exercise price of \$11.50 per share of Class A common stock; (ix) 182,700 shares of Class A common stock issuable upon the exercise of the exchange warrants; and (x) 5,155,455 shares of Class A common stock issuable upon exercise of options issued and held by the executive officers of Organogenesis.

We will not receive any proceeds from the sale of shares of Class A common stock by the Selling Stockholders or by us pursuant to this prospectus, except with respect to amounts received by us upon the exercise of the Warrants (as defined below) and Options (as defined below). However, we will pay the expenses, other than any underwriting discounts and commissions, associated with the sale of shares pursuant to this prospectus.

Our registration of the securities covered by this prospectus does not mean that the Selling Holders will offer or sell any of such securities. The Selling Holders may sell the securities covered by this prospectus in a number of different ways and at varying prices. We provide more information about how the Selling Stockholders may sell the shares in the section entitled "Plan of Distribution."

Our Class A common stock is listed on NASDAQ Capital Market ("NASDAQ") under the symbol "ORGO". Trading of our Class A common stock and public warrants was suspended as a result of the redemption on October 31, 2018 of all of AHPAC's public shares. On November 2, 2018, as a result of the redemption of the public shares, NASDAQ issued a delisting notice in respect of the AHPAC units, AHPAC Class A ordinary shares and AHPAC warrants to purchase Class A ordinary shares. On November 9, 2018, AHPAC submitted a request for an oral hearing before the Hearings Panel to appeal the delisting determination pursuant to the procedures set forth in the NASDAQ rules. That hearing occurred on December 13, 2018 and on January 4, 2019, NASDAQ notified us that the Hearings Panel granted our request for the continued listing of our Class A common stock and lifted the trading suspension at the open of the market on January 8, 2019. Pursuant to the Hearing Panel's decision, on or before March 31, 2019, we are required to demonstrate to the satisfaction of Staff and the Hearings Panel that we have a minimum of 300 round lot common stockholders and that we otherwise meet all applicable requirements for listing on Nasdaq. The Hearings Panel determined to delist our public warrants due to our non-compliance with the minimum 400 round lot holder requirement for initial listing on NASDAQ, as required by Nasdaq Listing Rule 5515(a)(4). Accordingly, the trading suspension in the Company's warrants was converted to a trading suspension effective at the open of the market on January 8, 2019, at which time the warrants became eligible to trade "over-the-counter" under the trading symbol "ORGOW."

**An investment in our securities involves risks. See "[Risk Factors](#)" beginning on page 5 of this prospectus, and any updates to those risk factors or new risk factors contained in our subsequent Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K filed with the SEC, all of which we incorporate by reference herein.**

We are an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, as amended (the "Securities Act") and are subject to reduced public company reporting requirements. This prospectus complies with the requirements that apply to an issuer that is an emerging growth company.

**Neither the SEC 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.**

The date of this prospectus is February 4, 2019.

TABLE OF CONTENTS

<a href="#">ABOUT THIS PROSPECTUS</a>	i
<a href="#">CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</a>	ii
<a href="#">FREQUENTLY USED TERMS</a>	iii
<a href="#">SUMMARY</a>	1
<a href="#">RISK FACTORS</a>	5
<a href="#">USE OF PROCEEDS</a>	42
<a href="#">SELLING STOCKHOLDERS</a>	43
<a href="#">DESCRIPTION OF SECURITIES BEING REGISTERED</a>	48
<a href="#">PLAN OF DISTRIBUTION</a>	53
<a href="#">LEGAL MATTERS</a>	55
<a href="#">EXPERTS</a>	55
<a href="#">WHERE YOU CAN FIND MORE INFORMATION</a>	55
<a href="#">DOCUMENTS INCORPORATED BY REFERENCE</a>	56

You should rely only on the information provided in this prospectus, as well as the information incorporated by reference into this prospectus and any applicable prospectus supplement. We have not authorized anyone to provide you with different information. We are not making an offer of these securities in any jurisdiction where the offer is not permitted. You should not assume that the information in this prospectus, any applicable prospectus supplement or any documents incorporated by reference is accurate as of any date other than the date of the applicable document. Since the respective dates of this prospectus and the documents incorporated by reference into this prospectus, our business, financial condition, results of operations and prospects may have changed.

## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission (the “SEC”) using a “shelf” registration process. Under this shelf registration process, the Selling Stockholders may, from time to time, offer and sell any combination of the securities described in this prospectus in one or more offerings. This prospectus generally describes our Company and our securities. We and the Selling Stockholders may use the shelf registration statement to sell up to an aggregate of 46,853,325 shares of our Class A common stock from time to time as described in the section entitled “Plan of Distribution.”

We will not receive any proceeds from the sale of shares of Class A common stock to be offered by the Selling Stockholders pursuant to this prospectus, except with respect to amounts received by us due to the exercise of the Warrants (as defined below) and the Options (as defined below). However, we will pay the expenses, other than underwriting discounts and commissions, associated with the sale of shares of Class A common stock pursuant to this prospectus. To the extent appropriate, we and the Selling Stockholders, as applicable, will deliver a prospectus supplement with this prospectus to update the information contained in this prospectus. The prospectus supplement may also add, update or change information included in this prospectus. You should read both this prospectus and any applicable prospectus supplement, together with additional information described below under the captions “Where You Can Find More Information” and “Documents Incorporated by Reference.”

No offer of these securities will be made in any jurisdiction where the offer is not permitted.

Unless the context indicates otherwise, the terms “Organogenesis,” “Company,” “we,” “us” and “our” refer to Organogenesis Holdings Inc. (formerly known as Avista Healthcare Public Acquisition Corp.), a Delaware corporation. References in this prospectus to the “Business Combination” refer to the consummation of the transactions contemplated by that certain Agreement and Plan of Merger, dated as of August 17, 2018, which transactions were consummated on December 10, 2018.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into this prospectus contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We may also make forward-looking statements in other reports filed with the SEC, in materials delivered to stockholders and in press releases. In addition, our representatives may from time to time make oral forward-looking statements.

These forward-looking statements relate to expectations for future financial performance, business strategies or expectations for our business. Specifically, forward-looking statements may include statements relating to:

- the benefits of the Business Combination;
- the future financial performance of the post-combination company following the Business Combination, including the Company's expected revenue for fiscal 2018 and fiscal 2019 and the breakdown of such revenues in both its Advanced Wound Care and Surgical & Sports Medicine categories as well as the estimated revenue contribution of its PuraPly products;
- changes in the market for our products;
- expansion plans and opportunities; and
- other statements preceded by, followed by or that include the words "may," "can," "should," "will," "estimate," "plan," "project," "forecast," "intend," "expect," "anticipate," "believe," "seek," "target" or similar expressions.

These forward-looking statements are based on information available as of the date of this prospectus and our management's current expectations, forecasts and assumptions, and involve a number of judgments, risks and uncertainties. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date. We do not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

You should not place undue reliance on these forward-looking statements in deciding whether to invest in our securities. As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. Some factors that could cause actual results to differ include:

- the inability to maintain the listing of our common stock on NASDAQ following the Business Combination;
- the risk that the Business Combination disrupts current plans and operations as a result of the announcement and consummation of the transactions described herein;
- the ability to recognize the anticipated benefits of the Business Combination, which may be affected by, among other things, competition and the ability of the combined business to grow and manage growth profitably;
- the impact of any changes to the reimbursement levels for the Company's products and the impact to the Company of the loss of preferred "pass through" status for PuraPly AM and PuraPly on October 1, 2020;
- costs related to the Business Combination;
- changes in applicable laws or regulations;
- the inability to launch new Organogenesis products or to profitably expand into new markets;
- the possibility that we may be adversely affected by other economic, business, and/or competitive factors; and
- other risks and uncertainties described in this prospectus under "Risk Factors," and any updates to those risk factors or new risk factors contained in our subsequent Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K filed with the SEC, all of which we incorporate by reference herein.

## FREQUENTLY USED TERMS

“*Organogenesis*,” “*us*,” “*Company*,” or “*our Company*” means Organogenesis Holdings Inc., a Delaware corporation.

“*AHPAC*” means Avista Healthcare Public Acquisition Corp., a Cayman Islands exempted company (which Organogenesis was formerly known as).

“*AHPAC Class A ordinary share*” means the Class A ordinary shares, par value \$0.0001 per share, of AHPAC.

“*AHPAC Class B ordinary share*” means the Class B ordinary shares, par value \$0.0001 per share, of AHPAC.

“*Amended and Restated Registration Rights Agreement*” means that certain Amended and Restated Registration Rights Agreement, which was entered into at the closing of the Business Combination, by and among AHPAC, the sponsor and the Restricted Stockholders.

“*Board*” means the board of directors of Organogenesis.

“*Business Combination*” means the transactions contemplated by the Merger Agreement, including: (i) the domestication and (ii) the merger of Merger Sub with and into Organogenesis, with Organogenesis surviving the merger as a wholly owned direct subsidiary of AHPAC.

“*Class A common stock*” means the shares of Class A common stock, par value \$0.0001 per share, of the Company.

“*Class B common stock*” means the shares of Class B common stock, par value \$0.0001 per share, of the Company.

“*common stock*” means the shares of common stock, par value \$0.0001 per share, of the Company.

“*DGCL*” means the General Corporation Law of the State of Delaware.

“*domestication*” means the deregistration of AHPAC as an exempted company in the Cayman Islands under the Cayman Islands Companies Law (2018 Revision), and domestication as a corporation incorporated under the laws of the State of Delaware under Section 388 of the Delaware General Corporation Law, pursuant to which AHPAC’s jurisdiction of incorporation was changed from the Cayman Islands to the State of Delaware.

“*effective time*” means the time specified in the certificate of merger with respect to the merger.

“*exchange warrants*” means warrants to purchase 182,700 shares of Class A common stock assumed in connection with the merger.

“*Founder Shares*” means the 1,390,993 shares of Class A common stock that were converted from shares of Class B common stock at the closing of the Business Combination, which were initially purchased by the sponsor and certain other accredited investors.

“*initial shareholders*” means holders of Founder Shares prior to the IPO.

“*IPO*” means AHPAC’s initial public offering, consummated on October 14, 2016, through the sale of 31,000,000 public units (including 1,000,000 units sold pursuant to the underwriters’ partial exercise of their over-allotment option) at \$10.00 per unit.

## [Table of Contents](#)

“*merger*” means the merger of Merger Sub with and into Organogenesis, with Organogenesis surviving the merger.

“*Merger Agreement*” means that certain Agreement and Plan of Merger, dated August 17, 2018, (as it may be amended from time to time), by and among AHPAC, Merger Sub and Organogenesis.

“*Merger Sub*” means Avista Healthcare Merger Sub, Inc., a Delaware corporation and a direct wholly owned subsidiary of AHPAC.

“*Options*” means options to purchase 5,155,455 shares of Class A common stock assumed in connection with the merger that are held by the executive officers of the Company.

“*PIPE Investors*” means Avista Capital Partners IV, L.P., a Delaware limited partnership and Avista Capital Partners IV (Offshore), L.P., a limited partnership organized under the laws of Bermuda.

“*PIPE Subscription Agreement*” means the subscription agreement entered into on August 17, 2018 between us and the PIPE Investors as it may be amended from time to time.

“*PIPE warrants*” means the warrants issued to the PIPE Investors in the equity financing in connection with the closing of the Business Combination.

“*private placement warrants*” means the warrants issued to the initial shareholders in a private placement simultaneously with the closing of the IPO.

“*public warrants*” means the warrants included in the units issued in AHPAC’s IPO, where two warrants must be exercised for one whole share of Class A common stock in accordance with the terms of the warrant agreements governing the warrants.

“*Restricted Stockholders*” means, collectively, the sponsor, certain directors of AHPAC (as set forth in the Amended and Restated Registration Rights Agreement), the Insider Lenders, the PIPE Investors, and certain Organogenesis Stockholders that receive Class A common stock in the Business Combination.

“*Securities Act*” means the Securities Act of 1933, as amended.

“*Selling Stockholders*” means the persons listed in the table in the “Selling Stockholders” section of this prospectus, and the pledgees, donees, transferees, assignees, successors and others who later come to hold any of the Selling Stockholders’ interest in Class A common stock other than through a public sale.

“*sponsor*” means Avista Acquisition Corp., a Cayman Islands exempted company and an affiliate of Avista Capital Holdings, L.P., a Delaware limited partnership.

“*Sponsor Subscription Agreement*” means the subscription agreement entered into on August 17, 2018 between us and our sponsor as it may be amended from time to time.

“*Subscription Agreements*” means the PIPE Subscription Agreements and the Sponsor Subscription Agreement.

“*transfer agent*” means Continental Stock Transfer & Trust Company.

“*units*” means one AHPAC Class A ordinary share and one redeemable public warrant of AHPAC, whereby each public warrant entitles the holder thereof to purchase one-half of one AHPAC Class A ordinary share, where two warrants must be exercised for one whole Class A share at an exercise price of \$11.50 per AHPAC Class A ordinary share, sold in the IPO.

“*Warrants*” means the PIPE warrants together with the public warrants and the exchange warrants.

## SUMMARY

*This summary highlights selected information contained in this prospectus and does not contain all of the information that is important to you. This summary is qualified in its entirety by the more detailed information included in or incorporated by reference into this prospectus. Before making your investment decision with respect to our Class A common stock, you should carefully read this entire prospectus, any applicable prospectus supplement and the documents referred to in “Where You Can Find More Information” and “Documents Incorporated by Reference.”*

*When we use the words “Organogenesis,” “the Company,” “we,” “us,” or “our,” we are referring to Organogenesis Holdings Inc. and its consolidated subsidiaries.*

### **The Company**

We are 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 surgical 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. The majority of the existing and pipeline products in our portfolio have premarket approval applications (“PMA”) approval, biologics license applications (“BLA”) approval or 510(k) clearance from the United States Food and Drug Administration (the “FDA”). Given the extensive time and cost required to conduct clinical trials and receive FDA approvals, we believe that our data and regulatory approvals provide us a strong competitive advantage. Our product development expertise and multiple technology platforms provide a robust product pipeline, which we believe will drive future growth.

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

In the Advanced Wound Care market, we focus on the development and commercialization of advanced wound care products for the treatment of chronic and acute wounds, primarily in the outpatient setting. We have a comprehensive portfolio of regenerative medicine products, capable of supporting patients from early in the 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 (“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.

We were formerly a special purpose acquisition company, incorporated under the laws of the Cayman Islands on December 4, 2015 under the name Avista Healthcare Public Acquisition Corp. 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, pursuant to the terms of the Merger Agreement, among other things, (i) AHPAC transferred by way of continuation out of the Cayman Islands into the State of Delaware as a corporation incorporated under the laws of the State of Delaware under Section 388 of the Delaware General Corporation Law; and (ii) Merger Sub merged with and into Organogenesis, the separate corporate existence of Merger Sub ceased and Organogenesis is the surviving corporation and a direct wholly owned subsidiary of AHPAC.

**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](http://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.



## THE OFFERING

Issuer	Organogenesis Holdings Inc.
Shares of Class A common stock offered by the Selling Stockholders	<p>Up to 46,853,325 shares of Class A common stock, which includes up to:</p> <ul style="list-style-type: none"><li>• 1,390,993 shares of Class A common stock, originally issued as Founder Shares;</li><li>• 9,022,741 shares of Class A common stock issued through the equity financing by and among the PIPE Investors;</li><li>• 6,538,732 shares of Class A common stock issued to the PIPE Investors in connection with the merger;</li><li>• 6,502,679 shares of Class A common stock issued in connection with the conversion of a portion of the outstanding obligations of Organogenesis owed to creditors who are insiders of Organogenesis;</li><li>• 131,744 shares of Class A common stock issued to the executive officers in connection with the merger;</li><li>• 378,281 shares of Class A common stock issued to Organogenesis PFG LLC in connection with the merger;</li><li>• 15,500,000 shares of Class A common stock, issuable upon the exercise of the public warrants;</li><li>• 2,050,000 shares of Class A common stock, issuable upon the exercise of the PIPE warrants;</li><li>• 182,700 shares of Class A common stock issuable upon the exercise of the exchange warrants; and</li><li>• 5,155,455 shares of Class A common stock issuable upon the exercise of the Options.</li></ul>
Shares of common stock outstanding prior to any exercise of Warrants or Options	91,989,961 shares of Class A common stock.
Lock-up	<p>Our initial shareholders have agreed not to transfer, assign or sell any of their shares of Class A common stock, which were originally issued as Founder Shares, until the earlier to occur of: (a) one year after the completion of our Business Combination, (b) the first date the closing price of the Class A common stock equals or exceeds \$12.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within any 30-trading day period commencing at least 150 days after the effective time or (c) the date on which the Company completes a liquidation, merger, stock exchange, reorganization or other similar transaction which results in all of the Company's stockholders having the right to exchange their Class A common stock for cash, securities or other property; unless the Board has authorized a release or waiver from such lock-up.</p>

Use of proceeds	<p>All of the shares of Class A common stock offered by the Selling Stockholders pursuant to this prospectus will be sold by the Selling Stockholders for their respective accounts. We will not receive any of the proceeds from these sales.</p> <p>We will receive up to an aggregate of approximately \$212 million from the exercise of Warrants and Options assuming the exercise in full of all Warrants and Options for cash. We expect to use the net proceeds from the exercise of the Warrants and Options for general corporate purposes.</p>
Market for our common stock and public warrants	<p>Our shares of common stock and our public warrants are currently listed on the NASDAQ Capital Market.</p>
NASDAQ Ticker Symbol	<p>Our Class A common stock is listed on NASDAQ under the symbol “ORGO”. Trading of our Class A common stock and public warrants was suspended as a result of the redemption on October 31, 2018 of all of AHPAC’s public shares. On November 2, 2018, as a result of the redemption of the public shares, NASDAQ issued a delisting notice in respect of the AHPAC units, AHPAC Class A ordinary shares and AHPAC warrants to purchase Class A ordinary shares. On November 9, 2018, AHPAC submitted a request for an oral hearing before the Hearings Panel to appeal the delisting determination pursuant to the procedures set forth in the NASDAQ rules. That hearing occurred on December 13, 2018 and on January 4, 2019, NASDAQ notified us that the Hearings Panel granted our request for the continued listing of our Class A common stock and lifted the trading suspension at the open of the market on January 8, 2019. Pursuant to the Hearing Panel’s decision, on or before March 31, 2019, we are required to demonstrate to the satisfaction of Staff and the Hearings Panel that we have a minimum of 300 round lot common stockholders and that we otherwise meet all applicable requirements for listing on Nasdaq. The Hearings Panel determined to delist our public warrants due to our non-compliance with the minimum 400 round lot holder requirement for initial listing on NASDAQ, as required by Nasdaq Listing Rule 5515(a)(4). Accordingly, the trading suspension in the Company’s warrants was converted to a trading suspension effective at the open of the market on January 8, 2019, at which time the warrants became eligible to trade “over-the-counter” under the trading symbol “ORGOW.”</p>
Risk Factors	<p>Any investment in the securities offered hereby is speculative and involves a high degree of risk. You should carefully consider the information set forth in our current and periodic reports filed with the SEC and under “Risk Factors” on page 5 of this prospectus.</p>

## RISK FACTORS

An investment in our securities involves a high degree of risk. Before you invest in our securities, you should carefully consider those risk factors described under the heading “Risk Factors” in our most recent Annual Report on Form 10-K filed on March 14, 2018, our Quarterly Report on Form 10-Q filed on November 9, 2018 and Current Report on Form 8-K filed on December 11, 2018 (other than, in each case, information furnished rather than filed), which are incorporated by reference herein and are accessible on the SEC’s website at [www.sec.gov](http://www.sec.gov), and those risk factors that may be included in any applicable prospectus supplement, together with all of the other information included in this prospectus, any prospectus supplement and the documents we incorporate by reference, in evaluating an investment in our securities. Our business, prospects, financial condition or operating results could be harmed by any of these risks, as well as other risks not currently known to us or that we currently consider immaterial. The trading price of our securities could decline due to any of these risks, and, as a result, you may lose all or part of your investment. Before deciding whether to invest in our securities, you should also refer to the other information contained in or incorporated by reference into this prospectus, including the section entitled “Cautionary Note Regarding Forward Looking Statements.”

*Unless the context otherwise requires, for purposes of this section, the terms “we,” “us,” “the Company,” “Organogenesis” or “our company” refer to Organogenesis Holdings Inc. and its subsidiaries as they currently exist under Delaware law.*

### **Risks Related to Organogenesis and its business**

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

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

- the announcement or introduction of new products by our competitors;
- failure of government health benefit programs and private health plans to cover our products or to timely and adequately reimburse the users of our products;
- the rate of reimbursement for purchases of our products by government and private insurers;
- whether our products are granted pass-through reimbursement status or included in the “bundled” reimbursement structure;
- our ability to upgrade and develop our systems and infrastructure to accommodate growth;
- our ability to attract and retain key personnel in a timely and cost effective manner;
- the amount and timing of operating costs and capital expenditures relating to the expansion of our business, operations and infrastructure;
- changes in, or enactment of new laws or regulations promulgated by federal, state or local governments;
- cost containment initiatives or policies developed by government and commercial payers that create financial incentives not to use our products;
- our inability to demonstrate that our products are cost-effective or superior to competing products;
- initiation of a government investigation into potential non-compliance with laws or regulations;
- sanctions imposed by federal or state governments due to non-compliance with laws or regulations;
- recall of one or more of our products by the FDA due to noncompliance with FDA requirements; and
- general economic conditions as well as economic conditions specific to the healthcare industry.

## [Table of Contents](#)

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

***We have incurred significant losses since our inception, and we anticipate that we will incur substantial losses for the foreseeable future.***

To date, we have financed our operations primarily through debt financings, and we have incurred losses from operations in many years since our inception. Our loss attributable to Organogenesis Inc. was \$(24.3) million, \$(17.0) million and \$(8.4) million for the years ended December 31, 2015, 2016 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of \$121.0 million. We expect to incur significant sales and marketing costs as we expand our operations to support the sale of our products. Our prior losses, combined with anticipated losses for the foreseeable future, have had, and may continue to have, an adverse effect on our business, results of operations and financial condition.

***We have identified material weaknesses in our internal control over financial reporting, and our management has concluded that our disclosure controls and procedures are not effective. We cannot assure you that additional material weaknesses or significant deficiencies will not occur in the future. If our internal control over financial reporting or our disclosure controls and procedures are not effective, we may not be able to accurately report our financial results or prevent fraud, which may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.***

We have historically had a small internal accounting and finance staff. This lack of adequate accounting resources has resulted in the identification of material weaknesses in our internal controls over financial reporting. A “material weakness” is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. In connection with the audit of our financial statements for the years ended December 31, 2016 and 2017, our management team identified material weaknesses relating to (i) our lack of a sufficient complement of personnel with an appropriate level of knowledge and experience in the application of GAAP commensurate with our financial reporting requirements and (ii) our lack of resources necessary to implement an appropriate level of review controls to properly evaluate the completeness and accuracy of the transactions we enter into.

The material weaknesses contributed to the following:

- 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. Additionally, we did not design and maintain controls over the appropriate classification and presentation of accounts and disclosures in the financial statements.
- We did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose complex transactions. Specifically, we did not design and maintain controls to analyze, account for and disclose asset impairment analyses, business combination accounting, variable interest entities, share-based compensation arrangements, deferred financing costs, warrants to purchase common shares and contingently issuable and redeemable equity.

## [Table of Contents](#)

- We did not design and maintain controls over our supervision and review of the completeness and accuracy of third-party vendors' computations supporting our common share valuations.

In addition to hiring a Chief Financial Officer in 2016, during 2017 we took additional steps to help remediate these material weaknesses, including hiring additional accounting staff who have a background and knowledge in the application of GAAP and performing a comprehensive review of our internal control over financial reporting. We engaged external experts to complement internal resources and we began implementation of a new companywide enterprise resource planning system. We plan to continue to take additional steps to remediate the material weaknesses and improve our financial reporting systems and implement new policies, procedures and controls. If we do not successfully remediate the material weaknesses described above, or if other material weaknesses or other deficiencies arise in the future, we may be unable to accurately report our financial results, which could cause our financial results to be materially misstated and require restatement.

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

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

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

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

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

- properly identify and anticipate physician and patient needs;
- develop and introduce new products or product enhancements in a timely manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;

## Table of Contents

- 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 using our products relative to the use of our competitors' products or alternative treatment modalities;

## [Table of Contents](#)

- 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.

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

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

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

Our operating plan may change as a result of many factors currently unknown to us and we may need additional funds sooner than planned. Additional funds may not be available when we need them on terms that are

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

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

Our business exposes us to the risk of product liability claims that are inherent in the manufacturing, processing, investigating and marketing of medical devices and human tissue products. We are, and may in the future be, subject to product liability claims and lawsuits, including potential class actions or mass tort claims, alleging that our products have resulted or could result in an unsafe condition or injury. Product liability claims may be made by patients and their families, healthcare providers or others selling our products. Defending a lawsuit, regardless of merit, could be costly, divert management attention and result in adverse publicity, which 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



## [Table of Contents](#)

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. Any unforeseen failure in the storage of our products or loss in supply could result in a loss of our market share and negatively affect our revenues and operations.

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

We obtain some of the components for our Apligraf and Dermagraft 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

From time to time, we may implement or may acquire new lines of business, such as our Surgical & Sports Medicine products that were acquired in connection with our acquisition of NuTech Medical, or we may offer new products and services within existing lines of business. There are risks and uncertainties associated with these efforts, particularly in instances where the markets are not fully developed or are evolving. In developing and marketing new lines of business and new products and services, we may invest significant time and resources. External factors, such as regulatory compliance obligations, competitive alternatives, lack of market

acceptance, and shifting market preferences, may also affect the successful implementation of a new line of business or a new product or service. Failure to successfully manage these risks in the development and implementation of new lines of business or new products or services could have a material adverse effect on our business, results of operations and financial condition.

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

We rely to a large extent upon sophisticated information technology systems to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property). We also have outsourced significant elements of our operations to third parties, including significant elements of our information technology infrastructure and, as a result, we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our information technology and information security systems, and those of our third-party vendors with whom we contract (and the large amounts of confidential information that is present on them), make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from malicious attacks by third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. While we have invested significantly in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. Although we have cyber-insurance coverage that may cover certain events described above, this insurance is subject to deductibles and coverage limitations and we may not be able to maintain this insurance. Also, it is possible that claims could exceed the limits of our coverage. Any interruption or breach in our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us or allow third parties to gain material, inside information that they use to trade in our securities.

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

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the HITECH Act, and the regulations that have been issued under it, impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of protected health information. The requirements and restrictions apply to “covered entities” (which include health care providers and insurers) as well as to their business associates that receive protected health information from them in order to provide services to or perform certain activities on their behalfs. The statute and regulations also impose notification obligations on covered entities and their business associates in the event of a breach of the privacy or security of protected health information. We occasionally receive protected health information from our customers in the course of our business. As such, we believe that we are business associates and therefore subject to HIPAA’s requirements and restrictions with respect to handling such protected health information, and have executed business associate agreements with certain customers. Requirements applicable to business associates are complex and subject to varying interpretation. If we fail to comply or are deemed to have failed to comply with applicable privacy protection laws and regulations such failure could result in government enforcement actions and create liability for us, which could include substantial civil and/or criminal penalties, as well as private litigation and/or adverse publicity that could negatively affect our operating results and business.

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

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

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

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

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

The Patient Protection and Affordable Care Act (the "PPACA") currently imposes, among other things, an excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States. Under these provisions, the Congressional Research Service predicts that the total cost to the medical device industry may be up to \$20 billion over the next decade. The Internal Revenue Service issued final regulations implementing the tax in December 2012, which require, among other things, bi-monthly payments and quarterly reporting. The Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed into law in December 2015, included a two-year moratorium on the medical device excise tax. A second two-year moratorium on the medical device excise tax was signed into law in January 2018 as part of the Extension of Continuing Appropriations Act, 2018 (Pub. L. 115-120), extending the moratorium through December 31, 2019. Thus, the medical device excise tax does not apply to the sale of a taxable medical device by the manufacturer, producer, or importer of the device during the period beginning on January 1, 2016, and ending on December 31, 2019. If this legislation is not repealed by December 31, 2019, we will be subject to this 2.3% excise tax on sales of certain of our products in the United States including Apligraf, Dermagraft and PuraPly, which could have a material adverse effect on our business, results of operations and financial condition.

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

Our long-term assets include property, plant and equipment of \$45.5 million and \$42.1 million for the years ended December 31, 2016 and 2017, respectively. Approximately \$22 million of each of these amounts is attributable to certain leasehold improvements that we made to the buildings we lease at 275 Dan Road as part of our Canton, Massachusetts corporate headquarters. We review our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The build out to this property was suspended prior to completion and we are currently evaluating our future use of this property. If we decide that we do not intend to complete this buildout, either due to insufficient funding for this purpose or other business reasons, then these assets would be impaired. If an asset is determined to be impaired, the asset is written down to fair value, which is determined based on appraised value. Any such

impairment could result in a non-cash charge equal to the full value of these improvements. During the year ended December 31, 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.

***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, 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.

**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 intended as wound coverings, to ensure that they meet the homologous use requirement and therefore continue to qualify as Section 361 HCT/Ps. To the extent that any cell- or tissue-based product that we distribute is deemed not to be an HCT/P or a Section 361 HCT/P, it will be subject to premarket clearance or approval requirements, as well as additional, more stringent post-market regulatory requirements. Further, it may be necessary to obtain FDA



approval of a BLA for NuCel and ReNu because those products may be deemed to be more than minimally manipulated, not for homologous use, or otherwise not regulated as Section 361 HCT/Ps. In the event NuCel and ReNu are deemed not to be Section 361 HCT/Ps, compliance with applicable pre- and post-market regulatory requirements will involve significant time and substantial costs. We may also be required to suspend sales of NuCel and ReNu until FDA approval is obtained. Thus, any action by the FDA to apply the principles set forth in the 361 HCT/P Guidance to the HCT/Ps that we distribute could have adverse consequences for us and make it more difficult or expensive for us to conduct our business. The 361 HCT/P Guidance indicates that the FDA is providing a 36-month enforcement grace period to allow sufficient time for distributors of HCT/Ps to make any regulatory submissions and obtain any premarket approvals necessary to comply with the guidance. Although we believe that the 36-month grace period provides adequate time to comply, if we are unable to obtain BLA approvals for NuCel and ReNu within the 36-month time period, we may be required to suspend sales of those products until FDA approval is obtained. The ability to obtain approval for the uses for which the product is currently marketed cannot be assured. 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 QSR and/or the FDA's Current Good Manufacturing Practices, or cGMP regulations, adverse event reporting, and FDA inspections. The costs and other resource burdens associated with maintaining regulatory approvals or clearances for our products and otherwise meeting our regulatory obligations may limit the resources available to us to fully exploit our technologies or may otherwise limit our ability to carry out other business activities

In some states, the manufacture or distribution of HCT/Ps requires a license or permit to operate as a tissue bank or tissue distributor. We believe that we have all required state licenses or permits applicable to the distribution of HCT/Ps, but there is a risk that there may be state or local license or permit requirements of which we are unaware or with which we have not complied. In the event that such noncompliance exists in a given jurisdiction, we could be precluded from distributing HCT/Ps in that jurisdiction and also could be subject to fines or other penalties. If any such actions were to be instituted against us, it could adversely affect our business and/or financial condition. In connection with our acquisition of NuTech Medical in March 2017, we did not timely file a change of ownership notice for NuTech's tissue bank license with the Florida Agency for Health Care Administration for our cadaveric orthopedic products. Although a change of ownership application was submitted, we could be subject to fines or other penalties, including distribution restrictions on those two products, for failure to timely file. In June 2018, the change of ownership application was denied on the ground that it had not been timely filed. Accordingly, a new license application was been submitted and a license was issued in October 2018.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## [Table of Contents](#)

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

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

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

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for, the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other government payers that are false or fraudulent;
- Section 242 of HIPAA codified at 18 U.S.C. § 1347, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or from making false or fraudulent statements to defraud any healthcare benefit program (*i.e.*, public or private);
- federal transparency laws, including the so-called federal “sunshine” law, which requires the tracking and disclosure to the federal government by pharmaceutical and medical device manufacturers of payments and other transfers of value to physicians and teaching hospitals as well as ownership and investment interests that are held by physicians and their immediate family members; and

## [Table of Contents](#)

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

If a government entity opens an investigation into possible violations of any of these laws (which may include the issuance of subpoenas), we would have to expend significant resources to defend ourselves against the allegations. Allegations that we, our officers, or our employees violated any one of these laws can be made by individuals called "whistleblowers" who may be our employees, customers, competitors or other parties. Government policy is to encourage individuals to become whistleblowers and file a complaint in federal court alleging wrongful conduct. The government is required to investigate all of these complaints and decide whether to intervene. If the government intervenes and we are required to pay money back to the government, the whistleblower, as a reward, is awarded a percentage. If the government declines to intervene, the whistleblower may proceed on her own and, if she is successful, she will receive a percentage of any judgment or settlement amount the company is required to pay. The government may also initiate an investigation on its own. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant fines, and other sanctions that may materially impair our ability to run a profitable

business. In particular, if our operations are found to be in violation of any of the laws described above or if we agree to settle with the government without admitting to any wrongful conduct or if we are found to be in violation of any other governmental regulations that apply to us, we, our officers and employees may be subject to sanctions, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, the curtailment or restructuring of our operations and the imposition of a corporate integrity agreement, any of which could adversely affect our business, results of operations and financial condition.

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

Our products are reimbursed by Medicare in physician office settings at a rate of ASP plus 6% less the sequestration amount (2% of the government's 80% portion). The ASP reimbursement methodology requires us to report, to the government, the ASP for each of our products every quarter. Government price reporting requirements are complex. If we do not report ASP at all or if we report ASP incorrectly we could be subject to civil monetary penalties and/or, if the violation is knowing or reckless, be subject to false claims act liability. In the case of very serious or repeated violations, we could be excluded from doing business with the Medicare program and other federal healthcare programs.

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

We are exposed to the risk that our officers, employees, independent contractors (including contract research organizations, or CROs), principal investigators, consultants and commercial partners may engage in fraudulent conduct or other illegal activity and/or may fail to disclose unauthorized activities to us. Misconduct by these parties could include, but is not limited to, intentional, reckless and/or negligent failures to comply with:

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

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



effective in preventing such conduct, mitigating risks, or reducing the chance of governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant fines, and other sanctions that may materially impair our ability to run a profitable business.

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

There have been and continue to be laws enacted by the federal government, state governments, regulators and third party payers to control healthcare costs, and generally, to reform the healthcare system in the United States. For example, the Healthcare Reform Act substantially changed the way healthcare is delivered and financed by both governmental and private insurers. These changes included the creation of demonstration programs and other value-based purchasing initiatives that provide financial incentives for physicians and hospitals to reduce costs, including incentives for furnishing low cost therapies for chronic wounds even if those therapies are less effective than our products. Under the Trump Administration, there are ongoing efforts to modify or repeal all or part of PPACA or take executive action that affects its implementation. Tax reform legislation was recently passed that includes provisions that will impact healthcare insurance coverage and payment such as the elimination of the tax penalty for individuals who do not maintain health insurance coverage beginning in 2019 (the so-called “individual mandate”). Such actions or similar actions could have a negative effect on the utilization of our products. We expect such efforts to continue and that there will be additional reform proposals at federal and state levels. We cannot predict whether additional reform proposals will be adopted, when they will be adopted, or what impact they may have on us, but any such proposals could have a negative impact on our business and provide incentives for hospitals and physicians to not use our products.

General legislative action may also affect our business. For example, the Budget Control Act of 2011 includes provisions to reduce the federal deficit. The Budget Control Act, as amended, resulted in the imposition of reductions of up to 2% in Medicare payments to providers which began in April, 2013 and will remain in effect through 2025 unless additional congressional action is taken. These or other similar reductions in government healthcare spending could result in reduced demand for our products or additional pricing pressure.

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

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

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

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

We are currently selling into foreign markets and plan to expand such sales. Managing a global organization is difficult, time consuming, and expensive. Conducting international operations subjects us to risks that could be



different than those faced by us in the United States. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subject us to extensive U.S. and foreign governmental trade, import and export and customs regulations and laws, including but not limited to, the Export Administration Regulations and trade sanctions against embargoed countries, which are administered by the Office of Foreign Assets Control within the Department of the Treasury, as well as the laws and regulations administered by the Department of Commerce. These regulations limit our ability to market, sell, distribute or otherwise transfer our products or technology to prohibited countries or persons.

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

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

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

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

**Risks Related to Reimbursement for our Products**

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

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

On March 2018, the United States Congress passed, and the President signed into law, the Consolidated Appropriations Act of 2018, or the Appropriations Act. The Appropriations Act restored the pass-through status effective October 1, 2018 for drugs or biologicals whose period of pass-through payment status ended on December 31, 2017 and for which payment was packaged into a covered hospital outpatient service furnished beginning on January 1, 2018; PuraPly and PuraPly AM met these conditions. As a result, PuraPly and PuraPly

## [Table of Contents](#)

AM were included in the “bundled” payment structure from January 1, 2018 through September 30, 2018 after which time Medicare resumed making pass-through payments to hospitals when they use PuraPly and PuraPly AM in the outpatient hospital setting and in ASCs. PuraPly and PuraPly AM will retain this “pass-through” reimbursement status through September 30, 2020. Other skin substitute products, including all of our other products, will remain in the bundled payment structure.

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

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

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

Payers are increasingly attempting to contain healthcare costs by limiting both the breadth of coverage and the level of reimbursement, particularly for new therapeutic products generally or specifically for new therapeutic products that target an indication that is perceived to be well served by existing treatments. Specifically, the Patient Protection and Affordable Care Act, or PPACA, enacted in 2010 contains provisions for Medicare demonstration programs that create financial incentives to treat patients with chronic wounds conservatively and not use our products. Furthermore, other than the PuraPly AM and PuraPly products through 2017, our products are not paid separately in the outpatient hospital setting which is our largest customer base. This payment policy has created incentives to use our competitors’ products. Accordingly, even if coverage and reimbursement are provided, market acceptance of our products has been and will be adversely affected if access to coverage is administratively burdensome to obtain and/or use of our products is administratively burdensome or unprofitable for healthcare providers or less profitable than alternative treatments. In addition, reimbursement from Medicare, Medicaid and other third-party payers is usually adjusted yearly as a result of legislative, regulatory and policy changes as well as budgetary pressures. Possible reductions in, or eliminations of, coverage or reimbursement by third-party payers, or the denial of, or provision of uneconomical reimbursement for new products, as a result of these changes may affect our customers’ revenue and ability to purchase our products. Any changes in the healthcare regulatory, payment or enforcement landscape relative to our customers’ healthcare services also has the potential to significantly affect our operations and revenue. In addition, Medicare uses regional contractors called Medicare Administrative Contractors, or MACs, to process claims, develop coverage policies and make payments within designated geographic jurisdictions. While our products are currently covered by most MACs, we cannot be certain they will be in the future.

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

***Our PuraPly AM and PuraPly products transitioned off “pass-through” reimbursement status to a “bundled” reimbursement structure beginning on January 1, 2018, which has resulted in a decline in our PuraPly AM and PuraPly revenues as compared to prior periods. Although new legislation restored pass-through status for these products beginning on October 1, 2018, they will again lose this preferred status on October 1, 2020.***

Under Medicare, our PuraPly AM and PuraPly products had pass-through reimbursement status through December 31, 2017 when used in the hospital outpatient and ASC setting. Hospitals and ASCs that use products with “pass-through” status receive a separate payment for the product in addition to the bundled payment, known as a “pass through” payment, resulting in a higher total reimbursement for procedures that use these products. “Pass through” status is typically granted for a two to three year period in order to encourage the development of innovative medical devices, drugs and biologics. As of January 1, 2018, PuraPly AM and PuraPly transitioned to the “bundled” payment structure applicable to other skin substitutes, which provides for a two-tiered payment system in the hospital outpatient and ASC setting and results in a single payment to the provider that covers both the application of the product and the product itself. Under the Appropriations Act, the pass-through status of certain products, including PuraPly AM and PuraPly, was restored effective October 1, 2018 and they will retain that status through September 30, 2020. As a result of the transition to the bundled payment structure, total Medicare reimbursement for procedures using our PuraPly AM and PuraPly products decreased during the nine months ended September 30, 2018 and may decrease substantially during fiscal 2018. While the precise impact of this transition to the bundled payment structure during 2018 is currently unknown, a substantial decrease in revenue from our PuraPly AM and PuraPly products, which are key products in our portfolio, could occur and have a material adverse effect on our business, results of operations and financial condition. Although Medicare resumed making pass through payments for PuraPly AM and PuraPly products in the outpatient hospital and ASC setting on October 1, 2018 pursuant to the Appropriations Act, all other skin substitute products, including all of our other products, remain in the bundled payment structure. Because CMS will remove from the bundled payment all amounts attributable to PuraPly AM and PuraPly while they have pass-through status, the bundled payments that will be applicable to our other skin substitute products, such as Apligraf and Dermagraft, will likely decrease and this decrease could also have a material and adverse effect our revenue from these products. In addition, legislation could be enacted in the future to repeal the provisions of the Appropriations Act that relate to pass-through status and terminate or shorten the period during which pass-through will apply to PuraPly AM and PuraPly. Per the existing terms of the Appropriations Act, PuraPly AM and PuraPly will transition back into the bundled payment structure on October 1, 2020 and the loss of the pass-through payment status may result in lower revenue for PuraPly AM and PuraPly which could have a material adverse effect on our business, results of operations and financial condition.

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

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

category. Even when we are the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN generally are free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause upon 60 to 90 days' notice. The healthcare industry has been consolidating, and the consolidation among third-party payers into larger purchasing groups will increase their negotiating and purchasing power. Such consolidation may result in greater pricing pressure on us due to pricing concessions and may further exacerbate the risks described above.

### **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, 2018, we and our subsidiaries had approximately \$113.8 million of aggregate principal amount of indebtedness outstanding (including \$5.0 million of deferred acquisition expenses related to our acquisition of NuTech Medical). Although we reduced the principal amount of our outstanding indebtedness by approximately \$67.7 million in connection with the business combination that closed on December 10, 2018, we still expect to have approximately \$[46.1] million of aggregate principal amount of indebtedness outstanding following the closing of the business combination. 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;



## [Table of Contents](#)

- 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 still be able to incur substantially more debt. This could further exacerbate the risks associated with our substantial leverage.***

We may be able to 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. 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



## [Table of Contents](#)

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 adjusted EBITDA covenant (measured as of the last day of each month) and a minimum monthly liquidity ratio (measured as of the last day of each month). The operating and financial restrictions and covenants in the senior secured credit facility, as well as any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. Our ability to comply with these covenants may be affected by events beyond our control, and we may not be able to meet those covenants. For example, in the past, we have not been in compliance with certain

## [Table of Contents](#)

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 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 are required to demonstrate to the satisfaction of Staff and the Hearings Panel that we have a minimum of 300 round lot common stockholders and that we otherwise meet all applicable requirements for listing on Nasdaq. The Hearings Panel determined to delist our public warrants due to our non-compliance with the minimum 400 round lot holder requirement for initial listing on NASDAQ, as required by Nasdaq Listing Rule 5515(a)(4). Accordingly, the trading suspension in the Company's warrants was converted to a trading suspension effective at the open of the market on January 8, 2019, at which time the warrants became eligible to trade "over-the-counter" under the trading symbol "ORGOW." The Company can provide no assurance that the hearings panel will grant the request for continued listing or that the Company can maintain compliance with the other NASDAQ listing standards.

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

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

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

Alan A. Ades, Albert Erani and Glenn H. Nussdorf, members of our board of directors, together with Dennis Erani, Starr Wisdom and certain of their respective affiliates, who we refer to collectively as the Controlling Entities, control a majority of the voting power of the Company's outstanding common stock. Such Controlling

## [Table of Contents](#)

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 73% of the Company’s common stock. As a result of this voting control, the Controlling Entities collectively can effectively determine the outcome of all matters requiring stockholder approval, including, but not limited to, the election and removal of the Company’s directors (subject to any contractual designation rights), as well as other matters of corporate or management policy (such as potential mergers or acquisitions, payment of dividends, asset sales, and amendments to the Company’s certificate of incorporation and bylaws). This concentration of ownership may delay or deter possible changes in control and limit the liquidity of the trading market for the Company’s common stock, which may reduce the value of an investment in its common stock. This voting control could also deprive stockholders of an opportunity to receive a premium for their shares of common stock as part of a potential sale of the Company. So long as the Controlling Entities and their affiliates continue to own a significant amount of the Company’s combined voting power, even if less than 50.0%, they may continue to be able to strongly influence or effectively control its decisions. The interests of the Controlling Entities and their affiliates may not coincide with the interests of other holders of the Company common stock.

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

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

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

- any derivative action or proceeding brought on behalf of the Company;
- any action asserting a claim of breach of a fiduciary duty owed by, or any wrongdoing by, any director, officer or employee of the Company to the Company or the Company’s stockholders;
- any action asserting a claim arising pursuant to any provision of the DGCL, the certificate of incorporation (including as it may be amended from time to time), or the bylaws;
- any action to interpret, apply, enforce or determine the validity of the certificate of incorporation or the bylaws; or

## [Table of Contents](#)

- any action asserting a claim governed by the internal affairs doctrine, in each case, except for, (1) any action as to which the Court of Chancery determines that there is an indispensable party not subject to the personal jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten (10) days following such determination) and (2) any action asserted under the Securities Exchange Act of 1934, as amended, or the rules and regulations promulgated thereunder, for which federal courts have exclusive jurisdiction.

These provisions of the Company bylaws could limit the ability of the Company stockholders to obtain a favorable judicial forum for certain disputes with the Company or with its directors, officers or other employees, which may discourage such lawsuits against the Company and its directors, officers and employees. Alternatively, if a court were to find these provisions of the Company bylaws inapplicable to, or unenforceable in respect of, one or more of the types of actions or proceedings listed above, the Company may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect its business, financial condition and results of operations.

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

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

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

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

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

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

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

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

- labor availability and costs for hourly and management personnel;
- profitability of the Company's products, especially in new markets and due to seasonal fluctuations;
- changes in interest or exchange rates;
- impairment of long-lived assets;
- macroeconomic conditions, both nationally and locally;
- negative publicity relating to our products;
- changes in consumer preferences and competitive conditions; and
- expansion to new markets.

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

The trading market for the Company common stock will be influenced by the research and reports that industry or securities analysts may publish about us, the Company's business, the Company's market, or the Company's competitors. Securities and industry analysts do not currently, and may never, publish research on the Company. If no securities or industry analysts commence coverage of the Company, the Company's stock price and trading volume would likely be negatively impacted. If any of the analysts who may cover the Company change their recommendation regarding the Company's stock adversely, or provide more favorable relative recommendations about the Company's competitors, the price of the Company common stock would likely decline. If any analyst who may cover the Company were to cease coverage of the Company or fail to regularly publish reports on it, we could lose visibility in the financial markets, which could cause the Company's stock price or trading volume to decline.

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

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

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

The Company's warrants were issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and AHPAC. The warrant agreement provides that the terms of the Company warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision, but requires the approval by the holders of at least 65% of the then-outstanding public the Company warrants to make any change that adversely affects the interests of the registered holders.

## [Table of Contents](#)

Accordingly, the Company may amend the terms of the warrants in a manner adverse to a holder if holders of at least 65% of the then-outstanding public warrants approve of such amendment. Although the Company's ability to amend the terms of the warrants with the consent of at least 65% of the then-outstanding public the Company warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the Company warrants, shorten the exercise period or decrease the number of shares of the Company common stock purchasable upon exercise of an the Company warrant.

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

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

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

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

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

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

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

The Company qualifies as an "emerging growth company" as defined in Section 2(a)(19) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, which we refer to as the "JOBS Act." As

## [Table of Contents](#)

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 are held by non-affiliates exceeds \$700 million as of the last business day of the Company's prior second fiscal quarter, and (ii) the date on which the Company has issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

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

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

## USE OF PROCEEDS

All of the shares of Class A common stock offered by the Selling Stockholders pursuant to this prospectus will be sold by the Selling Stockholders for their respective accounts. We will not receive any of the proceeds from these sales. We will receive up to an aggregate of approximately \$212 million from the exercise of the Warrants and Options, assuming the exercise in full of all of the Warrants and Options for cash. We expect to use the net proceeds from the exercise of the Warrants and Options for general corporate purposes.

The Selling Stockholders will pay any underwriting discounts and commissions and expenses incurred by the Selling Stockholders for brokerage, accounting, tax or legal services or any other expenses incurred by the Selling Stockholders in disposing of the shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, NASDAQ listing fees and fees and expenses of our counsel and our independent registered public accountants.



## SELLING STOCKHOLDERS

This prospectus relates to the possible resale by the Selling Stockholders of up to 46,853,325 shares of our Class A common stock. The Selling Stockholders may from time to time offer and sell any or all of the Class A common stock set forth below pursuant to this prospectus. When we refer to the “Selling Stockholders” in this prospectus, we mean the persons listed in the table below, and the pledgees, donees, transferees, assignees, successors and others who later come to hold any of the Selling Stockholders’ interest in Class A common stock other than through a public sale.

The following table sets forth, based on information currently known by us as of December 10, 2018, (i) the number of shares of Class A common stock held of record or beneficially by the Selling Stockholders as of such date (as determined below), (ii) the number of shares of Class A common stock that may be offered under this prospectus by the Selling Stockholders and (iii) any material relationships the Selling Stockholders may have had with us within the past three years. As indicated in the footnotes below, certain of the Selling Stockholders share voting or investment power over certain shares. The full amount of shares over which each Selling Stockholder has shared investment or voting power is reported for each Selling Stockholder sharing such power. Therefore, certain shares are reflected as being beneficially owned by multiple Selling Stockholders. In calculating percentages of shares of Class A common stock owned by a particular holder, we treated as outstanding the number of shares of our common stock issuable upon exercise of that particular holder’s Warrants and Options, if any, and did not assume exercise of any other holder’s Warrants and Options. The beneficial ownership of the common stock set forth in the following table is determined in accordance with Rule 13d-3 under the Exchange Act, and the information is not necessarily indicative of beneficial ownership for any other purpose. The applicable percentage ownership for each Selling Stockholder listed below is based upon 91,989,961 shares of Common Stock outstanding as of December 10, 2018.

We cannot advise you as to whether the Selling Stockholders will in fact sell any or all of such Class A common stock. In addition, the Selling Stockholders may sell, transfer or otherwise dispose of, at any time and from time to time, the Class A common stock in transactions exempt from the registration requirements of the Securities Act after the date of this prospectus.

Selling Stockholder information for each additional Selling Stockholder, if any, will be set forth by prospectus supplement to the extent required prior to the time of any offer or sale of such Selling Stockholder’s shares pursuant to this prospectus. Any prospectus supplement may add, update, substitute, or change the information contained in this prospectus, including the identity of each Selling Stockholder and the number of shares registered on its behalf. A Selling Stockholder may sell all, some or none of such shares in this offering. See “Plan of Distribution.”

Name of Selling Stockholder(1)	Before the Offering			After the Offering (assuming the sale of all shares that may be sold hereunder)	
	Number of Shares of Class A Common Stock Beneficially Owned as of December 10, 2018	Percentage of Outstanding Class A Common Stock Beneficially Owned as of December 10, 2018	Maximum Number of Shares of Class A Common Stock to be Offered	Number of Shares of Class A Common Stock Beneficially Owned after the Offering	Percentage of Outstanding Class A Common Stock Beneficially Owned after the Offering
Avista Acquisition Corp.	1,048,691	1.1%	1,048,691	—	*
Thompson Dean(2)	1,048,691	1.1%	1,048,691	—	*
David Burgstahler(2)	1,048,691	1.1%	1,048,691	—	*
Håkan Björklund	69,571	*	69,571	—	*
Charles Harwood	69,571	*	69,571	—	*
Brian Markison	133,589	*	133,589	—	*
Robert O’Neil	69,571	*	69,571	—	*

## Table of Contents

Avista Capital Partners IV, L.P.(3)	8,829,406(4)	9.5%	8,829,406	—	*
Avista Capital Partners (Offshore) IV, L.P.(3)	8,782,067(5)	9.4%	8,782,067	—	*
Organo PFG LLC	32,134,638(6)	34.9%	1,758,419(7)	30,376,219	33.0%
Organo Investors LLC	2,851,984(8)	3.1%	111,484(9)	2,740,500	3.0%
Alan A. Ades	44,466,394(10)	48.3%	3,580,455(11)	40,885,939	44.4%
Albert Erani	38,654,337(12)	42.0%	2,024,515(13)	36,629,822	39.8%
Dennis Erani	4,287,654(14)	4.7%	670,071(15)	3,617,583	3.9%
Glenn H. Nussdorf	14,838,663(16)	16.1%	2,475,822(17)	12,362,841	13.4%
Patrick Bilbo	381,640(18)	*	548,100(19)	—	*
Timothy M. Cunningham	223,848(20)	*	559,620(21)	—	*
Lori Freedman	16,240(22)	*	40,600(23)	—	*
Gary S. Gillheeny, Sr.	3,077,219(24)	3.2%	3,404,745(25)	—	*
Brian Grow	87,271(26)	*	204,416(27)	—	*
Antonio S. Montecalvo	98,488(28)	*	241,008(29)	—	*
Howard Walthall	166,910(30)	*	288,710(31)	—	*
Massachusetts Capital Resource Company	101,500(32)	*	101,500(33)	—	*
Life Insurance Community Investment Initiative, LLC	81,200(34)	*	81,200(35)	—	*
Any other selling stockholder or future transferee from any such holder(36)	15,500,000	14.4%	15,500,000	—	*

\* Less than 1%.

- (1) We do not know when or in what amounts the Selling Stockholders may offer shares of Class A common stock for sale. The Selling Stockholders may decide not to sell any or all of the shares offered by this prospectus. Because the Selling Stockholders may offer all or some of the shares pursuant to this offering, we cannot estimate the number of the shares that will be held by the Selling Stockholders after completion of the offering. However, for purposes of this table, we have assumed that, after completion of the offering, none of the shares covered by this prospectus will be held by the Selling Stockholders.
- (2) Mr. Dean and Mr. Burgstahler are deemed to beneficially own shares by virtue of their shared control over Avista Acquisition Corp. as its directors. The address of each of the foregoing is c/o Avista Capital Partners, 65 E. 55th Street, 18th Floor, New York, New York 10022.
- (3) Avista Capital Managing Member IV, LLC exercises voting and dispositive power over the shares held by the PIPE Investors. 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. 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.
- (4) Consists of (i) 7,801,651 shares of the Company's Class A common stock and (ii) 1,027,755 shares of the Company's class A common stock underlying warrants that are exercisable as of December 10, 2018 or will become exercisable within 60 days after such date.
- (5) Consists of (i) 7,759,822 shares of the Company's Class A common stock and (ii) 1,022,245 shares of the Company's class A common stock underlying warrants that are exercisable as of December 10, 2018 or will become exercisable within 60 days after such date.
- (6) Consists of (i) 32,134,638 shares of the Company's Class A common stock held by Organo PFG LLC. Alan A. Ades and Albert Erani are managing members of Organo PFG LLC they share voting and investment power over the shares of the Company's Class A common stock held by Organo PFG LLC. Each of

## Table of Contents

- Mr. Ades and Mr. Erani disclaim beneficial ownership of the shares of the Company's Class A common stock held by Organo PFG 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. Mr. Ades and Mr. Erani are members of the board of directors of the Company.
- (7) Consists of 1,758,419 shares of the Company's Class A common stock.
  - (8) Consists of 2,851,984 shares of the Company's Class A common stock held by Organo Investors LLC. Alan A. Ades and Albert Erani are managers of Organo Investors LLC and they share voting and investment power over the shares of the Company's Class A common stock held by Organo Investors LLC. Each of Mr. Ades and Mr. Erani disclaim beneficial ownership of the shares of the Company's Class A common stock held by 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. Mr. Ades and Mr. Erani are members of the board of directors of the Company.
  - (9) Consists of 111,484 shares of the Company's Class A common stock.
  - (10) Consists of (i) 7,989,993 shares of the Company's Class A common stock, (ii) 1,489,779 shares of the Company's Class A common stock held by Alan Ades as Trustee of the Alan Ades 2014 GRAT, (iii) 32,134,638 shares of the Company's Class A common stock held by Organo PFG LLC and (v) 2,851,984 shares of the Company's Class A common stock held by Organo Investors LLC. Mr. Ades exercises voting and investment power over the shares of the Company's 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 the Company's 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. Mr. Ades is a member of the board of directors of the Company.
  - (11) Consists of 3,580,455 shares of the Company's Class A common stock.
  - (12) Consists of (i) 936,516 shares of the Company's Class A common stock, (ii) 2,731,199 shares of the Company's Class A common stock held by the Albert Erani Family Trust dated 12/29/2012, (iii) 32,134,638 shares of the Company's Class A common stock held by Organo PFG LLC and (iv) 2,851,984 shares of the Company's Class A common stock held by Organo Investors LLC. Mr. Erani exercises voting and investment power over the shares of the Company's Class A common stock held by each of the Albert Erani Family Trust dated 12/29/2012, Organo PFG LLC and Organo Investors LLC. Mr. Erani disclaims beneficial ownership of the shares of the Company's Class A common stock held by each of the Albert Erani Family Trust dated 12/29/2012, 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. Mr. Erani is a member of the board of directors of the Company.
  - (13) Consists of 2,024,515 shares of the Company's Class A common stock.
  - (14) Consists of (i) 1,323,523 shares of the Company's Class A common stock and (ii) 2,964,131 shares of the Company's Class A common stock held by the Dennis Erani 2012 Issue Trust. Susan Erani, Mr. Erani's spouse, exercises voting and investment power over the shares of the Company's Class A common stock held by the Dennis Erani 2012 Issue Trust. Mr. Erani disclaims beneficial ownership of the shares of the Company's Class A common stock held by the Dennis Erani 2012 Issue Trust except to the extent of his pecuniary interest therein. The address of each of the foregoing is 2600 Island Blvd, 1104, Aventura, FL 33160. Mr. Erani is the first cousin of Albert Erani, a member of the board of directors of the Company.
  - (15) Consists of 670,071 shares of the Company's Class A common stock.
  - (16) Consists of (i) 2,658,663 shares of the Company's Class A common stock, (ii) 1,167,250 shares of the Company's Class A common stock held by GN 2016 Family Trust u/a/d August 12, 2016 and (iii) 11,012,750 shares of the Company's 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 the Company's Class A common stock held by each of GN 2016 Family Trust u/a/d August 12, 2016 and GN 2016 Organo 10-Year GRAT u/a/d September 30, 2016. Mr. Nussdorf disclaims beneficial ownership of the shares of the Company's Class A common stock held by each of GN 2016 Family Trust u/a/d August 12, 2016 and GN 2016 Organo 10-Year GRAT u/a/d September 30, 2016, except to the extent of his pecuniary interest

## [Table of Contents](#)

- therein. The address of each of the foregoing is 35 Sawgrass Drive, Bellport, NY 11713. Mr. Nussdorf is a member of the board of directors of the Company.
- (17) Consists of 2,475,822 shares of the Company's Class A common stock.
  - (18) Consists of (i) 121,800 shares of the Company's Class A common stock and (ii) 259,840 shares of the Company's Class A common stock underlying stock options that are exercisable as of December 10, 2018 or will become exercisable within 60 days after such date. The address of Mr. Bilbo is c/o Organogenesis Holdings Inc., 85 Dan Road, Canton, MA 02021. Mr. Bilbo is the Chief Operating Officer of the Company.
  - (19) Consists of (i) 121,800 shares of the Company's Class A common stock and (ii) 426,300 shares of the Company's Class A common stock underlying stock options.
  - (20) Consists of 223,848 shares of the Company's Class A common stock underlying stock options that are exercisable as of December 10, 2018 or will become exercisable within 60 days after such date. The address of Mr. Cunningham is c/o Organogenesis Holdings Inc., 85 Dan Road, Canton, MA 02021. Mr. Cunningham is the Chief Financial Officer of the Company.
  - (21) Consists of 559,620 shares of the Company's Class A common stock underlying stock options.
  - (22) Consists of 16,240 shares of the Company's Class A common stock underlying stock options that are exercisable as of December 10, 2018 or will become exercisable within 60 days after such date. The address of Ms. Freedman is c/o Organogenesis Holdings Inc., 85 Dan Road, Canton, MA 02021. Ms. Freedman is the Vice President and General Counsel of the Company.
  - (23) Consists of 40,600 shares of the Company's Class A common stock underlying stock options.
  - (24) Consists of 3,077,219 shares of the Company's Class A common stock underlying stock options that are exercisable as of December 10, 2018 or will become exercisable within 60 days after such date. The address of Mr. Gillheeney is c/o Organogenesis Holdings Inc., 85 Dan Road, Canton, MA 02021. Mr. Gillheeney is the President and Chief Executive Officer of the Company and is a member of the Company's board of directors.
  - (25) Consists of 3,404,745 shares of the Company's Class A common stock underlying stock options.
  - (26) Consists of (i) 1,462 shares of the Company's Class A common stock and (ii) 85,809 shares of the Company's Class A common stock underlying stock options that are exercisable as of December 10, 2018 or will become exercisable within 60 days after such date. The address of Mr. Grow is c/o Organogenesis Holdings Inc., 85 Dan Road, Canton, MA 02021. Mr. Grow is the Chief Commercial Officer of the Company.
  - (27) Consists of (i) 1,462 shares of the Company's Class A common stock and (ii) 202,954 shares of the Company's Class A common stock underlying stock options.
  - (28) Consists of (i) 8,482 shares of the Company's Class A common stock and (ii) 90,006 shares of the Company's Class A common stock underlying stock options that are exercisable as of December 10, 2018 or will become exercisable within 60 days after such date. The address of Mr. Montecalvo is c/o Organogenesis Holdings Inc., 85 Dan Road, Canton, MA 02021. Mr. Montecalvo is the Vice President, Health Policy and Contracting of the Company.
  - (29) Consists of (i) 8,482 shares of the Company's Class A common stock and (ii) 232,526 shares of the Company's Class A common stock underlying stock options.
  - (30) Consists of 166,910 shares of the Company's Class A common stock underlying stock options that are exercisable as of November 1, 2018 or will become exercisable within 60 days after such date. The address of Mr. Walthall is c/o Organogenesis Holdings Inc., 85 Dan Road, Canton, MA 02021. Mr. Walthall is the Executive Vice President, Strategy and Market Development, of the Company
  - (31) Consists of 288,710 shares of the Company's Class A common stock underlying stock options.
  - (32) Consists of 101,500 shares of the Company's Class A common stock underlying warrants that are exercisable as of December 10, 2018 or will become exercisable within 60 days after such date.
  - (33) Consists of 101,500 shares of the Company's Class A common stock underlying warrants.
  - (34) Consists of 81,200 shares of the Company's Class A common stock underlying warrants that are exercisable as of December 10, 2018 or will become exercisable within 60 days after such date.
  - (35) Consists of 81,200 shares of the Company's Class A common stock underlying warrants.
  - (36) We are unable to provide the names of certain holders of public warrants or our shares of Class A common stock issuable upon exercise of the public warrants, because they have not provided us with information

[Table of Contents](#)

and/or their public warrants are evidenced by a global warrant that has been deposited with DTC and registered in the name of Cede & Co., as DTC's nominee. Information concerning any such holders who are not listed in the above table will be set forth in prospectus supplements from time to time, if and as required by such holders. For purposes of completing this row, we have assumed that any other such holder or any future transferee from any such holder does not beneficially own any of our Class A common stock other than the shares issuable upon exercise of the public warrants.

## DESCRIPTION OF SECURITIES BEING REGISTERED

*The following summary of the material terms of our securities is not intended to be a complete summary of the rights and preferences of such securities. We urge you to read our certificate of incorporation in its entirety for a complete description of the rights and preferences of our securities.*

### **Authorized and Outstanding Stock**

Our 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 and 20,000,000 shares of Class B common stock, par value \$0.0001 per share and (ii) 1,000,000 shares of preferred stock, par value \$0.0001 per share. The outstanding shares of our common stock are duly authorized, validly issued, fully paid and non-assessable. As of December 10, 2018, there were 91,989,961 shares of Class A common stock outstanding, no shares of Class B common stock were outstanding, no shares of preferred stock were outstanding and Warrants to purchase 17,732,700 shares of Class A common stock were outstanding, including public warrants to purchase 15,500,000 shares of Class A common stock, PIPE warrants to purchase 2,050,000 shares of Class A common stock and exchange warrants to purchase 182,700 shares of 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 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 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 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 or other subscription rights and there will be no sinking fund or redemption provisions applicable to our common stock.

### **Election of Directors**

Under our certificate of incorporation, the Board consists of a single class, with all directors serving until the 2019 annual meeting. There are 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 common stock.

### **Founder Shares**

In connection with the consummation of the Business Combination our Founder Shares automatically converted into shares of Class A common stock. Our initial stockholders hold approximately 1.5% of the total number of all shares of common stock outstanding of the Company after consummation of the Business Combination, consisting of 500,000 shares of Class A common stock held immediately prior to the effective time of the merger and 890,993 shares Class B common stock, that were originally issued as Founder Shares, which were automatically converted into shares of Class A common stock at the closing of the Business Combination.

With certain limited exceptions, these shares are not transferable, assignable or salable (except to our officers and directors and other persons or entities affiliated with our sponsor, each of whom will be subject to the same transfer restrictions) until the earlier to occur of: (a) one year after the completion of our Business Combination, (b) the first date the closing price of the Class A common stock equals or exceeds \$12.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within any 30-trading day period commencing at least 150 days after the effective time or (c) the date on which the Company completes a liquidation, merger, stock exchange, reorganization or other similar transaction which results in all of the Company's stockholders having the right to exchange their Class A common stock for cash, securities or other property; unless the Board has authorized a release or waiver from such lock-up.

### **Dividends**

We have not paid any cash dividends on our 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 subsequent to completion of a business combination. The payment of any cash dividends subsequent to a business combination will be within the discretion of the Board at such time. In addition, the Company is not currently contemplating and does not anticipate declaring any stock dividends in the foreseeable future. Further, if the Company incurs any indebtedness, its ability to declare dividends may be limited by restrictive covenants it may agree to in connection therewith.

### **Certain Anti-Takeover Provisions of Delaware Law, the Company's Certificate of Incorporation and Bylaws**

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 common stock;
- or

## [Table of Contents](#)

- 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, and not by written consent, by an affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

In addition, our 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 authorized but unissued 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 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.

### **Rule 144**

Pursuant to Rule 144 of the Securities Act, which we refer to as "Rule 144", a person who has beneficially owned restricted shares of our common stock or Warrants for at least six months would be entitled to sell their securities, provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least three months before the sale and have filed all required reports under Section 13 or 15(d) of the Exchange Act during the 12 months (or such shorter period as we were required to file reports) preceding the sale.

Persons who have beneficially owned restricted shares of our common stock or Warrants for at least six months but who are our affiliates at the time of, or at any time during the three months preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of:

- one percent (1%) of the total number of shares of common stock then outstanding; or
- the average weekly reported trading volume of the common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales by our affiliates under Rule 144 are also limited by manner of sale provisions and notice requirements and to the availability of current public information about us.

### ***Restrictions on the Use of Rule 144 by Shell Companies or Former Shell Companies***

Rule 144 is not available for the resale of securities initially issued by shell companies (other than business combination related shell companies) or issuers that have been at any time previously a shell company. However, Rule 144 also includes an important exception to this prohibition if the following conditions are met:

- the issuer of the securities that was formerly a shell company has ceased to be a shell company;
- the issuer of the securities is subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act;
- the issuer of the securities has filed all Exchange Act reports and material required to be filed, as applicable, during the preceding 12 months (or such shorter period that the issuer was required to file such reports and materials), other than Form 8-K reports; and
- at least one year has elapsed from the time that the issuer filed current Form 10 type information with the SEC reflecting its status as an entity that is not a shell company.



## [Table of Contents](#)

As of December 10, 2018, we had 91,989,961 shares of Class A common stock and no shares of Class B common stock outstanding. All of the 1,390,993 Founder Shares owned by our initial stockholders are restricted securities under Rule 144, in that they were issued in private transactions not involving a public offering. The shares of our common stock we issued to the investors pursuant to the Subscription Agreements are restricted securities for purposes of Rule 144. All such restricted shares have been registered for resale under the Securities Act on the registration statement of which this prospectus is part.

As of the date of this registration statement, there are Warrants to purchase 17,732,700 shares of Class A common stock outstanding, consisting of public warrants to purchase 15,500,000 shares of our Class A common stock originally sold as part of the units issued in the Company's IPO, PIPE warrants to purchase 2,050,000 shares of our Class A common stock that were sold by the Company to our sponsor in a private sale prior to the Company's IPO and exchange warrants to purchase 182,700 shares of our Class A common stock. Each public warrant and each PIPE warrant entitles its holder to purchase one-half of one share of Class A common stock where two warrants must be exercised for one whole share of Class A common stock at an exercise price of \$11.50 per share, and can be exercised only for a whole number of shares of Common Stock, in accordance with the terms of the agreements governing the public warrants and PIPE warrants, respectively. Each exchange warrant entitles its holder to purchase one share of Class A common stock at an exercise price of \$3.95 per share. The shares underlying the Warrants have been registered for resale under the Securities Act pursuant to the registration statement of which this prospectus is a part.

While we were formed as a shell company, since the consummation of the Business Combination, we are no longer a shell company, and so, once the conditions set forth in the exceptions listed above are satisfied, Rule 144 will become available for the resale of the above noted restricted securities.

### **Registration Rights**

At the closing of the Business Combination, the Company, the sponsor and the Restricted Stockholders entered into the Amended and Restated Registration Rights Agreement, pursuant to which, among other things, the existing Organogenesis stockholders agreed not to sell, transfer, pledge or otherwise dispose of shares of common stock in the Company it received in connection with the Business Combination for six months from the closing date of the business combination, unless waived. In addition, the initial shareholders have agreed not to transfer, assign or sell any of its founder shares until the earlier to occur of: (A) one year after the completion of our Business Combination or (B) the date on which we complete a liquidation, merger, share exchange, reorganization or other similar transaction after our Business Combination that results in all of our public stockholders having the right to exchange their ordinary shares for cash, securities or other property.

The Restricted Stockholders and their permitted transferees are entitled to certain registration rights described in the Amended and Restated Registration Rights Agreement. Among other things, pursuant to the Amended and Restated Registration Rights Agreement, the Restricted 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. The registration statement of which this prospectus is part has been filed, in part, pursuant to the Amended and Restated Registration Rights Agreement.

### **Transfer Agent and Warrant Agent**

The transfer agent for our common stock and warrant agent for our public warrants and PIPE warrants is Continental Stock Transfer & Trust Company. We have agreed to indemnify Continental Stock Transfer & Trust Company in its roles as transfer agent and warrant 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 of Securities**

Our Class A common stock is listed on NASDAQ under the symbol “ORGO”. Trading of our Class A common stock and public warrants was suspended as a result of the redemption on October 31, 2018 of all of AHPAC’s public shares. On November 2, 2018, as a result of the redemption of the public shares, NASDAQ issued a delisting notice in respect of the AHPAC units, AHPAC Class A ordinary shares and AHPAC warrants to purchase Class A ordinary shares. On November 9, 2018, AHPAC submitted a request for an oral hearing before the Hearings Panel to appeal the delisting determination pursuant to the procedures set forth in the NASDAQ rules. That hearing occurred on December 13, 2018 and on January 4, 2019, NASDAQ notified us that the Hearings Panel granted our request for the continued listing of our Class A common stock and lifted the trading suspension at the open of the market on January 8, 2019. Pursuant to the Hearing Panel’s decision, on or before March 31, 2019, we are required to demonstrate to the satisfaction of Staff and the Hearings Panel that we have a minimum of 300 round lot common stockholders and that we otherwise meet all applicable requirements for listing on Nasdaq. The Hearings Panel determined to delist our public warrants due to our non-compliance with the minimum 400 round lot holder requirement for initial listing on NASDAQ, as required by Nasdaq Listing Rule 5515(a)(4). Accordingly, the trading suspension in the Company’s warrants was converted to a trading suspension effective at the open of the market on January 8, 2019, at which time the warrants became eligible to trade “over-the-counter” under the trading symbol “ORGOW.”

## PLAN OF DISTRIBUTION

We are registering 23,965,170 shares of our Class A common stock for possible sale by the Selling Stockholders, 15,500,000 shares of Class A common stock issuable upon the exercise of the public warrants by the holders thereof, 2,050,000 shares of Class A common stock issuable upon the exercise of the PIPE warrants by the holders thereof, 182,700 shares of Class A common stock issuable upon the exercise of the exchange warrants by the holders thereof and 5,155,455 shares of Class A common stock issuable upon the exercise of the Options.

The shares of Class A common stock beneficially owned by the Selling Stockholders covered by this prospectus may be offered and sold from time to time by the Selling Stockholders. The term "Selling Stockholders" includes donees, pledgees, transferees or other successors in interest selling shares received after the date of this prospectus from a Selling Stockholder as a gift, pledge, partnership distribution or other non-sale related transfer. The Selling Stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. Such sales may be made on one or more exchanges or in the over-the-counter market or otherwise, at prices and under terms then prevailing or at prices related to the then current market price or in negotiated transactions. The Selling Stockholders may sell or dispose of their shares by one or more of, or a combination of, the following methods:

- purchases by a broker-dealer as principal and resale by such broker-dealer for its own account pursuant to this prospectus;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- block trades in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- an over-the-counter distribution in accordance with the rules of the NASDAQ Capital Market;
- through trading plans entered into by a Selling Stockholder pursuant to Rule 10b5-1 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are in place at the time of an offering pursuant to this prospectus and any applicable prospectus supplement hereto that provide for periodic sales of their securities on the basis of parameters described in such trading plans;
- to or through underwriters;
- in "at the market" offerings, as defined in Rule 415 under the Securities Act, at negotiated prices, at prices prevailing at the time of sale or at prices related to such prevailing market prices, including sales made directly on a national securities exchange or sales made through a market maker other than on an exchange or other similar offerings through sales agents;
- in privately negotiated transactions;
- in options transactions; and
- through a combination of any of the above methods of sale. In addition, any shares that qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus.

To the extent required, this prospectus may be amended or supplemented from time to time to describe a specific plan of distribution. In connection with distributions of the shares or otherwise, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with such transactions, broker-dealers or other financial institutions may engage in short sales of the common stock in the course of hedging the positions they assume with Selling Stockholders. The Selling Stockholders may also sell the common stock short and redeliver the shares to close out such short positions. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). The Selling Stockholders may also pledge shares to a broker-dealer or other

## [Table of Contents](#)

financial institution, and, upon a default, such broker-dealer or other financial institution, may effect sales of the pledged shares pursuant to this prospectus (as supplemented or amended to reflect such transaction).

A Selling Stockholder may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by any Selling Stockholder or borrowed from any Selling Stockholder or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from any Selling Stockholder in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and will be identified in the applicable prospectus supplement (or a post-effective amendment). In addition, any Selling Stockholder may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

In effecting sales, broker-dealers or agents engaged by the Selling Stockholders may arrange for other broker-dealers to participate. Broker-dealers or agents may receive commissions, discounts or concessions from the Selling Stockholders in amounts to be negotiated immediately prior to the sale.

In offering the shares covered by this prospectus, the Selling Stockholders and any broker-dealers who execute sales for the Selling Stockholders may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. Any profits realized by the Selling Stockholders and the compensation of any broker-dealer may be deemed to be underwriting discounts and commissions.

In order to comply with the securities laws of certain states, if applicable, the shares must be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in certain states the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

We have advised the Selling Stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the Selling Stockholders and their affiliates. In addition, we will make copies of this prospectus available to the Selling Stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The Selling Stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

At the time a particular offer of shares is made, if required, a prospectus supplement will be distributed that will set forth the number of shares being offered and the terms of the offering, including the name of any underwriter, dealer or agent, the purchase price paid by any underwriter, any discount, commission and other item constituting compensation, any discount, commission or concession allowed or reallocated or paid to any dealer, and the proposed selling price to the public.

We have agreed to indemnify the Selling Stockholders against certain liabilities, including certain liabilities under the Securities Act of 1933, as amended, the Exchange Act of 1934, as amended, or other federal or state law.

We have agreed with the Selling Stockholders to use all reasonable efforts to keep the registration statement of which this prospectus constitutes a part effective until the earlier of (i) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement, or (ii) two years after the effective date of the registration statement.

## LEGAL MATTERS

Foley Hoag LLP, legal counsel to Organogenesis has provided a legal opinion regarding the validity of the securities being offered by this document.

## EXPERTS

The audited financial statements of Avista Healthcare Public Acquisition Corp. as of December 31, 2017 and December 31, 2016 and for the period from December 4, 2015 (inception) to December 31, 2015 have been incorporated by reference herein in reliance upon the report of Marcum LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

The audited consolidated financial statements of Organogenesis Inc. as of December 31, 2017 and 2016 and for each of the years in the three year period ended December 31, 2017 have been incorporated by reference herein in reliance upon the report of RSM US LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

The financial statements of NuTech Medical Target Business as of December 31, 2016 and for the year then ended have been incorporated by reference herein in reliance upon the report of RSM US LLP, an independent auditor, incorporated by reference herein and upon the reliance of such firm as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC's Public Reference Room located at One Station Place, 100 F Street, N.E., Washington, D.C. 20549. You can also request copies of the documents, upon payment of a duplicating fee, by writing the Public Reference Section of the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. These filings are also available to the public from the SEC's website at [www.sec.gov](http://www.sec.gov).

Our website address is [www.organogenesis.com](http://www.organogenesis.com). Through our website, we make available, free of charge, the following documents as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained on, or that may be accessed through, our website is not part of, and is not incorporated into, this prospectus.

## DOCUMENTS INCORPORATED BY REFERENCE

The SEC allows us to “incorporate by reference” into this prospectus the documents that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. We incorporate by reference into this prospectus the following documents:

- our joint proxy statement/prospectus dated November 30, 2018, which was filed on November 30, 2018 and is part of the Registration Statement on Form S-4 originally filed with the SEC on August 29, 2018 (Registration No. 333-2227090), including any amendments or supplements thereto.
- our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 14, 2018, as amended by Amendment No. 1 to our Annual Report on Form 10-K for the year ended December 31, 2017, filed on October 15, 2018.
- our Quarterly Reports on Form 10-Q, for the fiscal quarters ended March 31, 2018, June 30, 2018 and September 30, 2018, and filed with the SEC on May 10, 2017, August 7, 2018 and November 9, 2018 and each as amended by Amendment No. 1 to our Quarterly Reports on Form 10-Q/A, each as filed on October 15, 2018.
- our Current Reports on Form 8-K, which were filed with the SEC on January 9, 2018, January 22, 2018, February 9, 2018, February 14, 2018, June 28, 2018, August 17, 2018, August 30, 2018, October 4, 2018, October 9, 2018, October 30, 2018, October 30, 2018, November 5, 2018, December 11, 2018, December 12, 2018, December 14, 2018 (Form 8-K12G3), January 7, 2019 (Film No. 19512275), January 7, 2019 (Film No. 19513981) and January 31, 2019.
- the description of our capital stock contained in our joint proxy statement/prospectus dated November 30, 2018, which was filed on November 30, 2018 and is part of the Registration Statement on Form S-4 originally filed with the SEC on August 29, 2018 (Registration No. 333-2227090), including any amendments or supplements thereto.
- the description of our common stock contained in our Registration Statement on Form 8-A, as filed with the SEC on October 5, 2016, including any amendment or report filed for the purpose of updating such description.
- all documents filed by us with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act (Commission File Number 001-37906) on or after the date of this prospectus and before the completion of the offering contemplated hereby, excluding any information furnished pursuant to Item 2.02 or Item 7.01, unless such Form 8-K expressly provides to the contrary.

Any statement contained in this prospectus, or in a document incorporated or deemed to be incorporated by reference herein, shall be deemed to be modified or superseded to the extent that a statement contained herein, or in any subsequently filed document that also is incorporated or deemed to be incorporated by reference herein, modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

You may obtain copies of these documents, at no cost to you, from our website ([www.organogenesis.com](http://www.organogenesis.com)), or by writing or telephoning us at the following address:

Organogenesis Holdings Inc.  
85 Dan Road  
Canton, MA 02021  
(781) 575-0775