POLARITYTE, INC.
Form 10-K
January 30, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)
[X] Annual Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934
For the fiscal year ended October 31, 2017

OR

[ ] Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the Transition Period from to

Commission File No. 000-51128

POLARITYTE, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**06-1529524**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

615 Arapeen Drive

Salt Lake City, UT 84108

(Address of principal executive office)

Registrant's telephone number, including area code (732) 225-8910

Securities registered pursuant to Section 12(b) of the Act: NONE

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

Common Stock, Par Value $0.001	NASDAQ Capital Market
(Title of class)	(Name of exchange on which registered)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [ ]

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

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

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[ ] (Do not check if smaller reporting company)	Smaller reporting company	[X]
Emerging growth company	[ ]		

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

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

The aggregate market value of the common stock held by non-affiliates as of April 30, 2017 was $58.3 million.

The outstanding number of shares of common stock as of January 26, 2018 was 6,922,044.

The Registrant’s proxy or information statement is incorporated by reference into Part III of this Annual Report on Form 10-K.

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Item 1. Business.

Forward-looking Statements

Statements in this Annual Report on Form 10-K that are not historical facts constitute forward-looking statements that are made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended, or the "Exchange Act". Examples of forward-looking statements include statements relating to industry prospects, our future economic performance including anticipated revenues and expenditures, results of operations or financial position, and other financial items, our business plans and objectives, including our intended product releases, and may include certain assumptions that underlie forward-looking statements. Risks and uncertainties that may affect our future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements include, among other things, those listed under "Risk Factors" and elsewhere in this Annual Report. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "intends," "plan "anticipates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other comparable terminology. These statements are subject to business and economic risk and reflect management's current expectations, and involve subjects that are inherently uncertain and difficult to predict. Actual events or results may differ materially. Moreover, neither we nor any other person assumes responsibility for the accuracy or completeness of these statements. We are under no duty to update any of the forward-looking statements after the date of this Annual Report to conform these statements to actual results. References herein to "we," "us," and "the Company" are to PolarityTE, Inc.

Introduction

PolarityTE™ is a commercial-stage biotechnology and regenerative biomaterials company focused on transforming the lives of patients by discovering, designing and developing a range of regenerative tissue products and biomaterials for the fields of medicine, biomedical engineering and material sciences. We believe that our PolarityTE platform technology is a new approach to pragmatic and functional tissue regeneration that has the potential to address many of the challenges currently facing the regenerative medicine and cell therapy markets. Recognizing the natural complexity of human tissue, our core "TE" platform begins with a small piece of the patient's own, or autologous, healthy tissue, rather than artificially manipulated individual cells. From this small piece of healthy autologous tissue, we create an easily deployable, dynamic and self-propagating product designed to enhance and stimulate the patient's own cells to regenerate the target tissues. Rather than manufacturing with synthetic and foreign materials within artificially engineered environments, we manufacture with the patient's own tissue and use the patient's own body to support the regenerative process to create the same tissue from which it was derived. We believe that our innovative method promotes and accelerates growth of the patient's tissues to undergo a form of effective regenerative healing.

We believe our core "TE" platform has applications across many indications, including the regrowth of skin, bone, cartilage, fat, muscle, blood vessels and neural elements, as well as solid and hollow organ composite tissue systems.

Our first product, SkinTE™, is registered with the United States Food and Drug Administration, or the FDA, pursuant to the regulatory pathway for human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated solely under Section 361 of the Public Health Service Act, or 361 HCT/Ps, which permits qualifying products to be marketed without first obtaining FDA marketing authorization or approval. SkinTE is commercially available for the repair, reconstruction, replacement and regeneration of skin (i.e., homologous uses) for patients who have suffered from wounds, burns or injuries that require skin coverage over both small and large areas of their body.

We believe that living systems require more than a simple singular input, like a growth factor, stem cell or nano-particle, to produce a complex output. We have designed, engineered and developed our technology platform to allow us to induce, maintain and promote the complete development of cellular entities, their products and tissue elements in a way that mirrors regenerative healing in the body. We aim to maintain and promote key dynamic processes that drive integrative regeneration of our tissue products once deployed back to the patient to improve upon common issues seen with other tissue products, such as immune system rejection, inflammation, and other adverse reactions.

The following chart summarizes the development of our core products and product candidates.

SkinTE, our first of the core "TE" tissue products, was registered with the FDA on August 14, 2017, and is now commercially available for the repair, reconstruction, replacement or regeneration of skin in patients who have or require treatment of acute and chronic wounds, burns, surgical reconstruction events, scar revision, or removal of dysfunctional skin grafts. We have initiated a staged-commercial release of SkinTE to select medical institutions, and expect to scale up manufacturing efforts during 2018 following the buildout of our 200,000 ft^2 biomedical manufacturing facility.

In preclinical testing, we observed that SkinTE regenerated full-thickness skin complete with all of its layers (epidermis, dermis, hypodermis) and functional appendages, including hair follicles, sweat glands and sebaceous glands. Thus far, in the early stages of the human clinical application of SkinTE, we have observed results that are correlative with our preclinical observations. We intend to target sales of SkinTE toward the wound care market, which according to MedMarket Diligence LLC is expected to exceed 250 million wounds worldwide by 2020.

Because we do not expect our product candidates to require time-intensive, costly, multi-phase clinical trials or prior marketing approval or authorization like other therapeutics, biologics and devices, we plan to develop and commercialize several products simultaneously. As we believe our innovative platform technology has wide applicability—not only to regenerate multiple human tissues, organs, and composite structures, but also across other complex interacting biological systems (such as the immune system)—we believe that over time we can become a leader in the global regenerative medicine market, which according to Stratistics MRC is expected to exceed $100 billion by 2022.

We are a company built and run by physicians for patients and the physicians who care for them. We believe that developing tangible regenerative products requires an intimate knowledge of the realities that exist within the trenches of medicine. Our management team's expertise is the result of years of medical training and clinical practice, extensive direct experience in the field at major reconstructive surgery and burn centers, and, collectively, hundreds of articles published in peer-reviewed journals and other publications. Our founders, Chief Executive Officer, Dr. Denver Lough, and Chief Operating Officer, Dr. Edward Swanson, left the Department of Plastic and Reconstructive Surgery at the Johns Hopkins University School of Medicine to launch the Company and pursue their passion to impact the lives of patients on a much larger scale, and to address many of the clinical problems they encountered on a daily basis. Dr. Michael W. Neumeister, our Chief Medical Officer, is Professor and Chairman of the Department of Surgery at Southern Illinois University School of Medicine, and Dr. Stephen Milner, our Chief Clinical Officer, is former Professor of Plastic and Reconstructive Surgery and Pediatrics at the Johns Hopkins University School of Medicine and former Director of the Johns Hopkins Burn Center. Dr. Maurice Nahabedian, our Chief Surgical Officer, is Chairman of this year's meeting of the American Society of Plastic Surgeons, is former Professor and Section Chief of Plastic Surgery at MedStar Washington Hospital Center, and former Vice Chairman of the Department of Plastic Surgery at the Georgetown University.

We believe that our expertise is further bolstered by the vast knowledge and experience of our Clinical Board of Advisors, composed of leaders across a variety of medical and surgical specialties, including professors, chairmen of departments, and national surgical society presidents at a number of medical institutions, such as former President of the American Burn Association and Chairman of the American Board of Plastic Surgery, Dr. Martin C. Robson.

In addition to our Clinical Board of Advisors, we have assembled a Military and Mass Casualty Board led by Major General (U.S. Army – Retired) Jay Hood, who served as the Commander of First Army Division East, the Chief of Staff, United States Central Command and the Commander of Joint Task Force Guantanamo, among other high-level leadership positions during his 36 years of distinguished service. We intend to leverage the expertise of our Military and Mass Casualty Board to identify ways to use our technology platform to develop regenerative products with the potential to address the complex and devastating injuries of military service members, wounded warriors, veterans, and mass casualty victims.

Limitations of Current Wound Care and Regenerative Medicine Technologies and Products

To date, many wound care, regenerative medicine and tissue engineered products have focused on “large scale manufacturable materials” and “off the shelf” designs for products as opposed to employing a more patient-specific approach. Many products utilize animal-derived tissues, referred to as xenografts, or cadaveric-derived tissues, referred to as allografts, in part to allow for a robust supply chain of sourced raw materials. However, we believe these skin substitutes do not result in actual tissue regeneration.

We believe that, prior to PolarityTE, the evolving field of regenerative medicine has been characterized by tremendous potential, but has also been wedded to approaches that are fraught with significant challenges. We believe the approach to regenerative medicine that our predecessors and competitors employ has anchored itself within tissue engineering algorithms that—while potentially profitable because of mass production and scalability—are incongruent with living cells, dynamic tissues and reactive systems. Some current regenerative medicine approaches aim to isolate a single cellular population to regenerate a tissue, such as adipose-derived stem cells. Other approaches aim to deliver a molecule to manipulate cell function, such as driving cell growth and expansion, or coaxing one cell type to become another. The final prominent current approach aims to create some form of a scaffold that recapitulates the appearance of the target tissue with specific properties designed to mimic that tissue, such as polymers with similar mechanical properties of bone, and allow or encourage a targeted cellular function and tissue integration, such as 3-D printing of scaffolds and nano-particles.

We believe these approaches incorrectly focus on the synthesis and/or engineering of singularities (i.e. a type of cell, a type of molecule, and/or type of matrix) in an attempt to build a complex tissue from the ground up, which we believe creates an incomplete system without interactions, diverse cells and molecules, or a natural environment to direct organization.

Our Solution — The PolarityTE Core “TE” Platform Technology

We believe each person's cells and tissues have vastly different and dynamic profiles (genomic, transcriptomic, proteomic, metabolomic etc.), and therefore different requirements when it comes to the regenerative potential and/or healing capacity of tissue-based systems. With this in mind, we designed our core "TE" platform technology to focus not on singularities but on regenerating complete tissue systems.

Our core "TE" platform and self-complexing intelligent regenerative materials technologies are based on our ability to create minimally polarized functional units, or MPFUs, which contain polarizing multi-cellular aggregates capable of expanding, proliferating and synthesizing those cells, materials, factors and/or systems we believe are necessary for integrative full-thickness three-dimensional tissue regeneration, not simply two-dimensional cell sheets. Instead of starting with artificial materials, synthetic factors and/or altered cell suspensions, our platform begins with the patient's own (autologous) tissue and those components, appendages and substrates we believe are necessary for the development of an expandable and self-propagating complete system.

With SkinTE, often within 24-48 hours of the initial skin harvest, our product is applied to the patient, whose body then provides a receptive environment and nutrients for controlled healing. By both preserving the tissue's natural microenvironment and using the patient's body as an intrinsic bioreactor—which means using the body's own natural biological healing process rather than a manufactured or engineered environment to support the regenerative process—we believe a patient's own tissue can be regenerated, along with its natural coloring and texture, layers and structure, hair and appendages. We have designed our technology platform to use the patient's own healthy tissue, in part to increase the likelihood that the patient's immune system will identify the regenerating tissue as its own so that our product is neither rejected nor reacted to adversely. We believe that our platform has the potential to transform tissue regeneration, including potential regeneration of multiple tissue substrates, such as skin, bone, muscle, fat, cartilage, nerves, and blood vessels. The harvest, deployment, and application of our platform technology in SkinTE is shown in the images below.

Our product pipeline focuses on the development of regenerative products for a variety of tissue types and organ systems which are commonly altered, injured or destroyed by a variety of diseases, pathologies, traumatic events and medical interventions. We believe that our biomaterials platform capabilities extend to applications across many indications, including bone, cartilage, muscle, blood vessels and neural elements as well as solid and hollow organ composite tissue systems. The key attributes of our platform technology include the following:

Patient-Generated Cell Source: The human body often identifies and rejects foreign cells, creating the potential for tissue rejection, additional surgery, and foreign or allogeneic body reactions like residual scarring. We address this by using healthy autologous tissue taken from the patient to regenerate cells that the body identifies as “self” rather than foreign. Our goal is to allow a recipient to receive our product and generate new tissue without triggering an allogeneic, or foreign tissue, rejection, wherein the patient’s immune system destroys the transplanted tissue.

Stem Cell Niche Utilization for Functional Tissue with Full Thickness and Layer Regeneration: We utilize techniques for capturing the "stem cell niche," the microenvironment within a particular tissue that interacts with stem cells to signal cell growth, development, renewal and differentiation. While the stem cell niche historically has often been left behind by the commonly used split-thickness autograft methodology, we believe that it is necessary for the regeneration of functional tissue. Without the stem cell niche, we believe new tissue will form a scar and lose the functionality of the original tissue from which it was regenerated. By including the stem cell niche within the autologous tissue that is harvested, we believe the natural function of the small piece of tissue is preserved as it regenerates into a larger piece that can fill the patient's wound. This is designed to minimize painful scarring, or lesions, that often accompanies autologous regeneration without the stem cell niche, to allow for the regeneration of the tissue's normal layers and appendages, and to provide full-tissue coverage without relying on secondary surgery or in-growth of the surrounding tissue. We believe inclusion of the stem cell niche allows us to regenerate tissue with its naturally complex layers intact.

Polarity Maintenance and Enhancement to Harness Stem Cell Niche Regeneration: A cell's polarity refers to its interactive communication with neighboring cells, including the direction in which a cell should grow. This enables cells and tissues to carry out specialized functions. Our platform carefully maintains and enhances the polarity of the stem cell niche in order to harness its regenerative capacity by mirroring the way tissue develops in the human body. By maintaining and enhancing the polarity of regenerating tissue, our platform is designed to preserve the natural cell and three-dimensional tissue structure, and thereby the functionality of regenerated tissues and appendages.

Patient as Bioreactor: Instead of using a manufactured or engineered environment to support the regenerative process, our platform uses the human body as a bioreactor by applying our product to the patient and allowing regeneration to occur there. We believe this allows the patient's own body to provide the ideal nutrients and extracellular environment for controlled healing of the regenerative tissue. This approach also reduces turnaround time back to the patient, as our manufacturing process does not involve growing cells in an industrial, synthetic bioreactor.

Our Competitive Strengths

We believe that our key competitive strengths include the following:

Novel Platform Technology. Our technology platform deploys activated MPFUs into a wound or other tissue defect with the goal of regenerating fully-functional, polarized tissues and hierarchically organized tissue structures, such as skin with all of its layers, hair and glands. We design the MPFUs to facilitate the expansion, proliferation and synthesis of the cells, materials, factors and systems that we believe are necessary for complete, full-thickness generation and regeneration across a spectrum of tissue substrates and organ systems. Rather than relying on a single stem cell, growth factor, or scaffold, we believe that complex tissue regeneration requires a dynamic composite cellular interface to engineer a complex tissue that is expected to integrate into living systems. We design our core tissue substrate materials to create complex functional living tissue systems in a way that mirrors natural healing in the body and is not seen as foreign by the immune system.

Proof of Concept Through FDA-Registered, Commercialized SkinTE Product. SkinTE is registered with the FDA and is our first commercially available product. In our preclinical animal studies, we observed favorable outcomes using SkinTE to aid skin regeneration compared to natural wound healing. In a natural, unaided setting, skin defects heal through a process of wound contraction and often scar formation. Although skin grafts may reduce contraction, they also often leave patients with scarring. In our preclinical animal studies, we observed that SkinTE reduced scar formation and regenerated full-thickness, hair-bearing skin within the wound bed. The following images from our preclinical animal studies show the SkinTE skin regeneration and native wound healing we observed in one of our preclinical animal studies.

Since November 2017, we have sold and provided SkinTE to multiple medical providers across the country who have treated patients for acute and chronic wounds, surgical reconstruction, burns, and removal of scarred and contracted skin grafts for replacement with SkinTE. Preliminary results from the initial human clinical applications of SkinTE are yielding results that are correlative with our preclinical observations.

Deep Pipeline of Additional Potential Applications. In addition to the regrowth of skin, we believe our platform's capabilities can be extended across many indications, including bone, cartilage, muscle, blood vessels and neural elements, as well as solid and hollow organ composite tissue systems. For example, we believe there are currently unmet medical needs that can be addressed by the regeneration of cartilage for the treatment of osteoarthritis and facial reconstruction, the regeneration of fat-for-fat transfers during plastic surgery procedures, the regeneration of nerves following traumatic loss, the regeneration of blood vessels for vascular grafts, the regeneration of the urogenital epithelium and submucosa for urethral strictures and bladder reconstruction following tumor removal, the regeneration of liver tissue for liver fibrosis or failure, and the regeneration of bowel tissue to prevent leaking where the bowel is reconnected (prevention of anastomotic leak) or replaced due to excessive loss from trauma, surgery or congenital defects.

Shortened Product Development Timelines. Since our core "TE" product candidates all stem from a common platform technology, we believe we are able to accelerate research and development, pre-clinical model prototyping, and product development in a manner which is efficient and optimized across substrates.

Scalable Manufacturing and Distribution Capability. Because we believe our technology can be applied across a variety of tissue substrates, we believe we have the ability to prototype, model and develop products for commercialization relatively quickly. We have developed flexible manufacturing processes, systems and facilities that we believe can allow us to quickly respond to increases in demand and market forces. Because we believe we can apply our technology to many types of tissue and organ systems, we believe we can effectively scale and reproduce the manufacturing and distribution of multiple pipeline products at the same time. In addition, we believe we can leverage our platform technology to create a variety of substrate sub-platforms and related technology derivative arms, which can act either as additive technologies to core "TE" products, or as standalone products. We believe we may also be able to integrate our technology with other off-the-shelf products (e.g. to cellularize an acellular scaffold or function with existing dressings).

Efficient Regulatory Pathway. We believe our products and product candidates, including SkinTE, are appropriately regulated by the FDA as 361 HCT/Ps, which provides us with the potential to register and list products with the FDA, and begin commercializing quickly and efficiently. Unlike products regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (the "FD&C Act") and/or the Public Health Service Act as drugs, devices, or biologics, which require multi-phase clinical trials and premarket approvals, our SkinTE product is regulated by the FDA as human cells or tissues intended for implantation. We are developing our additional pipeline candidates to be regulated as 361

HCT/Ps as well. 361 HCT/Ps do not require premarket approval or other premarket authorization and may be lawfully marketed for appropriate human use in the United States following registration with the FDA.

Experienced and Recognized Physician-Led Leadership Team. We believe our extensive experience and knowledge in cell-tissue and molecular biology, reconstructive surgery, regenerative medicine, biomedical engineering, biomedical manufacturing and clinical pragmatism arms us with the ability to effectively commercialize our regenerative technologies for unmet medical needs. We are a company run by physicians for patients and the physicians who care for them. Our management team has spent considerable time in the operating room gaining direct front-line experience with many of the products that comprise the existing regenerative medicine market, and working on ways to address the limitations of these products. Our Chief Executive Officer, Dr. Denver Lough, and Chief Operating Officer, Dr. Edward Swanson, were Plastic Surgery Residents at the Johns Hopkins University School of Medicine prior to founding PolarityTE, and have hands-on experience working in wound care and tissue engineering. Dr. Michael W. Neumeister, our Chief Medical Officer, is Professor and Chairman of the Department of Surgery at Southern Illinois University School of Medicine, and Stephen Milner, our Chief Clinical Officer, was Professor of Plastic and Reconstructive Surgery and Pediatrics at the Johns Hopkins University School of Medicine and served as the Director of the Johns Hopkins Burn Center. We believe our front-line experience not only provides a deep understanding of the comparative standards of care for tissue regeneration, but also an understanding of the user experience and adoption mechanisms behind successful surgical products generally. We also benefit from the guidance of our Clinical Board of Advisors, which includes professors and directors of surgery at a number of medical institutions and former President of the American Burn Association and Chairman of the American Board of Plastic Surgery, Dr. Martin C. Robson.

Our Growth Strategy

Complete the full commercial launch of SkinTE and establish SkinTE as an improvement over the standard of care for skin tissue injuries, including wounds, burns and scars. We believe that SkinTE has the potential to supplant prevailing methods of wound and burn care because, unlike existing treatment options, it is designed to regenerate full-thickness skin using small samples of the patient's own tissue. Rather than being limited by dimensions of the tissue received, SkinTE is designed to regenerate significantly beyond the sample size. Our initial limited commercial roll-out of SkinTE commenced in November 2017 and has focused on severe wounds and burn patients at key regional centers as, in our experience, these patients are often in critical need of large areas of skin regrowth and may have limited available healthy skin to use for skin grafts. However, we expect to make SkinTE commercially available to address the broader wound market, which is expected to exceed 250 million wounds worldwide by 2020. Along with the treatment of acute and chronic wounds, we intend to market SkinTE for other surgical reconstruction events, including cosmetic and elective surgeries, and for scar revision or the removal of dysfunctional events. We are leveraging the front-line experience of our leadership team to enhance adoption of SkinTE by physicians and patients by designing our products with a focus on simplicity, the user experience, reliability and ease of application. For SkinTE, and for each of our product candidates we plan to commercialize, we intend to conduct prospective clinical evaluations to compare the products to the standard of care, to bolster adoption and reimbursement with third-party payers.

Capitalize on our scalable manufacturing capabilities and the 361 HCT/P regulatory pathway to commercialize additional pipeline products quickly and efficiently. In addition to SkinTE, we are actively preparing and advancing our other core "TE" pipeline candidates for FDA registration using the 361 HCT/P pathway that does not require FDA approval prior to marketing, and for market entry. We currently expect to register our bone regeneration product candidate, OsteoTE, with the FDA and to begin commercial roll-out by the end of 2018. We are also developing numerous other regenerative products including CartTE™ (cartilage for osteoarthritis, facial reconstruction and more), AdipoTE™ (fat transfers for plastic surgery procedures), AngioTE™ (vascular grafts), NeuralTE™ (nerve repair), UroTE™ (urogenital epithelium and submucosa), LiverTE™ (liver tissue for liver fibrosis or failure) and BowelTE™ (bowel tissue). Our current expectation is to rely on the versatility of our platform technology, the 361 HCT/P regulatory pathway, and our scalable manufacturing capability to develop and launch multiple products concurrently.

Explore partnership or collaboration opportunities for pipeline candidates as well as potential acquisitions or in-licenses of complementary product candidates. We are actively exploring the possibility of partnership or collaboration opportunities with third parties, which we believe could be used to facilitate the commercial adoption of our pipeline candidates worldwide or in certain territories. We are selectively evaluating the formation of collaborative alliances, product licensure and distribution agreements and integrative product offerings, as well as opportunities to accelerate the commercialization and development of our products. In the future, we also expect to consider the acquisition or in-license of complementary product candidates.

Our Products and Product Candidates

The following chart summarizes our product development pipeline.

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SkinTE

Our first product, SkinTE, is registered with the FDA and is now commercially available for treatment of defects of the skin. SkinTE is created from a small piece of the patient's own tissue, which is extracted, and then manufactured using our proprietary technology platform to expand and regenerate full-thickness, fully functional skin with what we believe to be the critical layers, including epidermis, dermis and hypodermis, and appendages including hair follicles and glands. Each package of SkinTE is patient-specific and designed for a single application. We believe SkinTE offers a compelling alternative to current standards of care for skin regeneration.

PolarityTE designed SkinTE for use by physicians and other healthcare professionals in the treatment of patients who have suffered from an event, disease, or process, or who have an acquired defect that has resulted in the functional loss or absence of the skin. Specifically, SkinTE is designed for the treatment of chronic wounds such as diabetic foot ulcers, acute wounds such as traumatic injuries, chronic burn wounds or scars, acute burn wounds, scars of the integument, and defects from medical or surgical resection or reconstruction events which require skin coverage. According to a 2015 report from MedMarket Diligence, LLC, more than 250 million wounds are expected globally by 2020. And according to Stratistics MRC's 2016 Global Regenerative Medicine Market Outlook, the global market for regenerative medicine and tissue engineering is expected to grow to $101.3 billion by 2020.

SkinTE was registered as a 361 HCT/P with the FDA pursuant to Section 361 of the Public Health Service Act and 21 CFR 1271. An HCT/P is defined as articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Products that qualify as 361 HCT/Ps are not subject to the FDA's pre-market clearance or approval requirements, but rather can be immediately listed for commercial use with the FDA and are then subject to post-market regulatory requirements such as compliance with current good tissue practices (cGTP), adverse event and deviation reporting, and post-market inspections by the FDA. For more information on the 361 HCT/P regulatory pathway, please see "Government Regulation" and "Risk Factors – Risks Related to Registration and/or Regulatory Approval of Our Product Candidates and Other Government Regulations."

Limitations of Current Wound Treatments

Current clinical standards and practice adhere to the concept that tissue should be replaced with like, or homologous, tissue. For example, skin should be replaced with skin whenever possible in settings where patients have suffered the loss of such tissue. Understanding this, medical professionals are left with a decision to attempt to temporize a wound bed with cadaveric skin (allograft), utilize the patient's own skin (autograft), or apply a variety of skin substitutes in order to provide a skin-like barrier while the margin of the wound heals through secondary intention and contraction. Presently, harvest and placement of autologous full-thickness skin results in the best outcome within wound beds because it most closely resembles the full-thickness skin that was lost. Full-thickness harvest of skin, however, also inherently results in a full-thickness skin defect at the donor site, which requires primary closure (skin edge

approximation and suturing) so as not to leave a gaping wound behind. There is a limit on how much autologous full-thickness donor skin can be harvested without leaving behind a non-closable wound. As a result, medical professionals can only harvest small, elliptically-shaped pieces of such skin from areas of redundancy, which are referred to as full-thickness skin grafts, or FTSGs.

Due to these limitations, medical professionals often rely on split-thickness skin grafts, or STSGs, which harvest only the top layer of the patient's own skin as a means to get more skin for better coverage of voids. Following harvest of the top layer of skin for an STSG—which leaves behind the many necessary structures, cellular elements and tissue interfaces from the STSG donor site—patients are often left with an incomplete top layer of skin covering the initial defect (recipient site) and a remaining bottom layer at the donor site. In this setting, both donor and recipient sites contain incomplete skin, which can result in dysfunctional, painful scar tissues that can result in lifelong morbidities.

Because of the limitations of STSGs and FTSGs, medical professionals and companies have continued to investigate skin substitutes and skin alternatives for use in place of a patient's own skin, such as a cultured form of manipulated autograft, allograft (cadaveric tissues), xenograft (animal tissues) and alloplast or synthetic materials. To our knowledge, no skin substitute has been able to replicate the appearance of native skin, or regenerate full-thickness skin or the cutaneous appendages (hair follicles, sweat glands, sebaceous glands, etc.), which are necessary for the development of full-thickness, functionally polarized, hierarchically organized skin. In its Local Coverage Determination for the Application of Skin Substitutes (L36466), the Centers for Medicare and Medicaid Services, or CMS, acknowledges that "sufficient data is available to establish distinct inferiority [of current skin substitutes] to human skin autografts and preclude their designation as skin equivalence." The CMS determination also finds that "without the component of the recipient's own distinct epithelium and cellular skin elements, permanent skin replacement or coverage by the graft cannot be accomplished."

Our Wound, Burn and Skin Reconstruction Treatment Solution – SkinTE

PolarityTE designed SkinTE to address the limitations from which current wound and burn treatment methods suffer. We designed SkinTE to combine the advantages of autologous STSGs with those of FTSGs. Notably, SkinTE is designed to provide not only the large surface area treatment capability of STSGs, but also the restoration and smaller, less morbid donor site associated with FTSGs. In essence, we believe our minimally manipulated SkinTE product can provide an expandable form of a FTSG.

SkinTE is composed of small viable cellular and tissue-based units, which we call MPFUs, that retain all of the components of skin that we believe are required to regenerate full-thickness skin. The initial processes underlying the function of SkinTE are analogous to those responsible for the healing of an autologous skin graft, namely imbibition, inosculation, and neo-vascularization. During imbibition, SkinTE, and the small cellular and tissue based units that comprise it, survive through the direct application of the SkinTE "paste" on the wound bed, exchanging nutrients and waste within the fluid of the wound bed. Inosculation is the stage in which the capillaries and blood vessels already present within the wound bed begin to align and connect with those present within the graft. Neovascularization marks the ingrowth of new blood vessels into the wound bed and out of the graft, with vasculogenesis describing the formation of new vessels from cellular precursors present within the wound and graft, and angiogenesis referring to the sprouting of new vessels from pre-existing ones. Due to their size and composition, we design the small cellular and tissue based units within SkinTE to have reduced metabolic demand and to be capable of surviving through diffusion, and to readily excrete metabolic waste, resulting in what we believe can be less ischemic damage when compared to FTSGs. Reduction in ischemic damage has the potential to decrease scar formation and provide a more functional result. Following completion of the initial stages of integrating and healing within the wound bed, the SkinTE product is designed to begin forming and organizing discrete areas of full-thickness skin. We have observed in preclinical animal testing that these regenerative centers of full-thickness skin then expand out radially across the wound, eventually coalescing with each other and the margins of the wound.

As compared to the currently marketed skin substitutes of which we are aware, each SkinTE tissue-product is derived entirely from the patient's own skin and is not combined with any other tissue-engineered substitutes. We believe these differences allow SkinTE to regenerate all of the important layers of the skin as well as the necessary cutaneous appendages for the development of functionally-polarized, hierarchically organized autologous, homologous skin.

How SkinTE Works

SkinTE is designed as an all-in-one system to make the process as simple and efficient as possible for the user—whether that individual is a surgeon, medical doctor, physician assistant or nurse in an operating room, wound clinic, emergency department, doctor's office or forward operating military facility. When a new clinical center or practice is

activated to begin using our SkinTE product, we ship a supply of all-inclusive harvest boxes (see the image furthest to the left above) to the facility for convenient on-site, off-the-shelf storage for that user and facility. Each harvest box contains all the materials and instruments needed to perform the relatively standard skin excision procedure to obtain the tissue sample, and all of the pre-paid/pre-completed shipping labels, and a one-touch NanoCool® shipping box that maintains the temperature within the harvest box as it is delivered to a PolarityTE biomedical manufacturing facility.

At our manufacturing facility, we use proprietary techniques to create a paste-like product from the small piece of healthy patient tissue that preserves the original tissue's microenvironment and allows new cells to integrate into existing, healthy cells, with similarly organized assembly and interface development. Following manufacturing at our facility, the SkinTE product is shipped back to the provider at a time that best suits the patient and provider's scheduling and location needs (i.e. operating room, procedure clinic, in-patient bedside, out-patient doctor's office). Our goal is to be able to return the ready-to-use SkinTE product to physicians as early as the same day. In our limited time selling SkinTE, we have observed that the majority of return requests have been for return within 24-72 hours from tissue harvest. At application time, once the patient wound bed is prepared per clinical guidelines, SkinTE is dispensed onto the surface of the wound bed (see the image in the middle above). The wound is dressed using a non-adherent, occlusive, non-absorbent dressing placed directly over the SkinTE product (see the image furthest to the right above), with recommended dressings that we include in the deployment box.

To assist physicians and other medical providers in using SkinTE, we developed a web application called the PolarityTE 24-Hour Real-Time Assistant, or the RTA, which permits experienced and medically trained PolarityTE physicians and staff to provide real-time support through a customer's computer or smart phone. The RTA permits HIPAA-compliant direct calling, video chat, text, emails and data sharing. Through the RTA, our customers can also track their packages and submit forms. We also use the RTA to gain advanced visibility into daily manufacturing requirements and product flow.

Preclinical Studies

In preclinical models of full-thickness swine burns and wounds, we observed that SkinTE generated healing with reduced scarring, hair follicle growth, complete wound coverage, and the progressive regeneration of all skin layers including epidermis, dermis and hypodermal layers. We believe swine models of burns and wounds are predictive of results found in humans due to the similarities between swine and human skin. We have included images below of the SkinTE-generated swine wound healing we observed.

Stereoscopic Imaging of Progressively Healing Wounds. (a.) Representative progression of wound healing in excised full-thickness burn wound (untreated control) vs. excised full-thickness burn wound treated with SkinTE. Image sequence – left column: day 0; middle column day 2; right column day 50. (b.) Cross-section of healed tissue in untreated control wound. Pseudo-epithelium (PsE); Contracted Scar (CS). (c.) Cross-section of healed tissue in SkinTE treated wound. Black arrows indicate where SkinTE propagated and expanded into the residual burn scar that remained in addition to regenerating full-thickness, hair-bearing skin in the excised tissue void. Hair Follicle (HF); Epidermis (Ep); Epidermal-Dermal Junction (EDJ); Neo-dermis (ND); Hypodermal Fat (HDF). The 9 images in the 3x3 grid to the right represent progressive regeneration of cutaneous appendages which progressively develop and directly promote the regeneration of full-thickness, hierarchically organized skin. Pore (P); Neo-dermal expansion (NDE); Cornification (CF). Top right image of 3x3 grid represents region of where the native skin meets (wound margin interface) the progressively healing SkinTE construct. Notice that at the margin of where native skin meets SkinTE ( ), the residual scar has a smaller width than individual hair shafts. The images and data presented here are from pre-clinical studies.

Comparing Native Skin and Skin Grafts to SkinTE. Stereoscopic Imaging of Comparative Healed Burn Wounds. Comparative images depict a baseline burn wound control (untreated excised burn) on the upper left and untouched native skin to its right. The right sequence of images depicts three rows of excised full-thickness burns treated with: (upper row) full-thickness allograft skin; (middle row) full-thickness autologous skin graft; (bottom row) autologous, homologous SkinTE product. Images were captured at day 54 following treatment. Type of wound treatment is indicated at the left side of the image (allograft, autograft, SkinTE); (white arrow) indicates the margin of interface between the peri-wound native skin and SkinTE; and untreated native skin is indicated at the right side of the image. Sequential images are increasing zoom to identify the margin of linear interface. The images and data presented here are from pre-clinical studies.

The following image shows our observations of the wound edge and interface between native skin and SkinTE following regenerative healing.

Comparing Native Skin at the Wound Edge (above) to SkinTE Following Regenerative Healing (below).) Depicts a region of the SkinTE treated wound bed (lower bracket) and marginal peri-wound bed containing native skin (upper bracket) and the direct interface between two tissue types, as indicated by the round-ended arrow heads and connecting dotted line. The images and data presented here are from pre-clinical studies.

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The following images show our observations of SkinTE healing, including full-thickness hair-bearing skin regeneration, compared to native wound healing.

Direct Comparison of SkinTE Full-thickness Hair-bearing Skin Regeneration vs. Native Wound Healing.

The following images compare mid-stage healing burn wounds, showing the differences in tissue formation and scar contraction in the control wound as compared to SkinTE-regenerated tissue.

Comparing Mid-stage Healing Processes Between Native Wounds and Defects Treated with SkinTE. Stereoscopic Imaging of Comparative Mid-stage Healing Burn Wounds Representing the Different Mechanisms of Tissue Formation Between Scar Contraction in the Control Wound and Full-thickness Skin Regeneration with SkinTE. (Left panels) The native Mid-stage contracting wound represents typical wound contracture and scar formation subsequent to keratinocyte migration from the margin of the wound to form overlying pseudo-epithelium. (Right panels) Expanding SkinTE undergoes regenerative healing from within the wound which permits wound edge margins and propagating SkinTE elements to interact in a manner which promotes integrative full-thickness healing with augmented levels of cross interface angio and vasculogenesis, resulting in significantly less contraction and scar formation. The images and data presented here are from pre-clinical studies.

The following images from our preclinical studies show stereoscopic imaging of progressively healing full-thickness burn wounds following the application of SkinTE as compared against an untreated control wound. The image indicates where growth of hair follicles, neo-dermal expansion and neo-glandular development can be seen in the SkinTE-treated wound. Also depicted is a comparison between the contraction of the underlying neo-dermis of an untreated control wound as compared to a SkinTE-treated wound.

Stereoscopic Imaging of Progressively Healing Wounds Following Application of SkinTE vs. Untreated Control Wound in a Preclinical Full-thickness Burn Wound. (a.) SkinTE, depicts stereoscopic image and correlative trichrome ancillary staining indicating regions of original wound edge (black arrow-ball dots); hair follicle (HF); Neo-dermal expansion (NDE with correlative white dot outline; Neo-glandular development (NGD). (b.) Control untreated wound, Contracted Scar (*CS) with correlative dual headed arrow spanning remaining scar width region. (c.) Bar graph showing the reduced contraction with SkinTE and full-thickness skin grafts relative to split-thickness skin grafts, allografts, scaffolds, and untreated controls wounds. (d.) Mid-stage expansion of the underlying neo-dermis of SkinTE prevents contraction early on by preventing myofibroblast directed collagen synthesis and contracting orientation from forming directly along stress lines and by preventing tension induced scar hypertrophy. The images and data presented here are from pre-clinical studies.

Direct Comparison of SkinTE Full-thickness Hair-bearing Skin Regeneration vs. Native Skin and Wound. Regenerative healing occurs through a process which not only regenerates the appropriate and necessary tissues, functions and interfaces but also prevents wound contraction, scar formation and fibrotic pseudo-tissue deposition (Top Row) Left- SkinTE at 54 days of healing. Middle - Depicts a region of the SkinTE treated wound bed (lower bracket) and marginal peri-wound bed containing native skin (upper bracket) and the direct interface between two tissue types, as indicated by the round-ended arrow heads and connecting dotted line. Right- Native wound undergoing healing at 54 days. (Bottom Row) Left- Comparative elastic modulus (kPA) across, SkinTE™, native skin and a native wound. X and Y coordinates represents the dimension tested and correlative area (14 cm x 14 cm) containing color spectrum associated units as described by kPA scale. Comparative Raman spectroscopy of the molecular fingerprint region of the of Native Control Wound, SkinTE (defined as a wound treated with SkinTE and the resultant tissue within the region at 6 months), Native Skin – Untreated, Spectral Δ: SkinTE vs. Native Untreated, (defined as a comparative analysis between SkinTE treated wound and the native skin), Spectral Δ: Wound vs. Native Untreated, (defined as the native wound compared to native skin). The images and data presented here are from pre-clinical studies.

In addition to the preclinical SkinTE animal results described above, we have conducted a series of *ex vivo* preclinical human tissue studies on full-thickness skin and the subsequent final tissue product, SkinTE, in order to identify potential variations between native skin and SkinTE. As described more fully below, in these studies we observed that the methods of harvest, processing and deployment necessary to produce SkinTE did not meaningfully alter viability and regenerative outcome of SkinTE in a treated wound.

Tissue Product Viability: In order to assess a variety of cell and tissue functional abilities, including cell viability, we utilized CellInsight CX7 High-Content Screening (HCS) systems in our R&D facilities. This high-content platform is a plate-based confocal imaging system with multi-assay integration to assess both relative and quantitative values within comparative specimens in real-time.

The results of our HCS Analytics on the impact of time, temperature and processing of SkinTE under commercial protocol simulation conditions are illustrated below.

High Content Screening Analytics on the Impact of Time, Temperature and Processing of SkinTE™ under Commercial Protocol Simulation Conditions. (a.) Comparative percent relative viability (%RV) before and following standard processing of human full-thickness skin into SkinTE™. %RV of specimen at day 1: Pre-processed substrate (Skin: 89.67 ± SD 1.36); Post-processed product (SkinTE™: 97.11 ± SD 1.78). (b.) Daily %RV of SkinTE™ following post-processing production. Dotted lines indicate associated predictive 95% Confidence Interval (95% CI). Blue line indicates linear predictive correlative regression. Red line indicates semi-logarithmic predictive correlate for time impact on %RV. Correlation (R^2: 0.9431); (P value 0.0012). (c.) Delay impact on %RV of skin and SkinTE™. Assumptions considered represent 1.) Late arrival for CGTP manufacturing (D2-D10:2-10 days) of pre-processed incoming full-thickness skin substrate [provider to PolarityTE]; 2.) Late receipt for clinical deployment (D2-D10:2-10 days) of outgoing full-thickness SkinTE™ construct. (d.) High temperature impact on %RV of pre-processed skin and post-processed SkinTE™ after 24 hours of exposure. P-values: (*)0.05; (**)0.001. Study (n) = 120.

From the viability studies described above, we observed the following:

- A delay in transport of the harvested, pre-processed full-thickness skin to a PolarityTE facility for processing resulted in minimal changes in cell/tissue viability, and subsequently did not impact regenerative outcomes of skin;
- Our cGTP processing to manufacture SkinTE improved the relative cell/tissue viability of the tissue product compared to native skin, a common outcome in allograft skin processing;
- A delay in transport of SkinTE following processing back to the provider/patient resulted in minimal changes in cell/tissue viability, and subsequently did not meaningfully impact regenerative outcomes of skin; and
- SkinTE maintained higher levels of viability when compared to native skin when exposed to extreme temperature (37°C) during transport, which we believe resulted from the heightened metabolic rate and less oxygen diffusion of full-thickness skin compared to SkinTE.

Human Tissue Expression Profile: In order to assess a variety of cell/tissue expression profiles across genes related to proliferation, cell stress, apoptosis, necrosis and cellular potency, we conducted focused gene tests on the same tissues analyzed in the human tissue viability tests describe above.

The results of these human gene expression tests evaluating the impact of time, temperature and processing of SkinTE under commercial protocol simulation conditions are illustrated in the comparative heat maps below.

Comparative Heat Maps of Focused Human Gene Expression Arrays Evaluating the Impact of Time, Temperature and Processing of SkinTE under Commercial Protocol Simulation Conditions. (a.) Relative gene

expression (84 gene apoptosis array) across 10 patient samples under specific conditions related to the effect of: Full-thickness unprocessed skin vs. Manufactured SkinTE on Day 1, representing the day of arrival, processing and preparation for return to provider in a standard commercial operations setting. Comparison of apoptosis of full-thickness skin and SkinTE at day 5, representing the relative profile between both tissue systems if a delay in transport occurred Comparison of apoptosis profile of unprocessed full-thickness skin at day 1 vs. day 5, representing a delay in transport from the provider facility to the PolarityTE Tissue Processing Center Comparison of apoptosis profile between SkinTE at day 1 vs. day 5 representing a delay in transport of SkinTE from the PolarityTE Tissue Processing Center back to the provider for clinical deployment (b.) Relative gene expression (84 gene stem cell array) across the same 10 patient samples under the same specific conditions described above. No statistical significance was found across the replicates.

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From these expression profile studies, we observed that:

1. The cGTP methods used to create SkinTE from full-thickness significantly increases the relative viability while reducing pro-apoptosis and pro-necrosis pathways following process manufacturing. This is commonly seen in allograft skin processing as full-thickness skin is thinned to create STSG allograft.

2. Full-thickness native skin and the autologous-homologous SkinTE tissue product have similar apoptosis and stem cell profiles after 5 days of storage in +4^{O}C crystalloid, suggesting storage over a period of time does not significantly alter biophysical properties or regenerative tissue functional outcomes.

To date, preliminary results from the initial human clinical applications of SkinTE are correlative with the preclinical results previously observed.

OsteoTE

We are using our platform technology to develop OsteoTE, our autologous, homologous bone regeneration product. We are designing OsteoTE to utilize the patient's own bone to target applications for bone repair, reconstruction, replacement, supplementation, and regeneration, including in the long bone (hard, dense bones that provide structure, strength and mobility such as the femur or humerus), craniomaxillofacial, spine, dental, hand, and foot/ankle markets. As with skin, we believe existing treatments for the repair of bone with autologous grafts suffer from significant limitations that we can address with OsteoTE. Below are preliminary images of OsteoTE bone regeneration in a preclinical model of a cranial defect.

Comparative Imaging of OsteoTE in Critical Sized Cranial Defect Model System. (a.) Three-dimensional (3-D) micro computed tomography (micro-CT) native cranial bone displaying pre-defect left parietal and right parietal bones of *in vivo* model system at timepoint T^{PDN}. (b.) Gross image of surgically-created, complete, bi-parietal critical sized defects of both the left and right parietal bones within the *in vivo* model system at timepoint T^{0}. (c.) 3-D micro-CT of surgically-created, complete (full-thickness), bi-parietal critical sized defects of both the left and right parietal bones within the *in vivo* model system. Indicates the right parietal bone region with 8 mm diameter defect at timepoint T^{0} which was un-treated and maintained as the defect control throughout study. Indicates the left parietal bone region with 8 mm defect which was treated with OsteoTE and maintained as the defect-treated control throughout the study. (d.) 3-D micro-CT of surgically-created, complete, bi-parietal critical sized defects of both the left and right parietal bones within the *in vivo* model system at 4 weeks post-procedure and intervention (timepoint $T^{PPI-4WK}$). Indicates the un-treated right parietal bone region (defect control) at 4 weeks. Indicates the treated left parietal bone region (OsteoTE) at 4 weeks. (e.) Depicts the relative margins of the primary bi-parietal defects (dotted

circles) at time point T^0; ROI (broken line box) indicates zoomed comparison of 4 weeks post-treatment defects of 3-D micro-CT and correlative 3-D thermal spectrum colored surface plot indicating relative surface depth and volumetric contour. Abbreviations: Pre-defect Native Timepoint (T^{PDN}): timepoint at which native skull was imaged prior to creation of defect; Defect Native Timepoint (T^0): timepoint at which complete (full-thickness) 8 mm critically sized defects were created in parietal skull regions; Post-procedure and intervention at 4 weeks timepoint ($T^{PPI-4WK}$): timepoint at which 4 weeks have passed since the defects were created +/- treated with intervention.

Based on our internal analysis of the Truven Health Analytics Market Scan Research Database, there were approximately 1.9 million addressable orthopedic cases in the United States, including patients suffering from pathology of the femur, radius, ulna, tibia, fibula, and/or humerus. (Copyright © 2017 Truven Health Analytics LLC, an IBM Company, All Rights Reserved). According to Markets and Markets, the global spinal fusion and implant market is expected to reach $17.3 billion by 2021, the global craniomaxillofacial implants market is expected to reach $2.5 billion by 2021, and the dental market is expected to reach $35.4 billion by 2021. We are targeting FDA registration of OsteoTE as a 361 HCT/P by the end of 2018, with commercial launch to take place soon thereafter into each of the markets listed above, in addition to hand and foot/ankle surgery.

CartTE

With our CartTE product candidate, we are aiming to deliver on a long-imagined product—one that is able to tackle the highly prevalent and debilitating process of osteoarthritis in an attempt to delay or prevent the need for more invasive procedures, such as prosthetic joint replacement and reconstruction. Furthermore, we believe the autologous cartilage construct delivered with CartTE can be utilized in a variety of other applications, including facial reconstruction, facial aesthetics, hand reconstruction, as well as wrist reconstruction.

Osteoarthritis of the hip or knee is estimated to affect 9% of the US population greater than 30 years of age, with costs of treatment totaling $28.6 billion in 2013, according to a review by Grande et al. Market projections by Krutz et al. in 2007 predict that the demand for primary (first-time) total hip and knee replacements will grow to 572,000 and 3.48 million procedures per year by 2030 in the US, respectively. In contrast to the staggering number of patients suffering from osteoarthritis and those pursuing joint replacement, the cartilage repair and regeneration market is only estimated to reach $6.7 billion by 2025, according to a Cartilage Repair/Regeneration Market Analysis report by Grand View Research. This lopsided market, in which cartilage repair and regeneration only captures a small fraction of the patient population that could benefit from articular cartilage regeneration, demonstrates a significant opportunity for our autologous cartilage regeneration product, CartTE, to displace the current trends and standards of care, delivering the regenerative medicine product that has remained elusive until now.

Additional Core "TE" Product Candidates

In addition, we intend to continue developing:

- AdipoTE™ to optimize the delivery of autologous fat beyond the capabilities of current fat transfer techniques utilized in procedures on, among others, the breast, buttocks, and face;
- AngioTE™ to address vascular regeneration including microscopic capillary networks all the way up to great vessel replacement;
- NeuralTE™ for peripheral nerve injuries of the extremities, as well as for patients with neuromas and/or chronic compression due to joint replacements, migraines, craniofacial injuries, carpal tunnel syndrome, and those who have undergone hernia or abdominal-based procedures;
- UroTE™ targeting the delivery of autologous urogenital epithelium and submucosa across a spectrum of diseases and processes, including urethral strictures, urethral creation, bladder reconstruction, and ureter reconstruction;
- LiverTE™ to address numerous causes of liver failure, including NASH, fibrosis/cirrhosis, surgical resection of the liver; and
- BowelTE™ to deliver an optimized autologous construct to aid in the regeneration of bowel tissue.

We intend to pursue the marketing of each of the product candidates described above via the 361 HCT/P regulatory pathway. If we successfully register and list a product with the FDA using the 361 HCT/P pathway, we plan to deploy a commercialization strategy that is similar to that for SkinTE.

Manufacturing

We do not separately engineer individual manufacturing processes around each individual tissue product. Rather, we design, develop and adapt our core "TE" products and product candidates to a common manufacturing process which we believe we can utilize across our product pipeline in order to establish fast, effective and cost-efficient systems,

enhance our production capacity and expansion strategy, and at the same time potentially reduce our cost of goods sold.

We have designed and developed manufacturing processes and quality systems that allow us to receive a specimen, qualify the incoming tissue, and process and manufacture the cell/tissue product proficiently and perform outgoing quality control and quality assurance work prior to expedited return shipping—often during the same day in which a sample is received.

We believe that our ultra-clean dual-barrier system, which involves clean room structures containing fully-isolated and air-locked internal ISO 4 containment systems, allows us to move specimen and product in an efficient manner, while maintaining protective quality systems.

We have designed our scalable manufacturing process to allow us to be flexible and agile in real-time, while allowing us to shift resources on a daily basis to meet acute production needs as well as respond to larger factors including market forces, multi-facility buildouts, and changes in rapidly evolving technology platforms. In designing our products and systems, we focused both on being able to meet market demand and to scale manufacturing. We believe that we have designed our manufacturing clean dual-barrier system to be efficient in flow processes, column production, and in repeated scalability in local, national and international arenas. In compliance with ISO standards and cGTP/cGMP, our repeating clean manufacturing column systems and fully-isolated and air-locked internal ISO 4 containment units are engineered and designed with scalable production in mind. We currently are expanding our manufacturing to have two separate product manufacturing facilities in the United States, which together comprise over 200,000 ft^2, and which we are continuing to build out for our commercially available SkinTE tissue product, and as we plan for the expected registration, listing, and commercial launch of our OsteoTE tissue product.

Suppliers

As part of our strategy of ensuring timely delivery of our products, we have avoided relying on any third-party supplier as a sole source vendor for any element of our production process. We aim to maintain multiple back-up suppliers for every item in the chain, with validated lead times allowing us to trigger alternative options at the first sign of constraint.

Reimbursement

We understand that coverage and reimbursement by third-party payers is critical for product adoption. As a result, we are focusing significant resources on understanding the coverage and reimbursement landscape for the application of SkinTE. Payment to us for SkinTE, including associated purchasing contracts, is derived from transactions between PolarityTE and those healthcare facilities, medical practices, and physicians utilizing the product for their patients, whereas payer reimbursement generally would be requested and made by the providers and medical practices. We believe our SkinTE customers may be able to use existing billing codes established in the Current Procedural Terminology (“CPT®”), Healthcare Common Procedure Coding System (“HCPCS”), or International Classification of Diseases, Tenth Revision, Procedural Coding System (“ICD-10-PCS”) code sets, to our products and related services on claims for reimbursement submitted to third-party payers. Because we only recently began selling SkinTE, our first commercial-stage product, the reimbursement landscape for SkinTE is uncertain at this time and we cannot guarantee that our customers will be able to successfully obtain adequate coverage and reimbursement, or whether they can rely on existing billing codes to report SkinTE and/or the related services. For more information on risks associated with coverage and reimbursement, please see “Risk Factors” including but not limited to the information under the heading “Our revenues from our regenerative medicine business will depend upon adequate reimbursement from public and private insurers and health systems.”

Government Regulation

Government authorities and/or laws and regulations in the United States and other countries regulate the manufacturing, approval, labeling, packaging, storage, record-keeping, and promotion of products such as those we have developed and are developing. Any product we are developing must comply with the standards required for the product category under which the product is classified by such government authorities and/or laws.

FDA Regulation of Tissue-Based Products

The FDA has specific regulations governing human cells, tissues and cellular and tissue-based products, or HCT/Ps. An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into a human patient. In the United States, HCT/Ps are subject to varying degrees of regulation by the FDA, depending on if they fall solely within the scope of Section 361 of the Public Health Service Act (the "PHS Act") (42 U.S.C. § 264) or if they are regulated as drugs, devices, and/or biological products under Section 351 of the PHS Act (42 U.S.C. § 262) and/or the FD&C Act.

If an HCT/P meets the criteria for regulation solely under Section 361 of the Public Health Service Act (so-called "361 HCT/Ps"), no premarket FDA review for safety and effectiveness under a drug, device, or biological product marketing application is required. However, the processor of the tissue is required to register and list its products with the FDA, comply with regulations regarding labeling, record keeping, donor eligibility and screening and testing, process the tissue in accordance with established current Good Tissue Practices (cGTP), and investigate and, in certain circumstances, report adverse events or deviations.

To be a 361 HCT/P, a product generally must meet all four of the following criteria:

1) It must be minimally manipulated;
2) It must be intended for homologous use;
3) Its manufacture must not involve combination with another article, except for water, crystalloids or a sterilizing, preserving or storage agent, provided the addition of such article does not raise new clinical safety concerns; and
4) It must not have a systemic effect and must not be dependent upon the metabolic activity of living cells for its primary function (unless the product is intended for reproductive use, autologous use, or use in a first- or second-degree blood relative).

We believe that SkinTE qualifies as a 361 HCT/P, and believe that our core "TE" products in development (e.g., OsteoTE) will qualify as 361 HCT/Ps. Other products we are developing are being evaluated with respect to regulatory classification, and we will prepare for any pathway of manufacturing or regulation that is required.

All establishments that manufacture 361 HCT/Ps must register and list their HCT/Ps with the FDA's Center for Biologics Evaluation and Research ("CBER") within five days after commencing operations. In addition, establishments are required to update their registration annually in December or within 30 days of certain changes, and submit changes in HCT/P listing at the time of or within six months of such change. Establishments that manufacture 361 HCT/Ps will know that they are registered in compliance with 21 C.F.R. § 1271.10(a) when they receive a validated form with the registration number ("FEI#") after submitting the Form FDA 3356 (registration form). Current Good Tissue Practice ("cGTP") requirements govern, as may be applicable, the facilities, controls, and methods used in the manufacture of HCT/Ps, including without limitation, recovery, donor screening, donor testing, processing, storage, labeling, packaging, and distribution of 361 HCT/Ps. FDA inspection and enforcement with respect to establishments described in 21 C.F.R. § 1271 includes inspections conducted, as deemed necessary, to determine compliance with the applicable provisions and may include, but is not limited to, an assessment of the establishment's facilities, equipment, finished and unfinished materials, containers, processes, HCT/Ps, procedures, labeling, records, files, papers, and controls required to be maintained under 21 C.F.R. § 1271. Such inspections can occur at any time with or without written notice at such frequency as is determined by the FDA in its sole discretion.

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If we fail to comply with the FDA regulations and laws applicable to our operation or tissue products, the FDA could take enforcement action, including, without limitation, pursuing any of the following sanctions, among others:

- Untitled letters, warning letters, fines, injunctions, product seizures, and civil penalties;
- Orders for product retention, recall, and/or destruction;
- Operating restrictions, partial suspension or total shutdown of operations;
- Refusing any requests for product clearance or approval;
- Withdrawing or suspending any applications for approval or approvals already granted; and/or
- Criminal prosecution.

For more information on this regulatory risk, please see the discussion below, “Risk Factors,” including but not limited to the information under the heading, “Risks Related to Registration and/or Regulatory Approval of Our Product Candidates and Other Government Regulations.”

Fraud, Abuse and False Claims

We are directly and indirectly subject to various federal and state laws governing relationships with healthcare providers and other potential referral sources for our products pertaining to healthcare fraud and abuse, including anti-kickback, false claims, and similar laws. In addition, federal and state laws are also sometimes open to interpretation. The Company could potentially face legal risks if our interpretation differs from those of enforcement authorities. Further, from time to time the Company may find itself at a competitive disadvantage if the Company’s interpretation differs from that of its competitors.

In particular, the federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration (in cash or in kind), directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of, a good or service for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. In implementing the statute, the Office of Inspector General of the U.S. Department of Health and Human Services (“OIG”) has issued a series of regulations, known as the “safe harbors.” These safe harbors set forth provisions that, if all their applicable requirements are met, except certain remuneration and remunerative arrangements from violating the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable element of a safe harbor may result in increased scrutiny by Government enforcement authorities, such as the OIG. Many states have laws similar to the federal law.

Also, the federal civil False Claims Act ("FCA") imposes civil liability on any person or entity that submits, or causes the submission of, a false or fraudulent claim to the U.S. government. Damages under the FCA can be significant, and consist of the imposition of fines and penalties. The FCA also allows a private individual or entity (i.e., a whistleblower) with knowledge of past or present fraud against the federal government to sue on behalf of the government and to be paid a portion of the government's recovery, which can include both civil penalties and up to three times the amount of the government's damages (usually the amount reimbursed by federal healthcare programs). The DOJ takes the position that the marketing and promotional practices of life sciences product manufacturers, including the off-label promotion of products, the provision of inaccurate or misleading reimbursement guidance, or the payment of prohibited kickbacks, may cause the submission of improper claims to federal and state healthcare entitlement programs such as Medicare and Medicaid by health care providers that use the manufacturer's products, which results in a violation of the FCA. In certain cases, manufacturers have entered into criminal and civil settlements with the federal government under which they entered into plea agreements, paid substantial monetary amounts and entered into corporate integrity agreements ("CIAs") that require, among other things, substantial government oversight, as well as reporting and remedial actions going forward

If we fail to comply with these laws, we could be subject to enforcement actions, including but not limited to:

- Multi-year investigations by federal and state governments;
- Criminal and civil fines and penalties;
- Obligations under settlement agreements, such as CIAs or Deferred Prosecution Agreements; and/or
- Exclusion from participation in federal and state healthcare programs.

For more information on this fraud, abuse, and false claim risk, please see the discussion below, "Risk Factors," including but not limited to the information under the heading, "We are subject to numerous federal and state healthcare laws and regulations, and a failure to comply with such laws and regulations could have an adverse effect on our business and our ability to compete in the marketplace."

Environmental Matters

Our tissue preservation activities generate some chemical and biomedical wastes, consisting primarily of diluted alcohols and acids, and human and animal pathological and biological wastes, including human and animal tissue and body fluids removed during laboratory procedures. The chemical and biomedical wastes generated by our tissue processing operations are placed in appropriately constructed and labeled containers and are segregated from other wastes. We contract with third parties for transport, treatment, and disposal of waste. We strive to remain compliant with applicable laws and regulations promulgated by the Resource Conservation and Recovery Act, the U.S. Environmental Protection Agency and similar state agencies.

Reimbursement

In the United States, demand for access to any medical product will depend in large part on both the availability and the amount of reimbursement from third-party payers, including government healthcare programs (including Medicare and Medicaid), and commercial healthcare insurers, including managed care organizations and other private health plans. Third-party payers have complex rules and requirements for coverage and reimbursement of healthcare products and services. Even the applications to such third-party payers to be eligible for reimbursement for product or services are complex and can be lengthy and time consuming. For new technologies coming to market, these payers are increasingly examining the clinical evidence supporting medical necessity and cost effectiveness decisions in addition to safety and efficacy, which can result in barriers to early coverage reimbursement, or denial of coverage and reimbursement altogether. Accordingly, significant uncertainty exists as to the availability of coverage and reimbursement status for new medical products. If third-party payer reimbursement is unavailable to our customer hospitals, physicians, and providers, our sales may be limited and we may not be able to realize an appropriate return on our investment in research and product development.

Payers often set payment rates depending on the site of service and many use the Medicare program as a benchmark for their own payment methodologies. In the hospital inpatient setting, Medicare payment generally is set at pre-determined rates for all products and services provided during a particular patient stay, and is based on such factors as the patient diagnosis, procedures performed, patient age, and complications. In the physician office or clinic setting, Medicare payment generally is based on a fee schedule, with payment rates set for each procedure performed and product used, although the schedule may in some instance bundle the product into the payment for the procedure. In some outpatient settings, such as in the case of the hospital outpatient clinic setting, Medicare payment rates generally are premised on classifications of services that have similar clinical characteristics and similar costs.

In order to better track utilization, we have applied for a product-specific billing code for SkinTE. Our application was submitted to the Centers for Medicare and Medicaid Services (“CMS”), the agency that administers the Medicare program and establishes new codes under the Healthcare Common Procedure Coding System (“HCPCS”) code set. If our application for a new HCPCS code is successful, we expect that the code could go into effect as early as the 2019 calendar year. In the interim, we believe SkinTE used in the office or clinic setting may be reported using an existing “not otherwise specified” HCPCS code.

Reimbursement policies depend in part on legislation designed to regulate the healthcare industry and federal and state governments continue to propose and pass new healthcare legislation and government agencies revise or change their regulations and policies from time to time. We cannot predict whether or how such reform measures and policy changes would affect reimbursement rates and demand for our products.

Patient Privacy

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, including the final omnibus rule published on January 25, 2013, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. Since we do not submit claims electronically to payers, we are not a covered entity under HIPAA; however, at present, it is unclear if we would be considered a business associate subject to HIPAA based on our business activities and service offerings. Because our products use autologous tissue sources that are tracked and reapplied to the same individual patient from which the tissue was harvested, our business maintains substantial amounts of patient identifiable health information. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties.

Transparency Laws

The Patient Protection and Affordable Care Act, through the enactment of the Physician Payments Sunshine Act, imposes, among other things, new annual reporting requirements for covered manufacturers for certain payments and other transfers of value provided to physicians and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members. We do not believe that we are a covered manufacturer under the Sunshine Act because our products are neither regulated as pharmaceuticals, biologics, nor medical devices by FDA, and 361 HCT/P autologous tissue sources are not expressly addressed by this law.

Intellectual Property

We do not own any granted patents. We have three pending U.S. non-provisional patent applications relating to methods for development and use of minimally polarized function cell micro-aggregate units in tissue applications using LGR4, LGR5 and LGR6 expressing epithelial stem cells. Each of these applications claims priority to a U.S. provisional application filed on December 2, 2014. We have one PCT International Patent Application and national phase applications have been entered in OAIP, ARIPO, Australia, Brazil, Canada, China, Colombia, Costa Rica,

Eurasia, Europe, Great Britain, Israel, India, Indonesia, Japan, South Korea, Mexico, Malaysia, New Zealand, Philippines, Singapore, South Africa, Thailand, United Arab Emirates, Ukraine, Vietnam.

In striving to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business, we currently rely heavily on trade secrets relating to our proprietary technology platform and on know-how. We enter into confidentiality 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.

Our objective is to continue to expand our portfolio of patents and patent applications, in conjunction with our trade secrets and know-how, in order to further protect our regenerative medicine platform and derivative technologies, as well as the manufacturing and deployment processes of those technologies.

Competition

The wound care industry, including the regenerative medicine industry, is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on intellectual property. To our knowledge, SkinTE is the only fully autologous, homologous skin regeneration product available for the treatment of wounds and functional losses of the skin of human patients. We face competition from providers of FTSGs and STSGs, as well as other companies developing and selling skin substitutes and other regenerative medicine products. We also face substantial competition from academic research institutions and governmental agencies and public and private research institutions.

We are aware of several companies focused on the wound market, including Integra LifeSciences, Wright Medical Group, MiMedx, Osiris, Organogenesis, Allosource, MTF and Vericel. Any advances in regenerative medicine by a competitor may be used to develop therapies competing against SkinTE or one of our product candidates.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours (if required), which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, convenience, price, and the availability of reimbursement from government and other third-party payers.

Property and Contact Information

Our principal executive offices are located at 615 Arapeen Drive, Salt Lake City, UT 84108 and our telephone number is 1-800-560-3983. Our web site address is www.polarityte.com.

On December 1, 2016, we entered into a lease with Paradigm Resources, L.C. pursuant to which we lease approximately 11,000 square feet of office and lab space in Salt Lake City, Utah at a monthly lease rate of $24,044. The office and lab space is located at 615 Arapeen Drive, Salt Lake City, Utah 84108, and the lease commenced on January 1, 2017 and will terminate on March 31, 2018.

On December 27, 2017, we entered into a commercial lease agreement with Adcomp LLC, a Utah limited liability company, pursuant to which we leased approximately 178,528 rentable square feet of warehouse, manufacturing, office, and lab space in Salt Lake City, Utah from the landlord. The initial term of the lease is five years and it expires on November 30, 2022. We have a one-time option to renew for an additional five years. The initial base rent under this lease is $98,190 per month ($0.55 per sq. ft.) for the first year of the initial lease term and increases 3.0% per annum thereafter.

We expect that we will require additional facilities to continue our research and development and our commercialization efforts, and are actively seeking suitable locations.

Employees

We had 33 full-time employees as of October 31, 2017.

Legal Proceedings

On February 26, 2015, a complaint for patent infringement was filed in the United States District Court for the Eastern District of Texas by Richard Baker, an individual residing in Australia, against Microsoft, Nintendo, Majesco Entertainment Company ("Majesco DE"), and a number of other game publisher defendants. The complaint alleged that the Zumba Fitness Kinect game infringed plaintiff's patents in motion tracking technology. The plaintiff is representing himself pro se in the litigation and is seeking monetary damages in the amount of $1.3 million. The case was subsequently transferred to the Western District of Washington. On June 16, 2017, final judgment was entered in favor of the defendants. The plaintiff has appealed that decision to the Court of Appeals for the Federal Circuit. The appeal is currently pending. On June 23, 2017, as part of a purchase agreement, liabilities and claims relating to this litigation were transferred to Zift Interactive LLC.

Corporate History

On December 1, 2016, Majesco Acquisition Corp., a Nevada corporation and wholly-owned subsidiary of Majesco Entertainment Company, a Delaware corporation ("Majesco DE") entered into an Agreement and Plan of Reorganization with PolarityTE, Inc., a Nevada corporation ("PolarityTE NV") and Dr. Denver Lough, the owner of 100% of the issued and outstanding shares of capital stock of PolarityTE NV. The asset acquisition was subject to shareholder approval, which was received on March 10, 2017 and the transaction closed on April 7, 2017. In January 2017, Majesco DE changed its name to "PolarityTE, Inc." ("PolarityTE"). Majesco Acquisition Corp. was then merged with PolarityTE NV, which remains a subsidiary of PolarityTE. Majesco Acquisition Corp. II, formed in November 2016 under Majesco Entertainment Company, remains a wholly-owned subsidiary of PolarityTE.

Previously, Majesco Holdings Inc. (formerly ConnectivCorp) was incorporated in 2004 under the laws of the State of Delaware. As a result of a merger, Majesco Sales Inc. became a wholly-owned subsidiary and the sole operating business of Majesco Holdings Inc., which changed its name to Majesco Entertainment Company (Majesco DE, as identified above). Majesco DE developed and published a wide range of video games on digital networks through its Midnight City label, including Nintendo's DS, 3DS, Wii and WiiU, Sony's PlayStation 3 and 4, or PS3 and PS4, Microsoft's Xbox 360 and Xbox One and the personal computer, or PC. On May 2, 2017, Majesco Entertainment Company, a Nevada corporation, or Majesco NV Sub, and wholly owned subsidiary of PolarityTE, was formed, into which all of the assets and liabilities of this gaming business were placed.

On June 23, 2017, PolarityTE sold the Majesco NV Sub to Zift Interactive LLC, a Nevada limited liability company, pursuant to a purchase agreement. Pursuant to the terms of the agreement, PolarityTE sold 100% of the issued and outstanding shares of common stock of Majesco NV Sub to Zift, including all of the right, title and interest in and to Majesco NV Sub's business of developing, publishing and distributing video game products through mobile and online digital downloading.

Available Information

We file annual, quarterly, and current reports, as well as proxy statements and other information with the Securities and Exchange Commission, available to the public free of charge over the Internet at our website at http://www.polarityte.com In addition, any materials we file with the SEC are available on the SEC's website as www.SEC.GOV free of charge.

Item 1A. Risk Factors.

Our business and operations are subject to a number of risks and uncertainties as described below. However, the risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we may currently deem immaterial, may become important factors that could harm our business, financial condition or results of operations. If any of the following risks actually occur, our financial condition or results of operations could suffer.

Risks Related to Our Business

If the clinical development and commercialization of our lead product candidate, SkinTE, is not successful, our ability to finance our operations may be adversely affected.

Our near-term prospects depend upon our ability to effectively market our lead product candidate, SkinTE, and to demonstrate its safety and effectiveness in humans, as well as its superiority over existing therapies and standards of care. Our ability to finance our company and to generate revenues will depend in part on our ability to obtain favorable results in the planned clinical evaluations of SkinTE and to successfully develop and commercialize SkinTE.

SkinTE could be unsuccessful if it:

- does not demonstrate acceptable safety and efficacy in humans, or otherwise does not meet applicable regulatory standards;

does not offer sufficient, clinically meaningful therapeutic or other improvements over existing or future therapies used to treat burns or other defects of skin tissues/integument for which it is being tested and evaluated;

is not capable of being produced in commercial quantities at acceptable costs or acceptable timelines; or

is not accepted as safe, efficacious, cost-effective, less costly and preferable to current therapies in the medical community and by third-party payers.

If we are not successful in developing and commercializing SkinTE or are significantly delayed in doing so, our financial condition and future prospects may be adversely affected and we may experience difficulties in raising the substantial additional capital required to fund our business.

We are an early stage company. Our limited operating history makes it difficult to evaluate our current business and future prospects, and our profitability in the future is uncertain.

Our limited operating history hinders an evaluation of our prospects, which should be considered in light of the risks, expenses and difficulties frequently encountered in the establishment of a business in a new industry, characterized by a number of market entrants and intense competition, and in the shift from development to commercialization of new product candidates based on innovative technologies.

We became a publicly traded company through our merger with Majesco Entertainment Company, and we could be liable for unanticipated claims or liabilities as a result thereof.

On December 1, 2016, we entered into an Agreement and Plan of Reorganization with Majesco Acquisition Corp., our wholly-owned subsidiary, PolarityTE NV and Dr. Denver Lough, the owner of 100% of the issued and outstanding shares of capital stock of PolarityTE NV pursuant to which, on April 5, 2017, we acquired the intellectual property rights and other assets of PolarityTE NV through the merger of Majesco Acquisition Corp. with and into PolarityTE NV, with PolarityTE NV surviving as our wholly-owned subsidiary.

We face substantial risks of known and unknown liabilities associated with Majesco Entertainment Company, including absence of accurate or adequate public information concerning the former public company; undisclosed liabilities; improper accounting; claims or litigation from former officers, directors, employees or stockholders; contractual obligations; and regulatory requirements. Although management performed due diligence on us, there can be no assurance that such risks will not occur. The occurrence of any such risk could materially adversely affect our financial condition.

Additionally, we are defendants in a patent infringement lawsuit filed against Majesco Entertainment Company. On February 26, 2015, a complaint for patent infringement was filed in the United States District Court for the Eastern District of Texas by Richard Baker, an individual residing in Australia, against Microsoft, Nintendo, us and a number of other game publisher defendants. The complaint alleged that the Zumba Fitness Kinect game infringed plaintiff's patents in motion tracking technology and the plaintiff sought damages in the amount of $1.3 million. In August 2015, the defendants jointly moved to transfer the case to the Western District of Washington. On May 17, 2016, the Washington Court issued a scheduling order that provided defendants leave to jointly file an early motion for summary judgement in June 2016. On June 17, 2016, the defendants jointly filed a motion for summary judgment that

stated that none of the defendants, including Majesco Entertainment Company, infringed upon the asserted patent. On July 9, 2016, Mr. Baker opposed the motion. On January 3, 2017, the Court granted the defendants' motion for summary judgment and the case was dismissed. On June 16, 2017, final judgment was entered in favor of the defendants. On July 5, 2017, Baker filed an appeal of the District Court's Final Order of Judgment in favor of the Defendants' to the Court of Appeals for the Federal Circuit. The appeal is currently pending. An adverse determination of the appeal could result in significant liability against us, although on June 23, 2017, as part of a purchase agreement, we believe that liabilities and claims relating to this litigation were transferred to Zift Interactive LLC.

We have a history of operating losses and may never achieve or sustain profitability.

We have to date incurred, and may continue to incur significant operating losses over the next several years. We have incurred significant net losses in each year since our inceptions, and have a net loss of $130.8 million for the year ended October 31, 2017. Our ability to achieve profitable operations in the future will depend in large part upon the successful development and commercialization of our product candidates and technologies. Factors impacting our ability to successfully develop and commercialize our product candidates include:

- approvals by and/or registrations with the FDA and other US and foreign government agencies;
- our ability to educate and train physicians and hospitals on the benefits of our product candidates;
- the rate at which providers adopt our technology and product candidates;
- our ability to scale up our global commercialization, including our selling and manufacturing activities;
- our ability to complete the development of our product candidates in a timely manner;
- our ability to obtain adequate reimbursement from third parties for our products and product candidates; and
- other activities generally necessary in order to introduce and bring new products and medical technologies to market.

The likelihood of the long-term success of our company must be considered in light of the expenses, difficulties and delays frequently encountered in the development and commercialization of new and innovative medical techniques and technologies, unknown and uncertain regulatory hurdles for a new and novel technology or technique, competitive factors and competition, as well as the uncertain nature of new business development and ongoing capital requirements.

We may have inadequate resources to complete the development and commercialization of our product candidates or to continue our development programs.

We are a development stage company, and thus we expect to continue to spend a significant amount of cash on the continued research and development of our product candidates. Until we are able to successfully commercialize our product candidates and achieve significant revenue, if any, we will be required to raise additional capital to fund our ongoing operations. We may not be able to raise capital on acceptable terms, or at all.

The cost and timing of completion of our preclinical and clinical development programs is uncertain.

We expect that a large percentage of our future research and development expenses will be incurred in support of current and future preclinical and clinical development programs. These expenditures are subject to numerous uncertainties in timing and cost of completion. We evaluate our objectives in preclinical models based upon our own development goals, but such evaluation may differ from requirements of regulatory authorities. We may conduct early stage clinical trials, which may differ for each of our targeted markets or markets we may target in the future (i.e., presently, skin, bone, muscle, cartilage, fat, blood vessels and nerves). As we obtain results from investigations, preclinical studies, and/or clinical trials, we may elect to discontinue or delay further evaluations for certain product candidates or programs in order to focus resources on more promising product candidates or programs. Completion of clinical trials may take several years and the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate. The cost of clinical trials is uncertain and may vary significantly over the life of a product or development project as a result of unanticipated differences, regulatory requirements, or other obligations, or challenges arising during clinical development.

Our product development programs are based on novel technologies. As result, our product candidates are inherently risky.

We cannot guarantee that the results we see in clinical applications will be comparable to the preclinical results we have observed in animals. We also cannot at this stage be certain of the safety of our platform technology in humans.

We are subject to the risks of failure inherent in the development of product candidates based on new technologies. The novel nature of our products creates significant challenges in regard to product development and optimization, manufacturing, government regulation, third-party reimbursement and market acceptance. For example, if regulatory agencies have limited experience or concerns in approving cellular and tissue-based therapies for commercialization, the development and commercialization pathway for our therapies may be subject to increased uncertainty, as compared to the pathway for new conventional drugs.

Further, when manufacturing autologous cell and tissue-based therapies, the number and the composition of the cell population varies from patient to patient, in part due to the age of the patient, since the therapy is dependent on patient-specific physiology. Such variability in the number and composition of these cells could adversely affect our ability to manufacture autologous cell and tissue-based therapies in a cost-effective manner and meet acceptable product release specifications for use in a clinical trial or, if approved and/or registered, for commercial sale. As a consequence, the development and regulatory approval and/or registration process for autologous cell and tissue-based product candidates could be delayed or may never be completed.

Our product candidates represent new classes of therapy that the marketplace may not understand or accept. Furthermore, the success of our product candidates is dependent on wider acceptance by the medical community.

The broader market may not understand or accept our product candidates. Our product candidates represent new treatments or therapies and compete with a number of more conventional products and therapies manufactured and marketed by others. The new nature of our product candidates creates significant challenges in regards to product development and optimization, manufacturing, government regulation, and third-party reimbursement.

As a result, the development pathway for our product candidates and the commercialization of our potential products may be subject to increased scrutiny, as compared to the pathway(s) for more conventional products.

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

- The clinical safety and effectiveness of our products and their perceived advantage over alternative treatment methods;
- Our ability to convince healthcare providers that the use of our products in a particular procedure is more beneficial than the standard of care or other available methods;
- Our ability to explain clearly and educate others on the autologous use of patient-specific human cells and tissue-based products, and to avoid potential confusion with and differentiate ourselves from the ethical controversies associated with human fetal tissue and engineered human tissue;
- Adverse reactions involving our products or the products or product candidates of others that are cell- or tissue-based;

Our ability to supply a sufficient amount of our product to meet regular and repeated demand in order to develop a core group of medical professionals familiar with and committed to the use of our products; and

The cost of our products and the reimbursement policies of government and other third-party payers, including the amounts of reimbursement made for our products and the conditions for such reimbursement.

If patients or the medical community do not accept our potential products as safe and effective for any of the foregoing reasons, or for any other reason, it could affect our sales, having a material adverse effect on our business, financial condition and results of operations.

Our revenues from our regenerative medicine business will depend upon adequate reimbursement from public and private insurers and health systems.

Our success will depend on the extent to which reimbursement for the costs of our treatments will be available from third-party payers, such as public and private insurers and health systems, as well as the amounts that they will agree to reimburse. Government and other third-party payers attempt to contain healthcare costs by limiting both coverage and the level of reimbursement, and the amount of reimbursement of new treatments. Therefore, significant uncertainty usually exists as to the reimbursement status of new healthcare treatments. If we are not successful in obtaining adequate reimbursement for our treatments from these third-party payers, the market's acceptance of our treatments could be adversely affected. Inadequate reimbursement levels also likely would create downward price pressure on our treatments. Even if we succeed in obtaining widespread reimbursement for our treatments at adequate treatment amounts, future changes in reimbursement policies could have a negative impact on our business, financial condition and results of operations.

Commercial third-party payers and government payers are increasingly attempting to contain healthcare costs by demanding price discounts, including by limiting coverage on which products they will pay for and the amounts that they will pay for new products, and by creating conditions to reimbursement, such as coverage eligibility requirements based upon clinical evidence development involving research studies and the collection of physician decision impact and patient outcomes data. Because of these cost-containment trends, commercial third-party payers and government payers that currently provide or in the future may provide reimbursement for one or more of our product candidates may reduce, suspend, revoke, or discontinue payments or coverage at any time, including those payers that designate one or more of our product candidates as experimental and investigational. Payers may also create conditions to coverage or contract with third-party vendors to manage laboratory benefit coverage, in both cases creating burdens for ordering physicians and patients that may make our product candidates more difficult to sell. The percentage of submitted claims that are ultimately paid, the length of time to receive payment on claims, and the average reimbursement of those paid claims, is likely to vary from period to period. Finally, payers may demand discounts or offer reimbursement that minimizes our ability to sell our products profitably, or simply choose to not cover or reimburse our products at all.

As a result, there is significant uncertainty surrounding whether the use of products that incorporate new technology, such as our product candidates, will be eligible for coverage by commercial third-party payers and government payers or, if eligible for coverage, what the reimbursement rates will be for these product candidates. The fact that a product has been approved for reimbursement in the past, or has received FDA approval, for any particular indication or in any particular jurisdiction, does not guarantee that such product will remain approved for reimbursement or that similar or additional products will be approved in the future. Reimbursement of our existing and future products by commercial third-party payers and government payers may depend on a number of factors, including a payer's determination that our existing and future products are:

- not experimental or investigational;
- medically reasonable and necessary;
- appropriate for the specific patient;
- cost effective;
- supported by peer-reviewed publications;
- included in clinical practice guidelines and pathways; and
- supported by clinical utility and health economic studies demonstrating improved outcomes and cost effectiveness.

Market acceptance, sales of products based upon our platform technology, and our profitability may depend on reimbursement policies and healthcare reform measures. Several entities conduct technology assessments and provide the results of their assessments for informational purposes to other parties. These assessments may be used by third-party payers and healthcare providers as grounds to deny coverage for a product. The levels at which government authorities and third-party payers, such as private health insurers and health maintenance organizations, may reimburse the price patients pay for such products could affect whether we are able to commercialize our product candidates. Our product candidates may receive negative assessments that may impact our ability to receive reimbursement of the test. Since each payer makes its own decision as to whether to establish a policy to reimburse our test, seeking these approvals may be a time-consuming and costly process. We cannot be sure that reimbursement in the United States or elsewhere will be available for any of our product candidates in the future. If reimbursement is not available or is limited, we may not be able to commercialize our product candidates.

The United States and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare. We expect that there will continue to be federal and state proposals to implement governmental controls or impose healthcare requirements. In addition, the Medicare program and increasing emphasis on managed or accountable care in the United States will continue to put pressure on product utilization and pricing. Utilization and cost control initiatives could decrease the volume of orders and payment that we would receive for any products in the future, which would limit our revenue and profitability. If we are unable to obtain reimbursement approval from commercial third-party payers and Medicare and Medicaid programs for our product candidates, or if the amount reimbursed is inadequate, our ability to generate revenues could be limited.

We are subject to numerous federal and state healthcare laws regulations, and a failure to comply with such laws and regulations could have an adverse effect on our business and our ability to compete in the marketplace.

There are numerous laws and regulations that govern the means by which companies in the healthcare industry may market their treatments to healthcare professionals and may compete by discounting the prices of their treatments, including for example, the federal Anti-Kickback Statute, the federal False Claims Act ("FCA"), the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and state law equivalents to these federal laws that are meant to protect against fraud and abuse and analogous laws in foreign countries. Violations of these laws are punishable by criminal and civil sanctions, including, but not limited to, in some instances civil and criminal penalties, damages, fines, and exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid. In addition, federal and state laws are also sometimes open to interpretation. Accordingly, we could potentially face legal risks if our interpretation differs from those of enforcement authorities. Further, from time to time we may find ourselves at a competitive disadvantage if our interpretation differs from that of our competitors.

Specifically, anti-kickback laws and regulations prohibit any knowing and willful offer, payment, solicitation or receipt of any form of remuneration (direct or indirect, in case or in kind) in return for the referral, use, ordering, or recommending of the use of a product or service for which payment may be made by Medicare, Medicaid or other Government-sponsored healthcare programs. We have entered into consulting agreements, research agreements and product development agreements with physicians, including some who may order our products or make decisions to use them. In addition, some of these physicians own our stock, which they purchased in arm's length transactions on terms identical to those offered to non-physicians, or received stock awards from us as consideration for services performed by them. While these transactions were structured with the intention of complying with all applicable laws, including state anti-referral laws and other applicable anti-kickback laws, it is possible that regulatory or enforcement agencies or courts may in the future view these transactions as prohibited arrangements that must be restructured or for which we would be subject to other significant civil or criminal penalties. There can be no assurance that regulatory or enforcement authorities will view these arrangements as being in compliance with applicable laws or that one or more of our employees or agents will not disregard the rules we have established. Because our strategy relies on the involvement of physicians who consult with us on the design of our potential products, perform clinical research on our behalf or educate the market about the efficacy and uses of our potential products, we could be materially impacted if regulatory or enforcement agencies or courts interpret our financial relationships with physicians who refer or order our potential products to be in violation of applicable laws and determine that we would be unable to achieve compliance with such applicable laws. This could harm our reputation and the reputations of the physicians we engage to provide services on our behalf. In addition, the cost of noncompliance with these laws could

be substantial since we could be subject to monetary fines and civil or criminal penalties, and we could also be excluded from federally-funded healthcare programs, including Medicare and Medicaid, for non-compliance. Further, even the costs of defending investigations of noncompliance could be substantial.

Also, the FCA imposes civil liability on any person or entity that submits, or causes the submission of, a false or fraudulent claim to the federal government. Damages under the FCA can be significant and consist of the imposition of fines and penalties. The FCA also allows a private individual or entity (i.e., a whistleblower) with knowledge of past or present fraud against the federal government to sue on behalf of the government and to be paid a portion of the government's recovery, which can include both civil penalties and up to three times the amount of the government's damages (usually the amount reimbursed by federal healthcare programs). The U.S. Department of Justice ("DOJ") on behalf of the government takes the position that the marketing and promotional practices of life sciences product manufacturers, including the off-label promotion of products, the provision of inaccurate or misleading reimbursement guidance, or the payment of prohibited kickbacks to doctors or other referral sources may cause the submission of improper claims to federal and state healthcare entitlement programs such as Medicare and Medicaid, by health care providers that use the manufacturer's products, which results in a violation of the FCA. In certain cases, manufacturers have entered into criminal and civil settlements with the federal government under which they entered into plea agreements, paid substantial monetary amounts and entered into corporate integrity agreements that require, among other things, substantial reporting and remedial actions going forward.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other health care providers. In addition to federal laws, some states, such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may run afoul of one or more of the requirements.

The scope and enforcement of all of these laws is uncertain and subject to rapid change, especially in light of the lack of applicable precedent and regulations. There can be no assurance that federal or state regulatory or enforcement authorities will not investigate or challenge our current or future activities under these laws. Any investigation or challenge could have a material adverse effect on our business, financial condition and results of operations. Any state or federal regulatory or enforcement review of us, regardless of the outcome, would be costly and time consuming. Additionally, we cannot predict the impact of any changes in these laws, whether these changes are retroactive or will have effect on a going-forward basis only.

We operate in a highly competitive and evolving field and face competition from regenerative medicine, biotech, and pharmaceutical companies, tissue engineering entities, tissue processors and medical device manufacturers, as well as new market entrants.

We operate in a very competitive and continually evolving field. Competition from other regenerative medicine, biotech, and pharmaceutical companies, tissue engineering entities, tissue processors, medical device companies and from research and academic institutions is intense, expected to increase, subject to rapid change, and could be significantly affected by new product introductions. In addition, consolidation in the healthcare industry continues to drive demands 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. Our failure to compete effectively would have a material and adverse effect on our business, results of operations and financial condition.

Specifically, we face significant competition in both the regenerative medicine and wound care space from multiple products, including Integra Bilayer Wound Matrix, EpiFix, Apligraf, Dermagraft, Grafix, Epicel, and others. Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

Our use of sensitive patient information is subject to complex regulations at multiple levels and we would be adversely affected if we fail to adequately protect this sensitive information.

We process, maintain and utilize personal health and other confidential and sensitive data. In particular, we have developed a web and mobile application through which our customers can communicate with physicians and others, which may involve sharing patient identifiable health information. The use and disclosure of such information is regulated at the federal, state and international levels, and these laws, rules and regulations are subject to change and increased enforcement activity, such as the audit program implemented by HHS under HIPAA. International laws, rules and regulations governing the use and disclosure of such information are generally more stringent than in the United States, and they vary from jurisdiction to jurisdiction. Noncompliance with any privacy or security laws or regulations, or any security breach, cyber-attack or cybersecurity breach, and any incident involving the theft, misappropriation, loss or other unauthorized disclosure of, or access to, sensitive or confidential information, whether by us or by another third party, could require us to expend significant resources to remediate any damage, interrupt our operations and damage our brand and reputation, and could also result in investigations, regulatory enforcement actions, material fines and penalties, loss of customers, litigation or other actions which could have a material adverse effect on our business, brand, reputation, cash flows and operating results.

Our business depends on provider and patient willingness to entrust us with health related and other sensitive personal information. Events that negatively affect that trust, including inadequate disclosure of our uses of their information, failing to keep our information technology systems and sensitive information secure from significant attack, theft, damage, loss or unauthorized disclosure or access, whether as a result of our action or inaction or that of third parties, could adversely affect our brand, reputation and revenues and also expose us to mandatory disclosure to the media, litigation (including class action litigation) and other enforcement proceedings, material fines, penalties and/or remediation costs, and compensatory, special, punitive and statutory damages, consent orders and/or injunctive relief, any of which could adversely affect our business, cash flows, operating results or financial position. There can be no assurance that any such failure will not occur, or if any does occur, that we will detect it or that it can be sufficiently remediated.

Many of our competitors have substantially greater resources than we do, and we expect that all of our product candidates will face intense competition from existing or future products.

All of our product candidates face intense competition from existing and future products marketed by large, well-established companies (including but not limited to Integra LifeSciences, Wright Medical Group, MiMedx, Osiris, Organogenesis, Allosource and Vericel). These competitors may successfully market products that compete with our product candidates, successfully identify product candidates or develop products earlier than we do, or develop products that are more effective or cost less than our products. These competitive factors could require us to conduct substantial new research and development activities to establish new product targets, which would be costly and time consuming. These activities would adversely affect our ability to effectively commercialize products and achieve revenue and profits.

We depend heavily on our senior management and we may be unable to replace key executives if they leave.

The loss of the services of one or more members of our senior management team or our inability to attract, retain and maintain additional senior management personnel could harm our business, financial condition, results of operations and future prospects. Our operations and prospects depend in large part on the performance of our senior management team, particularly Dr. Denver Lough, our Chief Executive Officer and Chief Scientific Officer. In addition, we may not be able to find qualified replacements if his services are no longer available. We do not presently maintain “key-man” life insurance on any of our executives or key employees.

Many executive officers and employees in the regenerative medicine business are subject to strict non-compete or confidentiality agreements with their employers, which would limit our ability to recruit them to join our company. In addition, some of our existing and future employees are or may be subject to confidentiality agreements with previous employers. Our competitors may allege breaches of and seek to enforce such non-compete agreements or initiate litigation based on such confidentiality agreements. Such litigation, whether or not meritorious, may impede our ability to hire executive officers and other key employees who have been employed by our competitors and may result in intellectual property claims against us.

Certain key members of our management team may be subject to conflicts of interest.

Certain members of our management team have full or part-time interests outside of our business, including employment at other institutions. Such management team members may face conflicts of interest, including conflicts in allocating time and the ability to present research and business opportunities learned in the scope of other positions. These conflicts could result in unanticipated actions that adversely affect us. Currently, we have no policy in place to address such conflicts of interest. In addition, many universities and medical institutions have policies that apply to faculty members' activities outside the scope of their employment at the university and medical institution. We do not independently review all of these policies or monitor our executive's compliance with these types of third party policies and policies of former employers of our executives. Instead, we rely on representations made by the executive and periodic confirmations from the executive that he or she is in compliance with PolarityTE's employment policies.

If serious adverse or inappropriate side effects are identified during the development of our product candidates or with any procedures with which our product candidates are used, we may need to abandon or limit our development of those product candidates.

None of our product candidates has been proven effective or safe in humans. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or, to the extent required, will receive marketing approval. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In addition, if any of the procedures with which our product candidates are used is determined to be unsafe, we may be required to delay, alter, or abandon our product development or commercialization.

We rely on third parties to assist in the development of our product candidates.

Our research and development relies upon the efforts and support of third parties over which we have little or no control. Accordingly, we may be subject to significant delays from third parties on which we rely or may rely, including but not limited to clinical research organizations, academic institutions, and/or other research collaborators, related to a variety of factors including but not limited to contract negotiations, funding, preparing research protocols, and identifying appropriate investigators.

We intend to, but may not be successful in, establishing and maintaining strategic partnerships.

We intend to enter into strategic partnerships in the future to enhance and accelerate the development and commercialization of our proposed products. We may rely on such partnerships to assist in launching, marketing and developing our product candidates. However, we may face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any future proposed products and programs because our research and development pipeline may be insufficient, our proposed products and programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy (or other requirements or goals that potential strategic partners may seek). Even if we are successful in our efforts to establish strategic partnerships, the terms that we agree upon may not be favorable to us and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved and/or registered product are disappointing.

Rapid technological change could cause our business to become obsolete.

The technologies underlying our product candidates 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.

The success of any of our product candidates or enhancements to an existing product will depend on numerous factors, including our ability to:

- properly identify and anticipate physician and patient needs;
- develop and introduce enhancements in a timely manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate safety and efficacy in humans; and
- obtain the necessary regulatory clearances, registrations, or approvals.

If we do not develop and, when necessary, obtain regulatory clearance, registration, or approval for product candidates 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 product candidates, these enhancements or new generations of product candidates may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of product candidates embodying new technologies or features.

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

We believe physicians will only adopt our treatment if they determine, based on experience, clinical data and published peer reviewed journal articles, that the use of our treatment is a favorable alternative to existing and conventional methods, including but not limited to skin grafting. Physicians may be slow to change their medical treatment practices for the following reasons, among others:

- lack of evidence supporting additional patient benefits from our treatments over existing and conventional methods;
- perceived liability risks generally associated with the use of new procedures and general resistance to change; and
- limited availability or amounts of reimbursement from third-party payers.

In addition, while acceptance by the medical community may be fostered by broad evaluation via peer-reviewed literature, we may not have the resources to facilitate sufficient publication. We also believe that recommendations for, and support of our treatments by, influential physicians are essential for market acceptance and adoption. If we do not obtain this support or are unable to demonstrate favorable long-term clinical data, physicians and hospitals may not use our treatments, which would have a material and adverse effect on our result of operations and prospects.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates we may not be successful in commercializing them.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of potential products. To achieve commercial success for any product candidate, we must either develop a sales and marketing team or outsource these functions to third parties. We also plan to recruit appropriate sales and marketing resources for countries or regions of countries in which we determine to commercialize our product candidates on our own, if any.

There are risks involved both with establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of SkinTE, OsteoTE or another product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any products ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our potential products or may be unable to do so on terms that are favorable to us. We likely will have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our potential products effectively and in compliance with applicable laws.

Significant disruptions of information technology systems or breaches of information security could adversely affect our business.

We rely to a large extent upon sophisticated information technology systems to protect our intellectual property and 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, our trade secrets and data, personal information, and intellectual property). The size and complexity of our information technology and information security systems 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. There can be no assurance that our efforts to protect our data and related information technology and intellectual property will prevent service interruptions or security breaches. 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.

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 and marketing of human cellular and tissue-based products. We may be subject to such claims if our product candidates cause, or appear to have caused, an injury during clinical trials or after commercialization. Claims may be made by patients, healthcare providers or others selling our product candidates. 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 product candidates in the market.

Although we have obtained product liability insurance, such insurance is subject to deductibles and coverage limitations and we may not be able to maintain this insurance. Also, it is possible that claims could exceed the limits of our coverage. If we are unable to obtain or 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. A product liability claim or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could result in significant costs and significant harm to our business.

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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 product candidates involves an inherent risk that our tissue products or processes do not meet applicable quality standards and requirements. 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 product candidates would be costly and would divert management resources. A recall or withdrawal of one of our product candidates, or a similar product processed by another entity, also could impair sales of our product candidates 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.

Our limited public company experience may adversely impact our ability to comply with the reporting requirements of the U.S. securities laws.

We have limited experience operating as a public company. As a public company, we are required to establish and maintain disclosure controls and procedures and internal control over financial reporting. Our limited public company experience could impair our ability to comply with legal and regulatory requirements such as those imposed by Sarbanes-Oxley Act of 2002. Such responsibilities include complying with federal securities laws and making required disclosures on a timely basis. We may not be able to implement programs and policies in an effective and timely manner that adequately respond to such increased legal, regulatory compliance and reporting requirements, including the establishing and maintaining internal controls over financial reporting. Any such deficiencies, weaknesses or lack of compliance could have a materially adverse effect on our ability to comply with SEC reporting requirements, which may be necessary in the future to maintain our public company status. If we were to fail to fulfill those obligations, our ability to continue as a public company would be in jeopardy.

If we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

Our management team has supervised the completion of the first full audit of our financial statements for the year ending October 31, 2017. If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, or, if we fail to timely remediate the material weakness or other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly. In addition, we cannot be certain that material weaknesses or significant deficiencies in our internal controls will not be discovered in the future.

We may not be able to effectively control and manage our growth.

Our strategy envisions a period of potentially rapid growth. We currently maintain minimal administrative and other personnel due to the startup nature of our business, and our expected growth may impose a significant burden on our future planned administrative and operational resources. The growth of our business may require significant investments of capital and increased demands on our management, workforce and facilities. We will be required to substantially expand our administrative and operational resources and attract, train, manage and retain qualified management and other personnel. Failure to do so or to satisfy such increased demands would interrupt or would have a material adverse effect on our business and results of operations.

Our 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 and private health plans to adequately and timely reimburse the users of our potential products;
- our ability to upgrade and develop our systems and infrastructure to accommodate growth;
- the continued availability of Dr. Denver Lough and other key executives and our ability to attract and retain additional 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;
- regulation by federal, state or local governments; and/or
- general economic conditions as well as economic conditions specific to the healthcare industry.

The change in value of our derivative liabilities could have a material effect on our financial results.

Included on our balance sheet at October 31, 2017 are derivative liabilities related to embedded features bifurcated from our preferred stock and certain warrant contracts. At each reporting period, we are required to determine the fair value of such derivatives and record the fair value adjustments as non-cash unrealized gains or losses. The share price of our common stock represents the primary underlying variable that impacts the value of the derivative instruments. Additional factors that impact the value of the derivative instruments include the volatility of our stock price, our credit rating, discount rates, and stated interest rates. Due to the volatile nature of our share price, we expect that we will recognize non-cash gains or losses on our derivative instruments each reporting period and that the amount of such gains or losses could be material.

We may increasingly become a target for public scrutiny, including complaints to regulatory agencies, negative media coverage, including social media and malicious reports, all of which could severely damage our reputation and materially and adversely affect our business and prospects.

We focus on the research and development (including through preclinical, animal testing) of therapies used in the regenerative medicine and wound care space, and such therapies may be the subject of regulatory, watchdog and media scrutiny and coverage, which also raise the possibility of heightened attention from the public, the media and our participants. From time to time, these objections or allegations, regardless of their veracity, may result in public protests or negative publicity, which could result in government inquiry or harm our reputation. Corporate transactions we or related parties undertake may also subject us to increased media exposure and public scrutiny. There is no assurance that we would not become a target for public scrutiny in the future or such scrutiny and public exposure would not severely damage our reputation as well as our business and prospects.

Risks Related to Our Intellectual Property

We do not currently own any issued patents and our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain and may be inadequate, which could have a material and adverse effect on us.

Our success depends significantly on our ability to protect our proprietary rights in technologies that presently consist of trade secrets and patent applications. We currently have no issued patents relating to any of our product candidates. We intend to expand our patenting activities and rely on patent protection, as well as a combination of copyright, trade secret and trademark laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology, and there can be no assurance these methods of protection will be effective. These legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive

advantage. In addition, our presently pending patent applications include claims to material aspects of our activities that are not currently protected by issued patents. The patent application process can be time consuming and expensive. We cannot ensure that any of the pending patent applications we acquire, have acquired, or may file will result in issued patents. Competitors may be able to design around our patents or develop procedures that provide outcomes that are comparable or even superior to ours. We also cannot assure you that the inventors of the patents and applications that we expect to own or license were the first-to-invent or the first-inventor-to-file on the inventions, or that a third party will not claim ownership in one of our patents or patent applications. We cannot assure you that a third party does not have or will not obtain patents that could preclude us from practicing the patents we own or license now or in the future.

The failure to obtain and maintain patents and/or protect our intellectual property rights could have a material and adverse effect on our business, results of operations, and financial condition. We cannot be certain that, if challenged, any patents we ultimately obtain would be upheld because a determination of the validity and enforceability of a patent involves complex issues of fact and law. If one or more of any patents we obtain is invalidated and/or held unenforceable, such an outcome could reduce or eliminate any competitive advantage we might otherwise have had.

In the event a competitor infringes upon any patent we obtain, or a third party including but not limited to a university or other research institution, makes a claim of ownership over our patents or other intellectual property rights, confirming, defending or enforcing those rights may be costly, uncertain, difficult, and time consuming.

There can be no assurance that a third party, including but not limited to a university or other research institution that our founders were associated with in the past, will not make claims to ownership or other claims related to our technology.

There can be no assurance that a third party, including but not limited to a university or other research institution that our founders were associated with in the past, will not make claims to ownership or other claims related to our technology. We believe we have developed our technology outside of any institutions, but we cannot guarantee such institutions would not assert a claim to the contrary. Even if successful, litigation to enforce or defend our intellectual property rights could be expensive and time consuming, and could divert our management’s attention. Further, bringing litigation to enforce our future patent(s) subjects us to the potential for counterclaims. In the event that one or more of our future patents is challenged in U.S. and/or foreign courts or the United States Patent and Trademark Office (“USPTO”) and/or foreign patent offices, the patent(s) may be found invalid and/or unenforceable, which could harm our competitive position. If any court or any patent office ultimately cancels or narrows the claims in any of our future patents through any pre- or post-grant patent proceedings, such an outcome could prevent or hinder us from being able to enforce the patent against competitors. Such adverse decisions could negatively affect our future, expected revenue.

We may be subject to claims that our employees have wrongfully appropriated, used, or disclosed intellectual property of their former employers.

We employ individuals who were previously employed by other companies, universities and/or other academic institutions. We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a prior employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have an adverse impact on our business, financial condition, results of operations, and cash flows.

We may be subject to claims that former or current employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. Litigation may be necessary to defend against any claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If we are unable to protect the confidentiality of our proprietary information and know-how related to any of our product candidates, our competitive position would be impaired and our business, financial condition and results of operations could be adversely affected.

Some of our technology, including our knowledge regarding the processing of our product candidates, is unpatented and is maintained by us as trade secrets. In an effort to protect these trade secrets, the information is restricted to our employees, consultants, collaborators and advisors on a need-to-know basis only. In addition, we require our employees, consultants, collaborators and advisors to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual’s relationship with us be kept confidential and not disclosed to third parties. These agreements, however, do not ensure protection against improper use or disclosure of confidential information, and these agreements may be breached. A breach of confidentiality could affect our competitive position. In addition, in some situations, these agreements and other obligations of our employees to assign intellectual property to the Company may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators or advisors have previous employment or consulting relationships. Also, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and could have a material adverse effect on our business, financial condition and results of operations.

We may become subject to claims of infringement of the intellectual property rights of others, which could prohibit us from developing our treatment, require us to obtain licenses from third parties or to develop non-infringing alternatives, and subject us to substantial monetary damages. We have not obtained and do not intend to obtain any legal opinion with regard to our freedom to practice our technology.

Third parties could assert that our processes, product candidates or technology infringe their patents or other intellectual property rights. Whether a process, product or technology infringes a patent or other intellectual property involves complex legal and factual issues, the determination of which is often uncertain. We cannot be certain that we will not be found to have infringed the intellectual property rights of others. Because patent applications may remain unpublished for certain periods of time and may take years to be issued as patents, there may be applications now pending of which we are unaware and/or that do not currently contain claims of concern that may later result in issued patents that our product candidates, procedure or processes will infringe. There may be existing patents that our product candidates, procedures or processes infringe, of which infringement we are not aware. Third parties could also assert ownership over our intellectual property. Such an ownership claim could cause us to incur significant costs to litigate the ownership issues. If an ownership claim by a third party were upheld as valid, we may be unable to obtain a license from the third party on acceptable terms, to continue to make, use, or sell technology free from claims by that third party of infringement of the third party's intellectual property. We have not obtained and do not intend to obtain any legal opinion with regard to our freedom to practice our technology at this time.

If we are unsuccessful in actions we bring against the patents of other parties, and it is determined that we infringe upon the patents of third parties, we may be subject to injunctions, or otherwise prevented from commercializing potential products and/or services in the relevant jurisdiction, or may be required to obtain licenses to those patents or develop or obtain alternative technologies, any of which could harm our business. Furthermore, if such challenges to our patent rights are not resolved in our favor, we could be delayed or prevented from entering into new collaborations or from commercializing certain product candidates and/or services, which could adversely affect our business and results of operations.

If we are successful in obtaining patent protection, we may not be able to enforce those patent rights against third parties.

Successful challenge of any future patents such as through opposition, reexamination, *inter partes* review, interference, or derivation proceedings could result in a loss of patent rights in the relevant jurisdiction. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. In addition, during the course of litigation there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

We may not be able to protect our intellectual property in countries outside of the United States.

Intellectual property law outside the United States is uncertain and, in many countries, is currently undergoing review and revisions. The laws of some countries do not protect patent and other intellectual property rights to the same extent as United States laws. Third parties may challenge our patents in foreign countries by initiating proceedings including pre- and post-grant oppositions, and invalidation proceedings. Developments during opposition or invalidation proceedings in one country may directly or indirectly affect a corresponding patent or patent application in another country in an adverse manner. It may be necessary or useful for us to participate in proceedings to determine the validity of our patents or our competitors' patents that have been issued in countries other than the United States. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition.

Risks Related to Registration and/or Regulatory Approval of Our Product Candidates and Other Government Regulations

Our business is subject to continuing regulatory oversight by the FDA and other authorities, compliance with whose requirements is costly, and our failure to comply could result in negative effects on our business.

The FDA has specific regulations governing human cell, tissue, and cellular and tissue-based products, commonly known as "HCT/Ps". The FDA has broad post-market and regulatory and enforcement powers. The FDA's regulation of HCT/Ps includes requirements for registration and listing of products, donor screening and testing, processing and distribution ("Current Good Tissue Practices"), labeling, record keeping, adverse-reaction reporting, and inspection and enforcement.

We believe that our current product candidates are appropriately regulated under Section 361 of the Public Health Service Act (so-called "361 HCT/Ps") and that as a result no premarket review or approval by the FDA is required. If the FDA does not agree that one or more of our HCT/P products meet its regulatory criteria for regulation solely as 361 HCT/Ps, our product candidates will be regulated as drugs, devices, and/or biological products, and we could be required to withdraw those potential products from the market until the required clinical trials are complete and the applicable premarket regulatory clearances or approvals are obtained.

In addition, other products we may develop may not be 361 HCT/Ps. As result, those product candidates would be subject to additional regulatory requirements, including premarket approval or clearance. Even if pre-market clearance or approval is obtained, the approval or clearance may place substantial restrictions on the indications for which the product(s) may be marketed or to whom the product(s) may be marketed, and may require warnings to accompany the product or impose additional restrictions on the sale and/or use of the product. In addition, regulatory approval is subject to continuing compliance with regulatory standards, including the FDA's current good manufacturing practice (cGMP) or quality system regulations and adverse event reporting regulations.

If we fail to comply with the FDA regulations regarding our products and manufacturing processes, the FDA could take enforcement action, including, without limitation, any of the following sanctions:

Untitled letters, warning letters, fines, injunctions, consent decrees, product seizures, and/or civil penalties;

Operating restrictions, partial suspension or total shutdown of clinical studies, manufacturing, marketing, or distribution;

Refusing requests for clearance or approval of new products, processes, or procedures, or for certificates or approval to enable export of the same;

Withdrawing or suspending current applications for approval or clearance, or any approvals or clearances already granted; and

Civil or criminal prosecution.

It is likely that the FDA's regulation of 361 HCT/Ps and other types of products (e.g., drugs, devices, and/or biologics) will continue to evolve in the future. Complying with any such new regulatory requirements, guidance or statutes may entail significant time delays and expense, which could have a material adverse effect on our business. While the FDA may issue new or revised guidance or regulations for 361 HCT/Ps, we do not know whether or when such revised draft or final guidance or regulations (if any) will be issued, the scope of such guidance, any new rules or regulations, whether they will apply to our technologies or products, or whether they will be advantageous or disadvantageous to us. In addition, even if it does not issue new regulations or guidance, FDA could in the future adopt more restrictive interpretations of existing regulations or increase its enforcement activity, which may adversely affect our business.

We believe our current product candidates, including the FDA-registered SkinTE product, satisfy applicable criteria for regulation as a 361 HCT/P and are therefore exempt from FDA requirements for premarket approval or clinical studies. If the FDA disagrees with our interpretation of the relevant laws and regulations as they apply to our product candidates, and requires an Investigational New Drug application ("IND") or Investigational Device Exemption application ("IDE") for any of our product candidates, we may need to delay, abandon, or revise our current development plans, discontinue ongoing marketing, and/or recall products. The submission of an IND, Biologics License Applications ("BLA"), New Drug Application ("NDA"), or other medical device clearance or approval application would require us to compile significant amounts of data related to our regulatory process, as well as data from preclinical and/or clinical testing. We cannot guarantee that we will ever be able to secure such approvals if required. Even if such approvals are obtained, regulation as a drug, biologic, or medical device would subject us to additional FDA postmarketing requirements that are complex and involve substantial expense, such as compliance with drug, biologic, or medical device current Good Manufacturing Practice or quality system requirements.

The FDA regulates HCT/Ps under a two-tiered framework. Certain higher risk HCT/Ps are regulated as new drugs, biologics or medical devices. Manufacturers of new drugs, biologics and some medical devices must complete extensive clinical trials, which must be conducted pursuant to an effective IND or IDE. In addition, the FDA must review and approve a BLA or NDA before a new drug or biologic may be marketed. For most medical devices, including novel or high-risk medical devices, FDA must approve a premarket approval application ("PMA") or grant clearance to a premarket notification ("510(k)") application prior to marketing of the device.

By contrast, the FDA exempts 361 HCT/Ps from these requirements if they meet certain specified criteria. We believe that our current product candidates, including SkinTE, meet the criteria for regulation as a 361 HCT/P rather than as a new drug or biologic or medical device and, therefore, we do not currently expect that any of our current product candidates will be subject to the requirement for an IND or IDE or FDA premarket review and approval. Thus, our financial and business plans assume that we will not need to seek or obtain premarket FDA approval or clearance for our product candidates. Rather, we will have to comply with the requirements for 361 HCT/Ps set forth in FDA regulations and develop adequate substantiation to support marketing claims we plan to make.

The Tissue Reference Group ("TRG") is a body within the FDA designed to provide recommendations regarding whether a particular product candidate will be regulated as a 361 HCT/P. The Office of Combination Products ("OCP")

at FDA provides informal and formal opinions regarding the classification of products as 361 HCT/Ps or drugs, biologics, or medical devices. Product manufacturers are not required to consult with the TRG or OCP and instead can market their products based on their own conclusion that the product meets the 361 HCT/P criteria.

We have not consulted the OCP or TRG. We continue to believe that our product candidates qualify as 361 HCT/Ps; however, the FDA could disagree with our conclusion.

The regulatory pathway for cell and tissue-based products is subject to significant uncertainty. The FDA's criteria for regulation as a 361 HCT/P are complex, and the FDA has not provided comprehensive guidance on the meaning of certain terms used in the criteria, such as "minimal manipulation," "homologous," or "combination of the cells and tissues with another article." In addition, our product candidates, including SkinTE, use new technology that may present a matter of first impression for the FDA in determining whether to require premarket authorization. Further, our product candidates may receive a high degree of scrutiny from the FDA. The FDA or Congress could change the relevant criteria or interpretations for determining which products qualify as 361 HCT/Ps or the regulatory requirements for HCT/Ps.

Additionally, it may be difficult to convince the courts to overturn any adverse decisions made against us by the FDA. Courts have recognized the longstanding principle that the FDA's decisions on scientific matters, including the agency's conclusion that a tissue processing procedure involves more than minimal manipulation, are entitled to substantial deference. This means that if the FDA disagrees with our conclusion that any of our product candidates should be regulated as a 361 HCT/P, and not as a new biologic, drug, or medical device, it may be very difficult to challenge the agency's position in court.

Even if the FDA regulates our product candidates, including SkinTE, as 361 HCT/Ps, we must still generate adequate substantiation for any claims we will make in our marketing. Failure to establish such adequate substantiation in the opinion of federal or state authorities could substantially impair our ability to generate revenue.

Although as 361 HCT/Ps, we may not need to submit our product candidates to the FDA for premarket approval or be subject to FDA requirements for labeling or promotion of new drugs, biologics, or medical devices, we still must generate adequate substantiation for claims we make in our marketing materials. Both the Federal Trade Commission ("FTC") and the states retain jurisdiction over the marketing of 361 HCT/Ps (and other) products in commerce and require a reasonable basis for claims made in marketing materials. Through our planned preclinical and clinical studies, as well as other endeavors, we intend to generate such adequate substantiation for any claims we make about our product candidates. If, however, after we commence marketing of any of our product candidates, including SkinTE, the FTC or one or more states conclude that we lack adequate substantiation for our claims, we may be subject to significant penalties and/or may be forced to alter our marketing of our product candidates in one or more jurisdictions. Any of this could materially harm our business. In addition, if our promotion of any of our product candidates suggests that the HCT/P is not intended for homologous use, the FDA might consider the product to be a new drug, biologic, or medical device. We will therefore be limited in the promotional claims that we can make about our product candidates.

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Any changes in the governmental regulatory classifications of our product candidates could prevent, limit or delay our ability to market or develop our product candidates.

The FDA establishes regulatory requirements based on the classification of a product. An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into a human patient. 361 HCT/Ps are not subject to any premarket clearance or approval requirements and are subject to less extensive post-market regulatory requirements. Because our product development programs are designed to satisfy the standards applicable to 361 HCT/Ps, any change in the regulatory classification or designation of our products would affect our ability to obtain FDA approval or clearance for and marketing of our product candidates.

If a product candidate is deemed not to be a 361 HCT/P, FDA regulations will require premarket clearance or approval requirements that will involve significant time and cost investments by us. Further, there can be no assurance that the FDA will not, at some future point, change its position on current or future products' 361 HCT/P status, and any regulatory reclassification could have adverse consequences for us and make it substantially more difficult or expensive for us to conduct our business by requiring extensive clinical trials, premarket clearance or approval and compliance with additional post-market regulatory requirements with respect to those product candidates. Moreover, increased regulatory scrutiny within the industry in which we operate could lead to increased regulation of HCT/Ps, including 361 HCT/Ps. We also cannot assure you that the FDA will not impose more stringent interpretations, restrictions, or requirements with respect to products that qualify as 361 HCT/Ps.

Even if we successfully launch any product candidate, it will be subject to ongoing regulation. We could be subject to significant penalties if we fail to comply with these requirements, and we may be unable to commercialize our product candidates.

Even if the FDA does not object to the marketing of any of our product candidates as a 361 HCT/P and, therefore, without an NDA, BLA, PMA, or 510(k), we will still be subject to numerous post-market requirements, including those related to registration and listing, record keeping, labeling, current good tissue practices, or cGTPs, donor eligibility, deviation and adverse event reporting, and other activities. HCT/Ps that do not meet the definition of a 361 HCT/P and, therefore, are required to be approved or cleared via an NDA, BLA, PMA, or 510(k) are also subject to these and/or additional obligations. If we fail to comply with these requirements, we could be subject to, without limitation, warning letters, product seizures, injunctions or civil and criminal penalties. We are currently relying on a third-party cGTP-compliant facility to conduct the various steps involved in our process. In the future, we plan to establish our own processing facility, which will need to be cGTP compliant. Any failure by us or the third-party facility on which we rely to maintain cGTP compliance would require remedial actions, which could potentially include actions such as product recalls or delays in distribution and sales of our product candidates, including SkinTE, as well as enforcement actions.

Moreover, even if the FDA allows any product candidate of ours to be marketed without premarket authorization, the FDA could still seek to withdraw the product from the market for a variety of reasons, including if the agency develops concerns regarding the safety or efficacy of the product or the product's manufacturing process.

We face significant uncertainty in the industry due to government healthcare reform.

There have been and continue to be proposals by the federal government, state governments, regulators and third-party payers to control healthcare costs (including but not limited to capitation – the generalized cap on annual fees for a type of service or procedure such as burn or wound care or rehabilitation), and generally, to reform the healthcare system in the United States. There are many programs and requirements for which the details have not yet been fully established or the consequences are not fully understood. These proposals may affect aspects of our business. We also cannot predict what further reform proposals, if any, will be adopted, when they will be adopted, or what impact they may have on us.

Risks Related to Our Manufacturing

Failure by our third-party manufacturers, including Cell Therapy and Regenerative Medicine, to comply with the regulatory guidelines set forth by the FDA with respect to our product candidates could delay or prevent the completion of market entry, clinical trials, the approval and/or registration of any product candidates, or the commercialization of our product candidates.

Third-party manufacturers, such as Cell Therapy and Regenerative Medicine ("CTRM") at the University of Utah School of Medicine, are subject to regulation and inspection by the FDA for current Good Tissue Practice, or cGTP, and/or current Good Manufacturing Practice, or cGMP, compliance before they can produce commercial product. We may be in competition with other companies for access to these manufacturers' facilities and may be subject to delays in manufacture if the manufacturers give other clients higher priority than they give to us. If we are unable to secure and maintain third-party manufacturing capacity, the development and sales of our product candidates and our financial performance may be materially affected.

Manufacturers are obligated to operate in accordance with FDA-mandated requirements. A failure of any of our third-party manufacturers to establish and follow cGTP and/or cGMP requirements, if applicable, and to document their adherence to such practices may lead to significant delays in the availability of material for clinical trials, may delay or prevent filing or approval of marketing applications for our product candidates, if applicable, and may cause delays or interruptions in the availability of our product candidates for commercial distribution. This could result in higher costs to us or deprive us of potential product revenues.

Complying with cGTP and/or cGMP and non-U.S. regulatory requirements will require that we expend time, money, and effort in production, recordkeeping, and quality control to assure that the product meets applicable specifications and other requirements. For any products for which we are required to obtain FDA pre-market approval, we, or our contracted manufacturing facility, must also pass a pre-approval inspection prior to FDA approval. Failure to pass a pre-approval inspection may significantly delay FDA approval of our product candidates. If we fail to comply with these requirements, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our product candidates. As a result, our business, financial condition, and results of operations may be materially harmed.

The manufacture of cell and tissue-based therapy products is characterized by inherent risks and challenges and has proven to be a costly endeavor relative to manufacturing other therapeutics products. We have limited experience in manufacturing products for commercial purposes and we cannot assure you that we will be able to successfully and efficiently manage the manufacturing of our product candidates, either ourselves or through third-party contractors with whom we may enter into strategic relationships.

The manufacture of cell and tissue-based therapy products, such as our product candidates, is highly complex and is characterized by inherent risks and challenges such as autologous raw material inconsistencies, logistical challenges, significant quality control and assurance requirements, manufacturing complexity, and significant manual processing. Unlike products that rely on chemicals for efficacy, such as most pharmaceuticals, cell and tissue-based therapy products are difficult to characterize due to the inherent variability of biological input materials. Difficulty in characterizing biological materials or their interactions creates greater risk in the manufacturing process. However, there can be no assurance that we will be able to maintain adequate sources of biological materials or that biological materials that we maintain in inventory will yield finished products that satisfy applicable product release criteria. Our inability to obtain necessary biological materials or to successfully manufacture cell and tissue-based therapy products that incorporate such materials could have a material adverse effect on our results of operations.

Additionally, we have limited experience in manufacturing products for commercial purposes and could experience difficulties in the continued manufacturing of our product candidates. Because our experience in manufacturing, sales, marketing and distribution is limited, we may encounter unforeseen difficulties in our efforts to efficiently manage the manufacturing, sale and distribution of our product candidates or have to rely on third-party contractors over which we may not have sole control to manufacture our product candidates. Moreover, there can be no assurance that we or any third-party contractors with whom we enter into strategic relationships will be successful in streamlining manufacturing operations and implementing efficient, low-cost manufacturing capabilities and processes that will enable us to meet the quality, price and production standards or production volumes to achieve profitability. Our failure to develop these manufacturing processes and capabilities in a timely manner could prevent us from achieving our growth and profitability objectives as projected or at all.

We intend to obtain assistance to market our product candidates and some of our future products through collaborative relationships with companies with established sales, marketing and distribution capabilities. Our inability to develop and maintain those relationships would limit our ability to market, sell and distribute our product candidates. Our

inability to enter into successful, long-term relationships could require us to develop alternate arrangements at a time when we need sales, marketing or distribution capabilities to meet existing demand. We may market one or more of our product candidates through our own sales force. Our inability to develop and retain a qualified sales force could limit our ability to market, sell and distribute our cell products.

We are subject to significant regulation with respect to the manufacturing of our product candidates.

All of those involved in the preparation of a cellular therapy for clinical trials or commercial sale, including our existing supply contract manufacturers and clinical trial investigators, are subject to extensive and continuing government regulations by the FDA and comparable agencies in other jurisdictions. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGTP and/or cGMP. These regulations govern manufacturing processes and procedures and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors and suppliers must pass inspection for compliance with the applicable regulations as a condition of FDA approval of our product candidates (if approval of any such candidates is required). The FDA also may, at any time following approval of a product for sale (if applicable), audit our manufacturing facilities or those of our third-party contractors. In addition, the FDA may, at any time, audit or inspect a manufacturing facility involved with the preparation of our current products or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted.

Any manufacturing facility we maintain and that of our third-party contract manufacturer(s) is subject to inspections by the FDA. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulation occurs independent of such an inspection or audit, we or the FDA may require remedial measures that may be costly and/or time consuming for us or a third party to implement and that may include the temporary or permanent suspension of clinical trials, product manufacture, commercial sales or exports, recalls, warning letters, market withdrawals, seizures or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

We have limited manufacturing capacity and our manufacturing operations in the U.S. depend primarily on one facility. If this facility is destroyed or we experience any manufacturing difficulties, disruptions or delays, this could limit supply of our product candidates or adversely affect our ability to conduct our clinical trials and our business would be adversely impacted.

We have entered into a manufacturing agreement with CTRM, an accredited, FDA-inspected facility at the University of Utah School of Medicine that maintains procedures for cGMP and cGTP compliance, and conduct all of our manufacturing operations at the CTRM facility located in Salt Lake City, Utah. As a result, all of the manufacturing of our product candidates takes place at a single U.S. facility. We will require additional and/or expanded manufacturing facilities to support our growth plans. If regulatory, manufacturing or other problems require us to discontinue production at this facility, we will not be able to supply our product candidates to patients or have supplies for any clinical trials, which would adversely impact our business. If this facility or the equipment in it is significantly damaged or destroyed by fire, flood, power loss or similar events, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace the facility at all. In the event of a temporary or protracted loss of this facility or equipment, we might not be able to transfer manufacturing to another third party. Even if we could transfer manufacturing from one facility to another, the shift would likely be expensive and time-consuming, particularly since an alternative facility would need to comply with the cGTP and/or cGMP (if applicable) regulatory and quality standard requirements and, if applicable, FDA approval would be required before any products manufactured at that facility could be made commercially available.

Risks Related to Liquidity and Capital Resources

Our financial resources are limited and we will need to raise additional capital in the future to continue our business.

As a result of the reorganization transactions, our business focus has changed from a gaming business to regenerative medicine. We do not expect to generate the level of revenues going forward that we have achieved in prior years, and no longer expect to generate meaningful revenues from other segments of our business which have been terminated or disposed of. This significantly reduced revenue will impact our needs for future capital. We cannot ensure that additional funding will be available or, if it is available, that it can be obtained on terms and conditions we will deem acceptable. Any additional funding derived from the sale of equity securities is likely to result in significant dilution to our existing stockholders. These matters involve risks and uncertainties that may prevent us from raising additional capital or may cause the terms upon which we raise additional capital, if additional capital is available, to be less favorable to us than would otherwise be the case. If we reach a point where we are unable to raise needed additional funds to continue as a going concern, we will be forced to cease our business activities and dissolve. In such an event, we will need to satisfy various severances, contract termination, and other dissolution-related obligations.

Our financial statements have been prepared on a going concern basis; we must raise additional capital to fund our operations in order to continue as a going concern.

In its report dated January 29, 2018, EisnerAmper LLP, our independent registered public accounting firm, expressed substantial doubt about our ability to continue as a going concern as we have suffered recurring losses from operations and have insufficient liquidity to fund our future operations. If we are unable to improve our liquidity position we may not be able to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that might result if we are unable to continue as a going concern and, therefore, be required to realize our assets and discharge our liabilities other than in the normal course of business which could cause investors to suffer the loss of all or a substantial portion of their investment.

As of October 31, 2017, we had $17.7 million of cash. We anticipate that our principal sources of liquidity will only be sufficient to fund our activities through approximately October 2018. In order to have sufficient cash to fund our operations, we will need to raise additional equity or debt capital and we cannot provide any assurance that we will be successful in doing so.

We may not be able to raise the required capital to conduct our operations and develop and commercialize our product candidates.

We incurred net losses of $130.8 million in fiscal 2017. We will require substantial additional capital resources in order to complete our product development programs, complete clinical trials, and market and commercialize our product candidates. In order to grow and expand our business, and to introduce our new product candidates into the marketplace, we will need to raise a significant amount of additional funds. We will also need significant additional funds or a collaborative partner, or both, to finance the research and development activities. Accordingly, we are continuing to pursue additional sources of financing.

Our future capital requirements will depend on numerous factors, including:

- our ability to generate future revenues;
- costs and timing of our product development activities;
- timing of conducting pre-clinical and clinical trials and seeking regulatory approvals and/or registrations;

our ability to commercialize our product candidates;

our ability to avoid infringement and misappropriation of third-party intellectual property;

our ability to obtain valid and enforceable patents;

competing technological and market developments;

our ability to establish collaborative relationships;

market acceptance of our product candidates;

the development of an infrastructure to support or business; and

our ability to scale up our production capabilities for larger quantities of our products; and

our ability to control costs.

We expect to devote substantial capital resources to, among other things, fund operations, continue development programs, and to build out and increase our portfolio of product candidates. If we are unable to secure such additional financing, it will have a material adverse effect on our business and we may have to limit operations in a manner inconsistent with our development and commercialization plans. If additional funds are raised through the issuance of equity securities or convertible debt securities, it will be dilutive to our stockholders and could result in a decrease in our stock price.

We have funded our operations primarily with proceeds from public and private offerings of our common stock. Our history of operating losses and cash uses, our projections of the level of cash that will be required for our operations to reach profitability, the terms of the private placement transactions that we completed in the past, and the restricted availability of credit for emerging industries, may impair our ability to raise capital on terms that we consider reasonable and at the levels that we will require over the coming months. We cannot provide any assurances that we will be able to secure additional funding from public or private offerings on terms acceptable to us, if at all. If we are unable to obtain the requisite amount of financing needed to fund our planned operations, it would have a material adverse effect on our business and ability to continue as a going concern.

If adequate funds are not available in the future, we may not be able to develop or enhance our product candidates, take advantage of future opportunities, or respond to competitive pressures or unanticipated requirements and we may be required to delay or terminate research and development programs, curtail capital expenditures, and reduce business development and other operating activities. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could have a material adverse effect on our business, operating results, financial condition and prospects.

Our financial condition may impair our ability to obtain credit terms with our suppliers.

Our revenues may be dependent and our reimbursement arrangement may provide us with extended payment terms. However, our financial condition may make it difficult for us to continue to receive payment terms from our suppliers or vendors making demand for adequate assurance, which could include a demand for payment-in-advance. If we are unable to obtain reasonable payment terms or if any of our material vendors or suppliers were to successfully demand payment-in-advance, it could have a material adverse effect on our liquidity.

Risks Related to Our Common Stock

Our Restated Certificate of Incorporation, our Restated Bylaws and Delaware law could deter a change of our management which could discourage or delay offers to acquire us.

Certain provisions of Delaware law and of our Restated Certificate of Incorporation, as amended, and by-laws, could discourage or make it more difficult to accomplish a proxy contest or other change in our management or the acquisition of control by a holder of a substantial amount of our voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or in our best interests. These provisions include:

establishing a classified Board requiring that members of the Board be elected in different years, which lengthens the time needed to elect a new majority of the Board; we currently have established and intend to continue to maintain a staggered Board;

authorizing the issuance of “blank check” preferred stock that could be issued by our Board to increase the number of outstanding shares or change the balance of voting control and thwart a takeover attempt; our Board is authorized to issue up to 10,000,000 shares of preferred stock without stockholder approval;

prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates; and

prohibiting stockholder action by written consent and requiring all stockholder actions to be taken at a meeting of our stockholders.

Our executive officers and directors have the ability to control all matters submitted to stockholders for approval.

On April 7, 2017, we issued 7,050 shares of our Series E Preferred Stock convertible into an aggregate of 7,050,000 shares of our common stock with a fair value of approximately $104.7 million to Dr. Denver Lough. Pursuant to the Certificate of Designation for the Series E Preferred Stock, such shares are entitled to two votes for each share of common stock into which such shares are convertible. Accordingly, Dr. Lough is entitled to cast votes equivalent to 14,100,000 shares of common stock on all matters presented for a vote of our stockholders on an "as-converted" basis. As of October 31, 2017, there were 6,515,524 shares of common stock issued and outstanding eligible to vote (in addition to our voting preferred stock). As a result, Dr. Lough, together with other executive officers and directors, would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs.

Substantial future sales of our common stock by us or by our existing stockholders could cause our stock price to fall.

Additional equity financings or other share issuances by us, including shares issued in connection with strategic alliances and corporate partnering transactions, could adversely affect the market price of our common stock. Sales by existing stockholders of a large number of shares of our common stock in the public market or the perception that additional sales could occur could cause the market price of our common stock to drop.

The market price of our common stock may be affected by factors different from those affecting the market price for our common stock in recent history.

On June 23, 2017, we entered into a purchase agreement with Majesco Entertainment Company, a Nevada corporation and our wholly-owned subsidiary, and Zift Interactive LLC, a Nevada limited liability company. Pursuant to the terms of the purchase agreement, we sold to Zift Interactive LLC 100% of the issued and outstanding shares of common stock of Majesco Entertainment Company, including all of the right, title and interest in and to Majesco Entertainment Company's business of developing, publishing and distributing video game products through both retail distribution and mobile and online digital downloading. As a result of the transactions, we disposed entirely of our gaming business assets and intend to devote its resources and attention to our regenerative medicine efforts.

As result, our business in recent history differs from that of our current business, and accordingly, the results of operations for our company may be affected by factors different from those affecting our results of operation in recent history. As such, the market price for our stock may be impacted differently in the future by those factors than it is currently.

We have experienced volatility in the price of our stock and are subject to volatility in the future .

The price of our common stock has experienced significant volatility. The high and low bid quotations for our common stock, as reported by NASDAQ, ranged between a high of $31.68 and a low of $2.79 during the past 12 months. The historic market price of our common stock may be higher or lower than the price paid for our shares and may not be indicative of future market prices, depending on many factors, some of which are beyond our control. In addition, our Chief Executive Officer controls approximately 61.34% of our voting capital stock and maintains effective majority control over decisions affecting our Company and business. As a result investors may be unwilling to purchase our common stock and our market price may be affected. The price of our stock may change dramatically in response to our success or failure and based upon our relationship and the decisions of our chief executive officer.

We may not be able to maintain our listing on NASDAQ.

Our common stock currently trades on NASDAQ. This market has continued listing requirements that we must continue to maintain to avoid delisting. The standards include, among others, a minimum bid price requirement of $1.00 per share and any of: (i) a minimum stockholders' equity of $2.5 million; (ii) a market value of listed securities of $35 million; or (iii) net income from continuing operations of $500,000 in the most recently completed fiscal year or in two of the last three fiscal years. Our results of operations and our fluctuating stock price directly impact our ability to satisfy these listing standards. In the event we are unable to maintain these listing standards, we may be subject to delisting.

On January 6, 2017, we were notified by NASDAQ of failure to comply with NASDAQ Listing Rule 5605(b)(1) which requires that a majority of the directors comprising our Board of Directors be considered "independent", as defined under Rule 5605(b). The notice had no immediate effect on the listing or trading of our common stock on NASDAQ. On February 22, 2017, we regained compliance with Listing Rule 5605(b)(1) with the appointment of Mr. Steve Gorlin and Dr. Jon Mogford.

On November 1, 2017, we were notified by NASDAQ of failure to comply with Nasdaq Listing Rule 5605(b)(1) which requires that a majority of the directors comprising our Board of Directors be considered "independent" and Listing Rule 5605(c)(2)(a) requiring an audit committee to be comprised of at least three independent directors. The Company plans to regain compliance upon appointment of one or more additional independent directors prior to the deadline provided by NASDAQ.

A delisting from NASDAQ would result in our common stock being eligible for quotation on the Over-The-Counter market which is generally considered to be a less efficient system than listing on markets such as NASDAQ or other national exchanges because of lower trading volumes, transaction delays and reduced security analyst and news media coverage. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our common stock. Additionally, trading of our common stock on the OTCBB may make us less desirable to institutional investors and may, therefore, limit our future equity funding options and could negatively affect the liquidity of our stock.

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The rights of our common stockholders are limited by and subordinate to the rights of the holders of Series A Convertible Preferred Stock, Series B Convertible Preferred Stock, Series C Convertible Preferred Stock, Series D Convertible Preferred Stock, Series E Convertible Preferred Stock and Series F Convertible Preferred Stock; these rights may have a negative effect on the value of shares of our common stock.

The holders of our preferred stocks have rights and preferences generally superior to those of the holders of our common stock. The existence of these superior rights and preferences may have a negative effect on the value of shares of our common stock. These rights are more fully set forth in the certificates of designations governing our preferred stocks, and include, but are not limited to:

- the right to receive a liquidation preference, prior to any distribution of our assets to the holders of our common stock; and
- the right to convert into shares of our common stock at the conversion price set forth in the certificates of designations governing the respective preferred stock, which may be adjusted as set forth therein.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

The Company leases office space in Hazlet, New Jersey at a cost of approximately $1,100 per month under a lease agreement that expires on March 31, 2018.

The Company also leases space in Salt Lake City, Utah at a cost of approximately $24,044 per month under a lease agreement that expires on March 31, 2018.

On December 27, 2017, the Company signed a five-year lease with one five-year option to renew on approximately 178,528 rentable square feet in Salt Lake City, Utah. The base rent for the first year of the lease is $1,178,285 and escalates at the rate of 3% per annum thereafter.

Item 3. Legal Proceedings.

On February 26, 2015, a complaint for patent infringement was filed in the United States District Court for the Eastern District of Texas by Richard Baker, an individual residing in Australia, against Microsoft, Nintendo, Majesco Entertainment Company ("Majesco DE"), and a number of other game publisher defendants. The complaint alleged that the Zumba Fitness Kinect game infringed plaintiff's patents in motion tracking technology. The plaintiff is representing himself pro se in the litigation and is seeking monetary damages in the amount of $1.3 million. The case was subsequently transferred to the Western District of Washington. On June 16, 2017, final judgment was entered in favor of the defendants. The plaintiff has appealed that decision to the Court of Appeals for the Federal Circuit. The appeal is currently pending. On June 23, 2017, as part of a purchase agreement, liabilities and claims relating to this litigation were transferred to Zift Interactive LLC.

In addition to the item above, the Company at times may be a party to claims and suits in the ordinary course of business. We record a liability when it is both probable that a liability has been incurred and the amount of the loss or range of loss can be reasonably estimated. The Company has not recorded a liability with respect to the matter above. While the Company believes that it has valid defenses with respect to the legal matter pending and intends to vigorously defend the matter above, given the uncertainty surrounding litigation and our inability to assess the likelihood of a favorable or unfavorable outcome, it is possible that the resolution of the matter could have a material adverse effect on our consolidated financial position, cash flows or results of operations.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market For Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is listed for trading on the Nasdaq Capital Market under the symbol "COOL." The market for our common stock has often been sporadic, volatile and limited.

The following table shows the high and low quotations for our common stock as reported by Nasdaq from November 1, 2015 through October 31, 2017. The prices reflect inter-dealer quotations, without retail markup, markdown or commissions, and may not represent actual transactions.

	High	Low
Fiscal Year 2016		
First Quarter	$13.68	$3.66
Second Quarter	$5.94	$4.20
Third Quarter	$6.30	$3.66
Fourth Quarter	$4.50	$3.03
Fiscal Year 2017		
First Quarter	$6.22	$2.61
Second Quarter	$18.90	$3.80
Third Quarter	$30.09	$10.33
Fourth Quarter	$32.63	$17.61

Holders of Common Stock . On January 26, 2018, we had 120 registered holders of record of our common stock. On January 26, 2018, the closing sales price of our common stock as reported on Nasdaq was $20.60 per share.

Dividends and dividend policy. Prior to October 31, 2015, we had never declared or paid any dividends on our common stock.

On January 4, 2016, we declared a special cash dividend of an aggregate of $10.0 million to be paid to holders of record on January 14, 2016 of our outstanding shares of: (i) common stock (ii) Series A Convertible Preferred Stock; (iii) Series B Convertible Preferred Stock; (iv) Series C Convertible Preferred Stock and (v) Series D Convertible Preferred Stock. The holders of record of our outstanding preferred stock participated in receiving their pro rata portion of the dividend on an “as converted” basis. The dividend was paid January 15, 2016.

We do not anticipate paying future dividends at the present time. We currently intend to retain earnings, if any, for use in our business.

Securities authorized for issuance under equity compensation plans. The information called for by this item is incorporated by reference from our definitive proxy statement relating to our 2017 Annual Meeting of Stockholders, which we intend to file within 120 days after our October 31, 2017 fiscal year end.

Recent Sales of Unregistered Securities. All prior sales of unregistered securities have been previously reported either on a current report on Form 8-K or a quarterly report on Form 10-Q.

Item 6. Selected Financial Data

As a smaller reporting company, we are not required to provide the information under this item, pursuant to Regulation S-K Item 301(c).

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with "Selected Financial Data" and our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Overview

On December 1, 2016, Majesco Entertainment Company (*n/k/a* PolarityTE, Inc.), a Delaware corporation (the "Company") entered into an agreement to acquire the assets of Polarity NV (as defined below), a regenerative medicine company. The asset acquisition was subject to shareholder approval, which was received on March 10, 2017 and the transaction closed on April 7, 2017, as more fully described below. In January 2017, the Company changed its name to "PolarityTE, Inc." ("Polarity").

On December 1, 2016, the Company appointed Dr. Denver Lough as Chief Executive Officer, Chief Scientific Officer and Chairman of our Board of Directors and Dr. Ned Swanson as Chief Operating Officer of the Company. Until their respective appointments, both doctors were associated with Johns Hopkins University, Baltimore, Maryland, as full-time residents. On December 1, 2016, Dr. Lough assigned the patent application as well as all related intellectual property to a newly-formed Nevada corporation, Polarityte, Inc. ("Polarity NV"), and the Company entered into an Agreement and Plan of Reorganization (the "Agreement") with Polarity NV and Dr. Lough. As a result, at closing, the patent application would be owned by the Company without the need for further assignments or recordation with the Patent Trademark Office.

On April 7, 2017, the Company issued 7,050 shares of its newly authorized Series E Preferred Stock (the "Series E Preferred Shares") convertible into an aggregate of 7,050,000 shares of the Company's common stock with a fair value of approximately $104.7 million which is equal to 7,050,000 common shares times $14.85 (the closing price of the Company's common stock as of April 7, 2017) to Dr. Lough for the purchase of Polarity NV's assets. Since the assets purchased were in-process research and development assets, the total purchase price was immediately expensed as research and development - intellectual property acquired since they have no alternative future use.

PolarityTE, Inc. is aiming to be the first company to deliver regenerative medicine into clinical practice through tissue engineering. Subsequent to the acquisition, the Company's platform technology will allow it to regenerate a patient's tissues using their own cells.

Research and Development Expenses. Research and development expenses primarily represent employee related costs, including stock compensation, for research and development executives and staff, lab and office expenses and other overhead charges.

Research and Development - Intellectual Property Acquired. On April 7, 2017, as payment for the Polarity NV asset acquisition, the Company issued 7,050 shares of Series E Preferred Stock convertible into an aggregate of 7,050,000 shares of the Company's common stock and with a fair value of approximately $104.7 million which is equal to 7,050,000 common shares times $14.85 (the closing price of the Company's common stock as of April 7, 2017). Since the assets purchased were in-process research and development assets, the total purchase price was immediately expensed as research and development - intellectual property acquired since they have no alternative future use.

General and Administrative Expenses. General and administrative expenses primarily represent employee related costs, including stock compensation, for corporate executive and support staff, general office expenses, professional fees and various other overhead charges. Professional fees, including legal and accounting expenses, typically represent one of the largest components of our general and administrative expenses. These fees are partially attributable to our required activities as a publicly traded company, such as SEC filings, and corporate- and business-development initiatives.

Discontinued Operations. On June 23, 2017, the Company sold Majesco Entertainment Company, a Nevada corporation and wholly-owned subsidiary of the Company ("Majesco") to Zift Interactive LLC, a Nevada limited liability company (the "Purchaser") pursuant to a purchase agreement (the "Agreement"). Pursuant to the terms of the Agreement, the Company sold to the Purchaser 100% of the issued and outstanding shares of common stock of Majesco, including all of the right, title and interest in and to Majesco's business of developing, publishing and distributing video game products through both retail distribution and mobile and online digital downloading. Pursuant to the terms of the Agreement, the Company will receive total cash consideration of approximately $100,000 ($5,000 upon signing the Agreement and 19 additional monthly payments of $5,000) plus contingent consideration based on net revenues.

Income Taxes. Income taxes consist of our provisions for income taxes, as affected by our net operating loss carryforwards. Future utilization of our net operating loss, or NOL, carryforwards may be subject to a substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code. The annual limitation may result in the expiration of NOL carryforwards before utilization. Due to our history of losses, a valuation allowance sufficient to fully offset our NOL and other deferred tax assets has been established under current accounting pronouncements, and this valuation allowance will be maintained unless sufficient positive evidence develops to support its reversal.

In December 2017, the federal government enacted numerous amendments to the Internal Revenue Code of 1986 pursuant to an act known by the Tax Cuts and Jobs Act (the "TCJA"). The TCJA may impact the Company's income tax expense (benefit) from continuing operations in future periods. The Company has recorded a full valuation allowance on its net deferred tax assets and therefore any impact on the value of the company's deferred tax assets will be offset by a change in the valuation allowance.

Critical Accounting Estimates

Our discussion and analysis of the financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP.

The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from these estimates under different assumptions or conditions.

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We have identified the policies below as critical to our business operations and to the understanding of our financial results. The impact and any associated risks related to these policies on our business operations is discussed throughout management's discussion and analysis of financial condition and results of operations when such policies affect our reported and expected financial results.

Accounting for Stock-Based Compensation. Stock-based compensation expense is measured at the grant date based on the fair value of the award and is recognized as expense over the vesting period. Determining the fair value of stock-based awards at the grant date requires judgment, including, in the case of stock option awards, estimating expected stock volatility. In addition, judgment is also required in estimating the amount of stock-based awards that are expected to be forfeited. If actual results differ significantly from these estimates, stock-based compensation expense and our results of operations could be materially impacted.

Accounting for Common and Preferred Stock and Warrant transactions. We issued units consisting of preferred shares and warrants and common stock and warrants and subsequently remeasured certain of those warrants. Determining the fair value of the securities in these transactions requires significant judgment, including adjustments to quoted share prices and expected stock volatility. Such estimates may significantly impact our results of operations and losses applicable to common stockholders.

Commitments and Contingencies. We record a liability for contingencies when the amount is both probable and reasonably estimable. We record associated legal fees as incurred.

Results of Operations

Year ended October 31, 2017 versus the year ended October 31, 2016

Research and Development Expenses. For the year ended October 31, 2017, research and development expenses were approximately $7.1 million. Research and development costs consist of salaries of approximately $2.4 million, stock-based compensation of approximately of $1.8 million, travel related expenses of approximately $664,000, trade show related expenses of $530,000, medical equipment depreciation of approximately $431,000, consulting expense of $240,000, rent expense of $206,000, samples expense of $179,000, medical study expense of $174,000, health insurance of $166,000 and various other expenses totaling approximately $393,000. There was no research and development activity in the comparative 2016 period.

Research and Development - Intellectual Property Acquired. For the year ended October 31, 2017, research and development - intellectual property acquired relates to the Polarity NV asset acquisition and the issuance of 7,050 shares of Series E Preferred Stock convertible into an aggregate of 7,050,000 shares of the Company's common stock with a fair value of approximately $104.7 million which is equal to 7,050,000 common shares times $14.85 (the closing price of the Company's common stock as of April 7, 2017). Since the assets purchased were in-process research and development assets, the total purchase price was immediately expensed as research and development - intellectual property acquired since there is no alternative future use. There was no research and development – intellectual property acquired activity in the comparative 2016 period.

General and Administrative Expenses. For the year ended October 31, 2017, general and administrative expenses increased $14.7 million to approximately $18.8 million compared to $4.1 million for the year ended October 31, 2016. The increase is primarily due to increased stock-based compensation of approximately $12.8 million and increased headcount and salaries related to the Company's new medical activities.

Loss from continuing operations. Loss from continuing operations for the year ended October 31, 2017 was approximately $130.5 million, compared to a loss of approximately $3.8 million in the comparable period in 2016, primarily reflecting higher research and development - intellectual property acquired expenses and stock-based compensation expenses.

Liquidity and Capital Resources

As of October 31, 2017, our cash and cash equivalents balance was $17.7 million and our working capital was approximately $2.5 million, compared to cash and equivalents of $6.5 million and working capital of $5.4 million at October 31, 2016.

As reflected in the consolidated financial statements, we had an accumulated deficit of approximately $259.0 million at October 31, 2017, a loss of approximately $130.5 million from continuing operations and approximately $7.6 million net cash used in continuing operating activities for the year ended October 31, 2017. These factors raise substantial doubt about the Company's ability to continue as a going concern.

We will continue to pursue fundraising opportunities that meet our long-term objectives, however, our cash position is not sufficient to support our operations through December 2018. The consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Series E Preferred Shares

On April 7, 2017, the Company issued 7,050 shares of its newly authorized Series E Preferred Stock (the "Series E Preferred Shares") convertible into an aggregate of 7,050,000 shares of the Company's common stock with a fair value of approximately $104.7 million which is equal to 7,050,000 common shares times $14.85 (the closing price of the Company's common stock as of April 7, 2017) to Dr. Lough for the purchase of the Polarity NV's assets.

The Preferred E Shares are convertible into shares of common stock based on a conversion calculation equal to the stated value of such Preferred E Shares, plus all accrued and unpaid dividends, if any as of such date of determination, divided by the conversion price. The stated value of each Preferred E Share is $1,000 and the initial conversion price is $1.00 per share, each subject to adjustment for stock splits, stock dividends, recapitalizations, combinations, subdivisions or other similar events. The Preferred E Shares, with respect to dividend rights and rights on liquidation, winding-up and dissolution, in each case will rank senior to the Company's common stock and all other securities of the Company that do not expressly provide that such securities rank on parity with or senior to the Preferred E Shares. Until converted, each Preferred E Share is entitled to two votes for every share of common stock into which it is convertible on any matter submitted for a vote of stockholders. The Preferred E Shares participate on an "as converted" basis with all dividends declared on the Company's common stock.

Redeemable Series F Preferred Shares

On September 20, 2017, the Company sold an aggregate of $17,750,000 worth of units (the "Units") of the Company's securities to accredited investors at a purchase price of $2,750 per Unit with each Unit consisting of (i) one share of the Company's newly authorized 6% Series F Convertible Preferred Stock, par value $0.001 per share (the "Series F Preferred Stock"), which are convertible into one hundred (100) shares of the Company's common stock, and (ii) a two-year warrant to purchase 322,727 shares of the Company's common stock, at an exercise price of $30.00 per share. The Company incurred issuance costs of approximately $356,000 associated with the Unit offering.

The Company entered into separate registration rights agreements, and subsequently amended such agreements, with each of the investors, pursuant to which the Company agreed to undertake to file a registration statement to register the resale of the conversion shares and warrant shares within 150 days of the closing of the transaction, to cause such registration statement to be declared effective by the Securities and Exchange Commission within ninety days following its filing and to maintain the effectiveness of the registration statement until all of such conversion shares and warrant shares have been sold or are otherwise able to be sold pursuant to Rule 144 under the Securities Act, without any restrictions. In the event the Company fails to file, or obtain effectiveness of, such registration statement with the specified period of time, the Company will be obligated to pay liquidated damages equal to the product of one 1% percent multiplied by the aggregate subscription amount paid by such investor for every thirty (30) days during which such filing is not made and/or effectiveness obtained, such fee being subject to certain exceptions, up to a maximum of twelve 12% percent.

Pursuant to the subscription agreements, for as long as the lead investor holds securities, except with certain issuances, the Company shall not incur any senior debt or issue any preferred stock with liquidation rights senior to the securities sold thereunder. During this period, the Company will not, without the consent of the investors holding a majority of the then issued and outstanding shares on the date of such consent (including the lead investor), enter into any equity line of credit or similar agreement, nor issue nor agree to issue any common stock, common stock equivalents, floating or variable priced equity linked instruments nor any of the foregoing or equity with price reset rights (subject to adjustment for stock splits, distributions, dividends, recapitalizations and the like).

The shares of Series F Preferred Stock are convertible into shares of the Company's common stock based on a conversion calculation equal to the stated value of the Series F Preferred Stock, plus all accrued and unpaid dividends, if any, on such Series F Preferred Stock, as of such date of determination, divided by the conversion price. The stated value of each share of Series F Preferred Stock is $2,750 and the initial conversion price is $27.50 per share, each subject to adjustment for stock splits, stock dividends, recapitalizations, combinations, subdivisions or other similar events.

Each holder of a Series F Preferred Share is entitled to receive dividends, in cash or in shares of the Company's common stock on the stated value of each share at the dividend rate, which shall be cumulative and shall continue to accrue and compound quarterly whether or not declared and whether or not in any fiscal year there shall be net profits or surplus available for the payment of dividends in such fiscal year. Dividends are payable quarterly in arrears on the fifteenth (15th) day of the next applicable quarter, to the record holders of the Series F Preferred Stock on the last day of the fiscal quarter immediately preceding the dividend payment date in shares of common stock, calculated using the VWAP of the common stock on the ninety (90) days immediately preceding the dividend record date; provided, however, that the Company may, at its option, pay dividends in cash or in a combination of common shares and cash.

Upon the liquidation, dissolution or winding up of the business of the Company, whether voluntary or involuntary, each holder of preferred shares shall be entitled to receive, for each share thereof, out of assets of the Company legally available therefor, a preferential amount in cash equal to (and not more than) $2,750.

On the two (2) year anniversary of the initial issuance date, any share of Series F Preferred Stock outstanding and not otherwise already converted, shall, at the option of the holder, either (i) automatically convert into common stock of the Company at the conversion price then in effect or (ii) be repaid by the Company based on the stated value of such outstanding shares of Series F Preferred Stock. In addition, in the event that the Company's common stock attains a consolidated bid price of $45 or greater for any four (4) trading days during any eight (8) trading day period, the Series F Preferred Stock shall be automatically converted to common stock, without any further action by the holder (subject to the conversion limitation in the event that such conversion would result in such holder holding in excess of four and ninety-nine one-hundredths (4.99%) percent of the common stock of the Company).

The warrants issued in connection with the Series F Preferred Stock are liabilities pursuant to ASC 815. The warrant agreement provides for an adjustment to the number of common shares issuable under the warrant and/or adjustment

to the exercise price, including but not limited to, if: (a) the Company issues shares of common stock as a dividend or distribution to holders of its common stock; (b) the Company subdivides or combines its common stock (i.e., stock split); (c) adjustment of exercise price upon issuance of new securities at less than the exercise price. Under ASC 815, warrants that provide for down-round exercise price protection are recognized as derivative liabilities.

The conversion feature within the Series F Preferred Stock is not clearly and closely related to the identified host instrument and, as such, is recognized as a derivative liability measured at fair value pursuant to ASC 815.

The initial fair value of the warrants and bifurcated embedded conversion feature, estimated to be approximately $4.3 million and $9.3 million, respectively, was deducted from the gross proceeds of the Unit offering to arrive at the initial discounted carrying value of the Series F Preferred Stock. The resulting discount to the aggregate stated value of the Series F Preferred Stock of approximately $13.6 million will be recognized as accretion, similar to preferred stock dividends, over the two-year period prior to optional redemption by the holders. The Company recognized accretion of the discount to the stated value of the Series F Preferred Stock of approximately $369,000 in the year ended October 31, 2017 as a reduction of additional paid-in capital and an increase in the carrying value of the Series F Preferred Stock. The accretion is presented in the Statement of Operations as a deemed dividend, increasing net loss to arrive at net loss attributable to common stockholders.

Preferred Share Conversion Activity

During the year ended October 31, 2017, 3,991,487 shares of Convertible Preferred Stock Series A, 6,512 shares of Convertible Preferred Stock Series B, 23,185 shares of Convertible Preferred Stock Series C and 129,665 shares of Convertible Preferred Stock Series D were converted into 1,590,631 shares of common stock.

Common Stock

On January 18, 2017, the Company entered into separate exchange agreements (each an “Exchange Agreement”) with certain accredited investors (the “Investors”) who purchased warrants to purchase shares of the Company’s common stock (the “Warrants”) pursuant to the prospectus dated April 13, 2016. Pursuant to the Offering, the Company issued 250,000 shares of the Company’s common stock and Warrants to purchase 187,500 shares of common stock (taking into account the reverse split of the Company’s common stock on a 1 for 6 basis effective with The NASDAQ Stock Market LLC on August 1, 2016). The common stock and Warrants were offered by the Company pursuant to an effective shelf registration statement.

Under the terms of the Exchange Agreement, each Investor exchanged each Warrant it purchased in the Offering for 0.3 shares of common stock. Accordingly, the Company issued an aggregate of 56,250 shares of common stock in exchange for the return and cancellation of 187,500 Warrants.

During the year ended October 31, 2017, certain employees exercised their options at a weighted-average exercise price of $4.84 in exchange for the Company's common stock for an aggregated amount of 268,847 shares.

Off-Balance Sheet Arrangements

As of October 31, 2017, we had no off-balance sheet arrangements.

Inflation

Our management currently believes that inflation has not had, and does not currently have, a material impact on continuing operations.

Cash Flows

Cash and cash equivalents and working capital were approximately $17.7 million and $2.5 million, respectively, as of October 31, 2017 compared to approximately $6.5 million and $5.4 million at October 31, 2016, respectively.

Operating Cash Flows. Cash used in continuing operating activities in the year ended October 31, 2017 amounted to approximately $7.6 million compared to approximately $1.9 million for the 2016 period. The increase in net cash used in continuing operating activities mostly relates to the increase in net loss, partially offset by the research and development - intellectual property acquired paid for in preferred shares and by the increase in share-based compensation.

Cash provided by discontinued operating activities in the year ended October 31, 2017 amounted to approximately $33,000 compared to approximately $113,000 for the 2016 period.

Investing Cash Flows. Cash used in continuing investing activities in the year ended October 31, 2017 amounted to approximately $2.5 million. The $2.5 million relates to the purchase of property and equipment (mostly medical equipment). There were no investing activities in the 2016 period.

Financing Cash Flows. Net cash provided by financing activities in the year ended October 31, 2017 amounted to approximately $21.2 million compared to approximately $8.8 million used in the 2016 period. For the year ended October 31, 2017, the $21.2 million related to capital raising activities and proceeds from option exercises. For the year ended October 31, 2016, the $8.8 million mostly related to a payment of a $10.0 million special cash dividend, partially offset by an equity capital raise of approximately $1.4 million.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide the information under this item, pursuant to Regulation S-K Item 305(e).

Item 8. Financial Statements and Supplementary Data.

The financial statements required by Item 8 are submitted in a separate section of this report, beginning on Page F-1, are incorporated herein and made a part hereof.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Exchange Act Rules 13a-15(e) and 15d-15(e), as of the end of the period covered by this report.

In designing and evaluating our disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

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No system of controls can prevent errors and fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur. Controls can also be circumvented by individual acts of some people, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with its policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Subject to the limitations above, management believes that the consolidated financial statements and other financial information contained in this report, fairly present in all material respects our financial condition, results of operations, and cash flows for the periods presented.

Based on the evaluation of the effectiveness of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) were not effective as of October 31, 2017 due to the material weakness identified below.

To address these material weaknesses, management performed additional analyses and other procedures to ensure that the financial statements included herein fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented.

Management's Annual Report on Internal Control Over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America, or GAAP. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect transactions involving our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with the authorization of our management; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

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

Management assessed the effectiveness of our internal control over financial reporting as of October 31, 2017. In making this assessment, management used the framework set forth in the report entitled Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013, or COSO. The COSO framework summarizes each of the components of a company's internal control system, including (i) the control environment, (ii) risk assessment, (iii) control activities, (iv) information and communication, and (v) monitoring. Based on this evaluation, management determined that our system of internal control over financial reporting was not effective as of October 31, 2017.

A material weakness is a deficiency, or a combination of deficiencies, within the meaning of Public Company Accounting Oversight Board ("PCOAB") Audit Standard No. 5, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Management has identified the following material weakness which has caused management to conclude that as of October 31, 2017 our ICFR were not effective at the reasonable assurance level:

Due to a lack of processes in place to address personnel changes, controls over the Company's process of accounting for stock-based compensation failed to ensure the completeness of stock options and restricted stock grants in the Company's calculation of stock-based compensation expense.

Notwithstanding the existence of the material weakness in the Company's internal control over financial reporting, the Company's management believes that the consolidated financial statements included in this Form 10-K fairly present in all material respects the Company's financial condition, results of operations and cash flows for the periods presented.

Other than as noted above, there have been no changes in our internal control over financial reporting during the year ended October 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

This annual report does not include an attestation report of the Company's registered independent public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the

Company’s registered independent public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management’s report in the Annual Report on Form 10-K.

Item 9B. Other Information.

None.

PART III

The information required by Part III of Form 10-K under the items listed below are incorporated by reference from our definitive proxy statement relating to the 2017 Annual Meeting of Stockholders, which we will file with the SEC within 120 days after our October 31, 2017 fiscal year end.

Item 10 - Directors, Executive Officers and Corporate Governance.

Item 11 - Executive Compensation.

Item 12 - Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Item 13 - Certain Relationships and Related Transactions and Director Independence.

Item 14 - Principal Accountant Fees and Services.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) Financial Statements.

The financial statements required by item 15 are submitted in a separate section of this report, beginning on Page F-1, incorporated herein and made a part hereof.

(2) Financial Statement Schedules.

Schedules have been omitted because of the absence of conditions under which they are required or because the required information is included in the financial statements or notes thereto.

(3) Exhibits.

The following exhibits are filed with this report, or incorporated by reference as noted:

2.1	Agreement and Plan of Reorganization (incorporated by reference to Exhibit 2.1 to our Form 8-K filed with the Commission on December 7, 2016)
3.1	Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to our Quarterly Report on Form 10-Q filed on September 15, 2014).
3.2	Restated Bylaws (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on June 17, 2005).
3.3	Certificate of Designations, Preferences and Rights of the 0% Series A Convertible Preferred Stock of Majesco Entertainment Company (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on December 18, 2014)
3.4	Certificate of Designations, Preferences and Rights of the 0% Series B Convertible Preferred Stock of Majesco Entertainment Company (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on April 30, 2015)
3.5	Certificate of Designations, Preferences and Rights of the 0% Series C Convertible Preferred Stock of Majesco Entertainment Company (incorporated by reference to Exhibit 4.4 to our Current Report on Form 8-K filed on June 9, 2015)
3.6	Certificate of Designations, Preferences and Rights for 0% Series D Convertible Preferred Stock (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on October 20, 2015)
3.7	Certificate of Amendment to Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to our Form 8-K filed with the Commission on July 29, 2016)
3.8	Form of Certificate of Designation of Series E Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to our Form 8-K filed with the Commission on December 7, 2016)
3.9	Certificate of Amendment to Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to our Form 8-K filed with the Commission on April 7, 2017)
3.10	Articles of Merger (incorporated by reference to Exhibit 3.2 to our Form 8-K filed with the Commission on April 7, 2017)
3.11	Certificate of Designations, Preferences and Rights of the 0% Series E Convertible Preferred Stock (incorporated by reference to Exhibit 3.3 to our Form 8-K filed with the Commission on April 7, 2017)

3.12	Certificate of Designations, Preferences and Rights of Series F Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to our Form 8-K filed with the Commission on September 20, 2017)

4.1	Form of Common Stock Purchase Warrant issued to investors (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on December 18, 2014).
4.2	Form of Warrant (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the Commission on April 14, 2016)
4.3	Form of Warrant (incorporated by reference to Exhibit 4.1 to our Form 8-K filed with the Commission on September 20, 2017).
#10.1	Form of Non-Qualified Stock Option Agreement (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q filed on June 14, 2005).
#10.2	Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q filed on June 14, 2005).
10.3	Form of Personal Indemnification Agreement (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q filed on June 15, 2009).
10.4	First Amendment to the Confidential License Agreement for the Wii Console (Western Hemisphere), effective January 4, 2010, by and between Nintendo of America Inc. and Majesco Entertainment Company (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q filed on June 14, 2010).
10.5	Add On Content Addendum to the Confidential License Agreement for the Wii Console, effective November 2, 2009, by and between Nintendo of America Inc. and Majesco Entertainment Company (incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q filed on June 14, 2010).
10.6	Second Amendment to the Confidential License Agreement for the Wii Console, effective February 20, 2013, by and between Nintendo of America Inc. and Majesco Entertainment Company (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on February 21, 2013).
10.7	Intentionally omitted.
10.8	XBOX 360 Publisher License Agreement, effective September 13, 2005, by and between Microsoft Licensing, GP and Majesco Entertainment Company (incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q filed on September 14, 2011).
+10.9	Amendment to the XBOX 360 Publisher License Agreement (2008 renewal, etc.), effective September 1, 2009, by and between Microsoft Licensing, GP and Majesco Entertainment Company (incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q filed on September 14, 2011).
+10.10	Amendment to the XBOX 360 Publisher License Agreement (Russian Incentive Program, Hits Program Revisions), effective February 4, 2010, by and between Microsoft Licensing, GP and Majesco Entertainment Company (incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q filed on September 14, 2011).
#10.11	Amended and Restated 2004 Employee, Director and Consultant Incentive Plan (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on April 24, 2012).
#10.12	Amended and Restated 2004 Employee, Director and Consultant Incentive Plan (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the Commission on May 1, 2014).
10.13	Form of December 2014 Subscription Agreement between the Company and investors (incorporated by reference to Exhibit 10.1 to our form 8-k filed with the commission on September 21, 2015).
10.14	Form of December 2014 Registration Rights Agreement between the Company and investors (incorporated by reference to Exhibit 10.2 to our form 8-k filed with the commission on December 18, 2014).
#10.15	2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on April 1, 2015).
10.16	Form of May 2015 Subscription Agreement between the Company and Investors (incorporated by reference to Exhibit 10.1 to our form 8-k filed with the commission on May 21, 2015)
10.17	Form of May 2015 Registration Rights Agreement between the Company and investors (incorporated by reference to Exhibit 10.2 to our form 8-k filed with the commission on May 21, 2015).
#10.19	Separation Agreement between Majesco Entertainment Company and Jesse Sutton, dated as of July 27, 2015 (incorporated by reference to Exhibit 10.2 to our form 8-k filed with the commission on July 28, 2015)

10.20	Agreement of Conveyance, Transfer and Assignment of Assets and Assumption of Obligations between the Company and Zift Interactive LLC (incorporated by reference to Exhibit 10.1 to our form 8-k filed with the commission on August 6, 2015)
10.21	Stock Purchase Agreement for Zift Interactive LLC between the Company and Jesse Sutton (incorporated by reference to Exhibit 10.2 to our form 8-k filed with the commission on August 6, 2015)
10.22	Amendment Agreement for Subscription Agreement dated December 17, 2014 (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on October 1, 2015)
10.23	Amendment Agreement for Subscription Agreement dated May 15, 2015 (incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on October 1, 2015)
10.24	Form of Exchange Agreement dated September 30, 2015 (incorporated by reference to Exhibit 10.3 to our Current Report on Form 8-K filed on October 1, 2015)
#10.25	Executive Employment Agreement with Barry Honig (incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K filed on October 1, 2015)
#10.26	Restricted Stock Agreement with Barry Honig (incorporated by reference to Exhibit 10.6 to our Current Report on Form 8-K filed on October 1, 2015)
#10.27	Restricted Stock Agreement with John Stetson (incorporated by reference to Exhibit 10.7 to our Current Report on Form 8-K filed on October 1, 2015)
#10.28	Restricted Stock Agreement with Michael Brauser (incorporated by reference to Exhibit 10.8 to our Current Report on Form 8-K filed on October 1, 2015)

#10.29	Restricted Stock Agreement with Mohit Bhansali (incorporated by reference to Exhibit 10.9 to our Current Report on Form 8-K filed on October 1, 2015)
#10.30	Restricted Stock Agreement with Edward Karr (incorporated by reference to Exhibit 10.10 to our Current Report on Form 8-K filed on October 1, 2015)
#10.31	Restricted Stock Agreement with Andrew Kaplan (incorporated by reference to Exhibit 10.11 to our Current Report on Form 8-K filed on October 1, 2015)
10.32	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the Commission on April 14, 2016)
10.33	Placement Agency Agreement (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the Commission on April 14, 2016)
#10.34	Form of Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to our Form 8-K filed with the Commission on December 7, 2016)
10.35	Stockholders Agreement (incorporated by reference to Exhibit 10.4 to our Form 8-K filed with the Commission on December 7, 2016)
10.36	Voting Agreement (incorporated by reference to Exhibit 10.5 to our Form 8-K filed with the Commission on December 7, 2016)
10.37	Warrant Bill of Sale of Laboratory Equipment (incorporated by reference to Exhibit 10.6 to our Form 8-K filed with the Commission on December 7, 2016)
10.38	Lease by and Between the Company and Paradigm Resources LC (incorporated by reference to Exhibit 10.7 to our Form 8-K filed with the Commission on December 7, 2016)
10.39	Form of Subscription Agreement (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the Commission on December 16, 2016)
10.40	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the Commission on December 16, 2016)
10.41	Form of First Amendment to Agreement and Plan of Reorganization (incorporated by reference to Exhibit 10.3 to our Form 8-K filed