POLARITYTE, INC.
Form 10-K
January 14, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

[X] Annual Report Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

For the fiscal year ended October 31, 2018

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.)

123 Wright Brothers Drive

Salt Lake City, Utah 84116

(Address of principal executive office)

Registrant's telephone number, including area code (385) 237-2279

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes [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	[X]
Non-accelerated filer	[ ]	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, 2018, was $192 million.

The outstanding number of shares of common stock as of January 7, 2019, was 21,456,643.

Documents incorporated by reference: None.

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As used in this annual report, the terms "we", "us", "our", "the Company", and "PolarityTE" mean PolarityTE, Inc., a Delawar corporation, and our wholly owned Nevada subsidiaries (direct and indirect), PolarityTE, Inc., PolarityTE MD, Inc., PolarityTE RD, Inc., Utah CRO Services, Inc., IBEX Preclinical Research, Inc., and IBEX Property LLC., unless otherwise indicated or required by the context.

PolarityTE, the PolarityTE Logo, POLARITYRD, POLARITYIS, POLARITYRX, "WELCOME TO THE SHIFT", WHERE SELF REGENERATES SELF, COMPLEX SIMPLICITY, IBEX, SkinTE, OsteoTE, CartTE, AdipoTE, MyoTE, NeuralTE, AngioTE, LiverTE, UroTE, and BowelTE are all trademarks or registered trademarks of PolarityTE. Solely for convenience, the trademarks and trade names in this report may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that we will not assert, to the fullest extent under applicable law, our rights thereto.

Forward-looking Statements

This Annual Report on Form 10-K contains forward-looking statements. Risks and uncertainties are inherent in forward-looking statements. Furthermore, such statements may be based on assumptions that fail to materialize or prove incorrect. Consequently, our business development, operations, and results could differ materially from those expressed in forward-looking statements made in this Annual Report. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Annual Report are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “target,” “would,” or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the initiation, timing, progress, and results of our research and development programs;
- the timing or success of commercialization of our products;
- the pricing and reimbursement of our products;
- the initiation, timing, progress, and results of our preclinical and clinical studies;
- the scope of protection we can establish and maintain for intellectual property rights covering our product candidates and technology;
- estimates of our expenses, future revenues, and capital requirements;
- our need for, and ability to obtain, additional financing in the future;
- our ability to comply with regulations applicable to the manufacture, marketing, sale and distribution of our products;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- developments relating to our competitors and industry; and
- other risks and uncertainties, including those listed under Part I, Item 1A. Risk Factors.

Given the known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by our forward-looking statements, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

Item 1. Business

PolarityTE - Welcome to the SHIFT

PolarityTE Inc., headquartered in Salt Lake City, Utah, is a young and growing commercial-stage, biotechnology company founded in 2016 - and we believe the first of its kind. We are focused on the design and development of novel technology platforms that promote the regeneration of complex, cellular-derived tissue substrates and the propagation of self-organizing composite systems. We have developed, and will continue to evolve these technologies and platforms through uniquely targeted and yet comprehensive approaches to the interactome. The interactome is the complete set of physical interactions between molecules within a cell that underlies most genotype-to-phenotype relationships and modulates nearly all complex biological pathways and cellular networks seen in living systems. Understanding this, we believe that to effectively deliver our advanced technologies to patients we must not simply deliver products, but rather robust platform systems and evolving technology foundations that are intelligent, multi-functional, and able to adapt and evolve. Over the last year we have established and advanced three of our pipeline programs consisting of our core “TE” program, (which includes our first commercial product, SkinTE), our Related Technology Derivative program (“RTD”), and our Advanced Research Center program (“ARC”).

A glossary is provided at the end of this Item 1, which you may find helpful in reading this report.

Vision

We aspire to be a global biotechnology company that provides superior, tangible, and pragmatic platform technologies that provide superior results to patients, while reducing costs and promoting improved health economics for patients, providers, and payors. We believe this can be accomplished through our pursuit of complex simplicity, which embodies the development of robust cell/tissue-derived therapies that can be efficiently produced and deployed. PolarityTE is committed to delivering transformative technology that positively impacts humanity.

PolarityTE was founded by a dedicated group of doctors and scientists from The Johns Hopkins University School of Medicine, who left to become part of something bigger. Something that could transform the future of medicine. We believe that living systems require more than a simple singular input (for example a growth factor, stem cell, or nano-particle), to produce a complex output. Therefore, we took a different direction and developed multi-tiered platform technologies that propagate the necessary complex substrate required for regenerating fully-functional tissue, such as skin, bone, cartilage, muscle, blood vessels, and neural elements, as well as solid and hollow organ composite tissue systems. We have engineered and developed our regenerative materials and core tissue substrate technology platforms to allow us to induce, maintain, and promote the integrated polarity, organized assembly, and interface development of cells and tissues, so that they replicate regenerative healing in the body and are not seen as foreign by

the immune system.

The core technology of TE products is minimally polarized functional units (“MPFUs”) consisting of self-complexing intelligent regenerative materials (“SCIRM”). SCIRM within an MPFU form polarizing, multi-cellular aggregates that act as an intrinsic, regenerative bio-reactor capable of expanding, proliferating, and synthesizing cells, materials, factors, or systems necessary for regenerating full-thickness, three-dimensional tissue. The TE products we develop begin with the patient’s own tissue to produce SCIRM that address the specific tissue or system needed for the patient’s care. Our product pipeline focuses on the development of regenerative products for a variety of tissue types and organ systems that are commonly altered, injured, or destroyed by a variety of diseases, pathologies, traumatic events, and medical interventions.

SkinTE, our first tissue product, was registered with the United States Food and Drug Administration (FDA) in August 2017, and is now commercially available for the repair, reconstruction, replacement, and regeneration of skin in patients who have a need for treatment of acute or chronic wounds, burns, surgical reconstruction events, scar revision, or removal of dysfunctional skin grafts. We are pursuing a regional plan for commercial rollout that began in late October 2018, and we now have 24 sales representatives in the field marketing SkinTE.

OsteoTE is designed to utilize the patient’s bone to repair, reconstruct, replace, supplement, or regenerate bone damage or defects. We registered OsteoTE with the FDA in December 2018. We are preparing for the first application of the product in a clinical setting, which we are endeavoring to achieve in the first half of 2019.

Human cells, tissues and cellular and tissue-based products ("HCT/Ps") are governed by specific FDA regulations the provide for a registration pathway that is different than the pathway for traditional drug candidates. SkinTE and OsteoTE are both registered as HCT/Ps under Section 361 of the Public Health Service Act.

We have a number of additional TE products under development. The following table illustrates the status of our TE product pipeline.

RTD and ARC represent research and development of new science and product opportunities based on what we learned while developing the TE platform. RTD is focused on altered state analytes for the generation of composite materials that can be utilized for the augmentation, modulation, and regulation of cell and tissue-derived systems. ARC is focused on the design and development of gene transfer, small molecule synthesis, composite therapeutics, and alteration of self-propagating cell/tissue-derived bioreactors.

The following table shows the research projects we are pursuing through RTD and ARC programs.

We have significant research facilities and a well-educated and skilled team of scientists and researchers. These resources are highly beneficial to the work we are doing on our TE products and in RTD and ARC. We also offer research services to unrelated third parties on a contract basis, which we offer under the trademark POLARITYRD. Contract research services help us defray the costs of maintaining a first-rate research facility and allow us to meet companies pursuing new technologies that may be opportunities for collaborative or strategic relationships going forward.

Limitations to Clinical Standards of Care, Regenerative Technologies and Tissue Substitutes

Clinical Standards of Care for Tissue Replacement

While both the literature and current practice indicate that the clinical standard of care remains the replacement of "like with like" (i.e. skin for skin, bone for bone, cartilage for cartilage), to date, many regenerative technologies, tissue engineered products and wound care products, have focused on "large scale manufacturable materials" and "off the shelf"

designs, as opposed to employing a more patient-specific approach. Many of these types of products are xenografts, allografts, or alloplasts in part to allow for abundant sources of raw materials for the products. We believe these products merely act as synthetic cell/tissue substitutes, which are incapable of delivering true regeneration or regenerative potential of complex tissue systems and, therefore, why such products continue to fail to deliver results that are comparable to an autologous tissue graft (i.e. skin graft, bone graft, cartilage grafts etc.).

We believe that historically the fields of regenerative medicine, tissue engineering, and, to some extent, cell-therapy have remained characterized by tremendous potential and promise for the future yet continue to remain limited by the pursuit of "artificial and/or synthetic" approaches that are overly reductionist, and thus fail to deliver "complete systems." Some current regenerative medicine approaches try to isolate a single cellular population to regenerate a tissue, such as adipose-derived stem cells. Others try to deliver a molecule to manipulate cell function, such as driving cell growth and expansion, or coax one cell type to become another. Another approach tries to create some form of a scaffold that resembles the target tissue with specific properties designed to mimic that tissue. We believe these approaches incorrectly focus on the synthesis or engineering of singularities (i.e., a type of cell, a type of molecule, 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.

Real Limitations: Using Skin as an Example

Current clinical standards and practice adhere to the concept that 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 an allograft, use the patient's own skin in a skin graft, or apply a variety of skin substitutes 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. However, full-thickness harvest of skin inherently also 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. Because of this absolute limit on how much autologous full-thickness donor skin can be harvested without leaving behind a non-closable wound, medical professionals can only harvest small elliptically-shaped pieces of such skin from areas of redundancy which is termed full-thickness skin graft (FTSG).

It is because there remains only a finite supply of FTSG donor material and sites that medical professionals often rely on the harvest of split-thickness skin grafts (STSG) for coverage of voids of the integument to get better coverage and more skin. STSGs, however, do not represent the true anatomy or function of native skin because such graft harvest procedures only take the top 1/10,000th of an inch of the patient's own skin and therefore do not capture all the necessary cellular and tissue elements and structures required for the regeneration of normal skin (Figure I).

Figure I. Common Site Locations for Skin Graft Harvesting. The left figure depicts the process and common location of where a split-thickness skin graft (STSG) is harvested from with a vibrating razor that shaves off the very top 1/10,000th of an inch of skin as depicted in the skin cross section. STSGs are often then meshed (pocked with holes like a screen door) to allow for improved stretch over surfaces and to permit fluid drainage to pass through the graft and avoid build up under the graft like a bubble. The right figure depicts the common sites where full-thickness skin grafts are harvested from patients. Note that these areas are often hidden in anatomic locations where there are creases

or folds to place the resulting scar from primary linear closure in aesthetically considerate places.

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After the failure to harvest all the necessary structures, cellular elements and tissue interfaces from the STSG donor site, the patient is 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 results in dysfunctional, painful scar tissues and lifelong morbidities.

Because of the limits of STSG and FTSG and the type of procedures required for such harvests, industry has continued to investigate skin substitutes and skin alternatives that can be used in place of native cutaneous substrate. Among these alternatives or options are a culture form of manipulated autograft, allograft, xenograft, and alloplast. None of these substitutes have been able to replicate the appearance of native skin or regenerate full-thickness skin or the cutaneous appendages (hair follicle, sweat gland, sebaceous glands, etc.), which are necessary for the development of full-thickness, functionally polarized, hierarchically organized skin.

The forgoing skin example shows that the traditional approach to regenerative medicine that competitors employ is anchored within tissue engineering algorithms that—while cost-effective because of mass production and scalability—are incongruent with living cells, dynamic tissues, and reactive systems, and, therefore, fail to produce outcomes that effectively heal and alleviate suffering.

Our Solution

We believe that our bio-generative SCIRM technology platforms are fundamentally new and inherently promote a drastically different approach to current conventional cell therapy efforts, regenerative technologies, and current products. Therapeutic singularities such as a single stem cell, a single growth factor, a single scaffold, or a combination of such singularities are unable to engineer a complex tissue in vitro for subsequent deployment into living systems. Recognizing the complexity of tissue regeneration as absolutely requiring cell-to-cell and cell-to-tissue polarity, interfaces, gradients, modulation, and multiplex system interactivity and real-time integration, we embrace a substantially more complete form of tissue regeneration that is biologically sound and evolutionarily cohesive with the dynamics of living systems.

We have designed and developed an entirely new form of regenerative cell/tissue therapy platform based on SCIRMs organized in complex MPFUs that when deployed into a wound or tissue defect undergo integrative regenerative healing within the system in which it was deployed by effectively acting as its own bioreactor and thus expanding, proliferating, and synthesizing those cells, materials, factors, and systems necessary for full-thickness generation and regeneration across a spectrum of tissue substrates and organ systems.

Our technology platform is based on complex living tissue systems and the interfaces that drive cell-tissue-matrix polarization events. We recognize there is something powerful, reactive, and dynamic controlling tissue generation,

which is the interactome; the whole set of interactions a cell is impacted by, both intra and extra-cellularly. Cells rarely act on their own to create functional repair or regeneration, but rather tissues have functionally-organized cellular aggregates called appendages (almost like small organs), which run, and even regenerate, the composite tissues they are a part of when altered, stimulated, and processed in certain ways.

We believe each person's cells and tissues have vastly different and dynamic profiles (genes, RNA, proteins, metabolites, etc.) and, therefore, different requirements when it comes to the regenerative potential 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 MPFUs, which contain polarizing multi-cellular aggregates capable of expanding, proliferating, and synthesizing those cells, materials, factors 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, 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. 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 and tissues 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.

Stem Cell Niche Utilization for Self-Propagating and Self-Organizing Functional Tissues: We utilize techniques for capturing the "stem cell niche," the microenvironment within a 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 targeted tissue. This is designed to minimize painful scarring, lesions, and other growth anomalies that often accompany autologous regeneration without the stem cell niche. This design approach also allows regeneration of the tissue's normal layers and appendages and provides 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 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.

The Person as the 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 for delivering product to the patient, as our manufacturing process does not involve growing cells in an industrial, synthetic bioreactor. In addition, utilization of the patient as the bioreactor during cellular tissue propagation further reduces relative costs, which are passed onto patients, providers, and payor systems.

Reducing Barriers ~ Arming More Healthcare Providers with Tangible and Pragmatic Technologies: We believe that novel technologies must thrive in the trenches of medicine and be easily utilized by a full spectrum of providers to truly deliver value and make an impact in patients' lives. We recognize that a technology that is limited by who can administer it or setting of care where it can be used creates barriers and limits access to those who need it. Our goal is to design and develop therapies, technologies and products which overcome these limits by delivering new standards of care, which are easily utilized by ALL providers, across ALL settings of care.

Our Competitive Strengths

We believe that our key competitive strengths include the following:

Pursuing the Development of a Complete System that Rivals the Clinical Standard of Care: We believe that we have designed and developed a technology platform that may displace the current clinical standard of care in complex tissue regeneration, reconstruction and/or replacement efforts. Currently, the clinical standard of care for the reconstruction of complex tissue voids relies on autologous tissue transplantation. For example, critical defects of the

skin, bone, cartilage and other tissues are most appropriately treated through the autologous graft or flap coverage. While these efforts remain the clinical standard of care in most settings, such processes result simply in the transplantation of tissue from one area of the body to another region. Such movement of autologous tissue materials often provides “coverage” but does not result in significant expansion of the cellular entities or tissue substrates. After the limited ability to expand beyond 1:1 – 1:4 ratios, donor site size and morbidity must be taken into consideration when harvesting autologous tissues. Understanding these limitations that exist within the clinical standard of care, we have sought to design and develop an autologous tissue that requires minimal donor site and can be significantly expanded on the patients themselves.

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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. 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. We believe our platform technology will produce superior outcomes for providers and patients.

Deep Pipeline of Additional Potential Applications. We believe our platform's capabilities can be extended across many indications, including skin, 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 or replaced due to excessive loss from trauma, surgery, or congenital defects. We believe the significant number of product opportunities afforded by our platform will generate sustainable growth opportunity.

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

Scalable Manufacturing and Distribution Capability. Because we believe our technology can be applied across a variety of tissue substrates, we believe we are able 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 stand-alone 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).

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 regional commercial rollout of SkinTE commenced in late October 2018, and is 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. Along with the treatment of severe wounds and burns, we intend to market SkinTE for chronic wounds, surgical reconstruction events, including cosmetic and elective surgeries, and for scar revision or the removal of dysfunctional events.

Based on our internal analysis of annual patient volumes and relative wound sizes, we estimate the annual addressable markets within the United States for burn wounds, surgical reconstruction and traumatic wounds, and chronic wounds are $3 billion, $23 billion, and $24 billion, respectively. These markets are largely contained within the approximately 127 burn centers, 600 level I-III trauma centers, and greater than 2,000 wound care centers and clinics within the United States.

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 two additional TE core products, OsteoTE and CartTE, for FDA registration using the 361 HCT/P pathway that does not require FDA approval prior to market entry. 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 these two new products over the next two years.

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 integrated 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.

SkinTE

General

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 application of SkinTE is patient-specific and designed for a single deployment. 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, chronic burn wounds or scars, acute burn wounds, scars of the integument, and defects from medical or surgical resection or reconstruction events that 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 Statistics 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.

During the fiscal year ended October 31, 2018, we established the product logistics, interactions with hospitals, and our clinical operations and market access teams, so that we can handle all aspects of manufacturing and commercializing an autologous skin product. During this limited market release we serviced over 50 patients. We have no reported adverse reactions from any of the applications of SkinTE. We hired our first sales force and have been building out our first regional release since October 2018. The full national release of SkinTE is planned for 2019.

SkinTE is 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 an article 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 or Regulatory Approval of Our Product Candidates and Other Government Regulations."

Our Wound, Burn and Skin Reconstruction Treatment Solution – SkinTE

We described in detail above the real limitations of the standard of care in tissue regeneration as applied to skin. We 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.

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. We are aware of several companies focused on the wound market, including Avita Medical, Integra LifeSciences, Wright Medical Group, MiMedx, Osiris, Organogenesis, Allosource, MTF Biologics and Vericel. Any advances in regenerative medicine by a competitor may be used to develop therapies competing against SkinTE. However, to our knowledge SkinTE is the only fully autologous homologous skin regeneration product available for the treatment of wounds and functional losses of skin that enables the patient to regenerate his or her own skin with all the functions of full thickness skin, including hair, sweat glands, sebaceous glands, capillary beds, and all layers of skin, including epidermis, dermis, hypodermis, and subdermal fat. We believe SkinTE produces a superior result for patients that challenges the current standard of care and the therapies offered by other companies in the wound care market.

SkinTE is composed of small viable cellular and tissue-based units, which we call MPFUs, that retain all 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.

Unlike 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 the important layers of the skin as well as the necessary cutaneous appendages for the development of functionally-polarized, hierarchically organized autologous, homologous skin.

The SkinTE Process

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 base. 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 the pre-paid/pre-completed shipping labels, and a one-touch, cool pack 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. We have observed, however, that most physician 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.

Selling SkinTE

In 2018, we completed the first two stages of our SkinTE commercial roll-out strategy. The first was the limited market release phase, which focused on generating trial/ utilization with the goal of securing real-world clinical data and experience to prepare the organization and product for a broader commercial release. The second stage was the regional market release that began in late October 2018 with the additional build out of our commercial organization to establish SkinTE with major burn and trauma centers across the United States. Each hospital targeted requires an assessment by their Value Analysis Committee (VAC) prior to commencing commercial SkinTE deployment. This is a formal process that can take approximately 4-6 months to complete. After VAC approval, terms of the SkinTE purchase agreement are finalized and patient identification and treatment initiates, which can take several months.

Once purchase agreements are in place, our sales team and clinical operations staff maintain close contact with the facility to support the initial therapeutic applications of SkinTE. Due to the transformational nature of the product, this relationship helps to ensure the facility's ability to effectively incorporate SkinTE into their existing burn or wound management protocols.

The selling process to achieve an initial sale averages between six and nine months. The sales process is affected by several factors, including the incidence and nature of burn and wound care cases at target accounts and the receptiveness of the health care providers to adopt a new therapeutic approach.

Once the first deployment of SkinTE has occurred, there is generally a delay before subsequent deployments at the same facility. The timeframe is typically between three and six months, as we have found physicians appear to pause until the clinical outcome of the first application can be fully appreciated. To help decrease the time between the first and second deployment, we are actively pursuing multiple randomized controlled clinical trials to further illustrate SkinTE clinical outcomes and overall value proposition. Furthermore, as SkinTE gains in utilization and acceptance by health care providers, the lead time to first sale should decrease as information on SkinTE and clinical results are more broadly disseminated in the medical community.

SkinTE is billed by the square centimeter size of the skin defect to be treated, as is standard for skin wound treatments. Because SkinTE is created from the patient's own tissue, we can price below other treatment options like skin substitutes. Unlike other treatment options, SkinTE can deliver permanent, functional full-thickness skin replacement with only one application, compared to the multiple procedure regimens common for split-thickness skin grafts, full-thickness skin grafts, autograft, allograft, and alloplast therapies.

Payment and Reimbursement

Inpatient Setting. In the inpatient setting, facility reimbursement is dictated by the associated bundled Medicare Severity-Diagnosis Related Group (MS-DRG) payment for the entire episode of care under the Medicare Inpatient Prospective Payment System (IPPS). The bundled DRG facility payment is determined by the DRG code applied, which factors in the primary diagnosis and patient characteristics, such as co-morbidities present on admission. In this scenario, all products and supplies utilized during the episode of care are paid for with the bundled DRG facility payment, including products like SkinTE. In addition, physician services are billed and reimbursed outside of the bundled DRG facility payment, including any procedures performed during that admission, which are billed for and reimbursed utilizing Current Procedural Terminology (CPT) codes associated with the respective procedures. SkinTE has been used within the inpatient setting and reimbursed underneath the applicable DRG bundled facility payments, and to our knowledge all associated procedures billed for outside the DRG as physician services with CPT codes have been reimbursed, as well.

Hospital Outpatient Department (HOPD) and Ambulatory Surgical Center (ASC) Setting. Like the inpatient setting, bundled Ambulatory Classification Payment (APC) facility payments are received under the Medicare Outpatient Prospective Payment System (OPPS) for services and supplies utilized during episodes of care within Hospital Outpatient Departments (HOPDs) and Ambulatory Surgical Centers (ASCs). In these settings, bundled APC facility payments are dictated by the procedure(s) performed and billed for through the appropriate CPT codes. SkinTE has been used in these settings and covered with the associated bundled APC facility payments and physician services

have been paid for outside of the APC payment utilizing CPT codes to bill for the associated procedures. In addition, we are working towards applying for pass-through status, which would allow SkinTE to be billed for outside of the bundled APC facility payment.

Office or Clinic Setting. In contrast to the inpatient, HOPD, and ASC settings, care provided in a physician office or clinic is reimbursed based on individual Healthcare Common Procedure Coding System (HCPCS) and CPT codes, facilitating reimbursement for the specific products utilized and procedures performed during the clinic visit. The CPT codes used in the setting are the same or similar to the CPT codes used to bill for physician services in the other settings of care. In 2018, providers utilized HCPCS Q code 4100 (skin substitute not otherwise specified) to bill for the use of SkinTE in the office. Of the providers that used SkinTE in the office or clinic setting throughout 2018, to our knowledge all were reimbursed utilizing Q4100. Early in 2018 we filed an application with The Centers for Medicare and Medicaid Services (“CMS”) for a unique HCPCS SkinTE Q code. We were successful and received Q code 4200, which was effective January 1, 2019. Therefore, beginning January 1, 2019, providers using SkinTE in the office or clinic setting can use Q4200, the unique SkinTE specific Q code, when billing for the product. Reimbursement rates in the Medicare Hospital Outpatient Payment System (HOPPS) vary based on whether the product is designated a low-cost product or high cost product. Assignment is based on average selling Price (ASP) as reported to CMS. New Q codes with limited ASP on file with CMS are automatically assigned to the low-cost product category. We reported our first ASP in October 2018, so SkinTE’s Q code will initially be designated a low-cost product limiting the reimbursement to $483 for a single application in a clinic setting. We will continue to report ASP and work with CMS on this process because we believe that SkinTE can qualify as a high-cost product reimbursable at $1,548 for a single application in a clinic setting.

Clinical Studies

We initiated a head-to-head trial comparing SkinTE to the split-thickness skin graft, the clinical standard of care, in the first quarter of 2018. Enrollment is in progress and we expect it will be completed in 2019. In parallel with this clinical trial, we have been accumulating clinical results on non-trial patients from our market release for application of SkinTE for various indications, including acute burn, burn reconstruction, surgical reconstruction, scar revision, and chronic wounds, such as diabetic foot ulcers and venous stasis ulcers. Some of these cases have been presented independently by, or in collaboration with, providers at national conferences including the 2018 American Professional Wound Care Association Conference, the 2018 Diabetic Foot Global Conference; 2018 American Society of Plastic Surgery - The Meeting; 2018 Symposium on Advanced Wound Care; and, the 2018 Innovations in Wound Healing. We believe peer-reviewed publication of these results will occur in 2019. Following very encouraging pilot results, preparations are underway to list on clinicaltrials.gov and enroll patients in two separate randomized controlled trials in diabetic foot ulcers and venous stasis ulcers, which constitute the most common causes of chronic lower extremity wounds that affect over a million Americans. These trials will each treat over 100 patients, compare SkinTE to the standard of care, and evaluate the efficacy and cost benefit of a single application of SkinTE providing important reimbursement information for the Centers for Medicare & Medicaid Services and outpatient applications. These will be multi-center trials that will enroll throughout 2019.

OsteoTE

We applied our platform technology to develop OsteoTE, our autologous, homologous bone regeneration product. OsteoTE is designed 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. We have conducted several preclinical large animal studies using established bone treatment models, including critical-sized cranial bone defects and spinal fusion models. The preclinical results for OsteoTE are very encouraging and parallel the results seen with SkinTE – the ability to regenerate complex tissues recapitulating the structure and function of the native tissue from which it was created. 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

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.

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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, or humerus. We believe OsteoTE can be deployed in numerous indications in the Craniomaxillofacial, Foot and Ankle, Hand and Wrist, Hip and Pelvis, Spine, Long Bone and Dental markets. Each of these markets presents a potential multi-billion dollar market opportunity for OsteoTE. According to a report issued by the research firm MarketsandMarkets, 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 registered OsteoTE with the FDA as a 361 HCT/P tissue-based product in December 2018, and our goal is to commercialize OsteoTE through a phased release starting in early 2019.

CartTE

With our CartTE product candidate, we are aiming to deliver on a long-imagined product—one that can tackle the highly prevalent and debilitating process of osteoarthritis 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. We have initiated the preclinical studies needed to evaluate cartilage replacement in critical-sized defects and will continue to evaluate CartTE’s potential in various cartilage replacement indications.

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. In 2016, according to the American Society for Aesthetic Plastic Surgery, approximately 100,000 fat transfer procedures were performed when combining the breast, buttocks, and face, including a 41% increase in fat transfers to the breast (American Society for Aesthetic Plastic Surgery).

AngioTE to address vascular regeneration including microscopic capillary networks all the way up to great vessel replacement. Approximately 400,000 coronary bypass grafts are performed per year in the US according to the CDC. In addition, 650,000 patients per year in the US and 2 million patients per year worldwide are affected by end stage renal disease (ESRD), who may benefit from placement of hemodialysis access, including arteriovenous fistula creation.

NeuralTE for peripheral nerve injuries of the extremities, as well as for patients with neuromas 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. According to the CDC, 1.6% of US adults are diagnosed with liver disease, which fails to recognize the portion that are at risk of liver disease, or those with distant metastases within their liver that may undergo resection of a significant portion of the organ.
BowelTE to deliver an optimized autologous construct to aid in the regeneration of bowel tissue. According to the CDC, approximately 10 million outpatient procedures and 6 million inpatient procedures were performed on the digestive system in 2010. Anyone undergoing surgical repair or anastomosis of the bowel could potentially benefit from a product delivering bowel regeneration.

We believe a number of the product candidates described above will be suitable for marketing 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 like that for SkinTE. Any products not suitable for the 361 HCT/P regulatory pathway will need to go through the FDA pre-market approval process, which usually involves the filing, as applicable, of an Investigational New Drug Application or Biologics License Application that will require further preclinical and clinical testing and substantially extend the time of bringing the product to market.

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 that allows us to establish fast, effective, and cost-efficient systems. Adopting a common manufacturing process enhances our production capacity and expansion strategy, and at the same time potentially reduces 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, process and manufacture the cell/tissue product, and perform outgoing quality control and quality assurance work prior to shipping. 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 daily 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 scalability. In

compliance with ISO standards and cGTP, 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 operate a facility in Salt Lake City, Utah, consisting of approximately 178,528 square feet. We use this facility for product manufacturing and research and development work. We intend to establish over time remote manufacturing facilities we call “nodes” at locations close to health care providers we believe will be significant purchasers of our products. One of the significant benefits of nodes is the creation of manufacturing redundancy, so that production can be sustained if one of our manufacturing facilities is unable to produce due to natural disaster or other cause. We also believe nodes have the potential to lower shipping costs, which would improve our gross margin on products sold in the areas where the nodes are located.

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. In the past year, we have signed agreements with major suppliers to reduce costs, ensure faster fulfillment, and increase our bulk purchasing capability. We have identified alternate suppliers and, where appropriate, supply alternatives for any sourcing challenges.

Intellectual Property

As we advance our platform technology, our RTA, and our RTDs, we seek to apply a multilayered approach for protecting intellectual property relating to our innovation – with patents (utility and design), copyrights, trademarks, as well as know-how and trade secret protection.

We do not currently own any granted patents, but have a number of patent applications pending in the U.S. and around the world. We have four pending U.S. non-provisional utility patent applications relating to MPFUs – U.S. Serial Nos. 14/954,335; 15/650,656; 15/650,659; and 16/165,169. Each of these applications claims priority to a U.S. provisional application filed on December 2, 2014. We have one Patent Cooperation Treaty (PCT) International Patent Application (PCT International Publication No. WO 2016/089825) and national phase applications have been entered in OAIP, ARIPO, Australia, Brazil, Canada, China, Colombia, Costa Rica, Eurasia, Europe, Great Britain, Hong Kong, Israel, India, Indonesia, Japan, South Korea, Mexico, Malaysia, New Zealand, Philippines, Singapore, South Africa, Thailand, United Arab Emirates, Ukraine, Vietnam. These applications, as well as our pending non-public applications (which will only be identified after publication), are proceeding along the normal timeline of patent office examination in each respective country. The receipt of office actions from patent offices is part of the examination process, as is our response to such office actions. To date, no application has been abandoned or lapsed. Nor has any application been rejected in a manner that forecloses the possibility of receiving a granted patent from that same application. All our patent applications are currently alive and actively being pursued. We cannot predict when or where the first set of patent claims might be granted, nor can we speculate on the scope of claims in such a future patent.

We seek to complement the protection of our innovation with a portfolio of trademarks and service marks in the United States and around the world. The POLARITYTE trademark has been registered in the United States, Australia, Brazil, China, the European Union, Iceland, India, Israel, Japan, South Korea, Malaysia, Mexico, Norway, the Russian Federation, Singapore, Switzerland, Taiwan, and Turkey. Additional registered trademarks in the United States include our logo, WELCOME TO THE SHIFT, and WHERE SELF REGENERATES SELF.

In striving to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business, we also rely heavily on trade secrets relating to our proprietary technology 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.

Competition

The regenerative medicine industry is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on intellectual property. We face substantial competition from companies developing and selling regenerative medicine products, as well as academic research institutions and governmental agencies and public and private research institutions.

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 our programs are likely to be their efficacy, safety, convenience, price, and the availability of reimbursement from government and other third-party payers.

RTD and ARC

We believe our TE platform technology is a revolutionary approach to regenerative medicine in and of itself, but we also find that it suggests new areas of inquiry and potential innovation. To this end, we have active research we are pursuing through our Related Technology Derivatives (RTD) and Advanced Research Center (ARC) programs. RTDs can be designed to augment the application and regenerative outcomes of our pipeline products or be used as standalone products. ARC programs focus on the improvement of RTDs as well as augmentation of our pipeline products. We are excited about the recent advancements in the field of gene therapy and are interested in the possibility of genetically altering our products, including SkinTE, to better treat and possibly cure rare diseases, such as Epidermolysis Bullosa, a genetic condition that causes the skin to be very fragile and to blister easily.

Contract Research Services

In May 2018, we purchased the assets of a preclinical research sciences business and related real estate from Ibex Group, L.L.C., a Utah limited liability company, and Ibex Preclinical Research, Inc., a Utah corporation. We acquired these assets to accelerate research and development of our TE product candidates, and now operate the business as IBEX to advance our product development and deliver preclinical research services to third parties. The business consists of a “good laboratory practices” (GLP) compliant preclinical research facility that is USDA registered and includes vivarium, operating rooms, preparation rooms, storage facilities, and surgical and imaging equipment. The real property includes two parcels in Logan, Utah, consisting of approximately 1.75 combined gross acres of land, together with the buildings, structures, fixtures, and personal property located on the real property.

PolarityTE RD offers a complimentary array of research services to those offered through IBEX, providing access to experimental planning, histology, and in vivo and in vitro imaging, including micro-ct. The PolarityTE RD arm is well equipped with state of the art equipment and sophisticated research staff that provide a range of services including veterinary and preclinical services, advanced imaging, biomedical engineering and validation, molecular biology assays and proteomics analyses.

Government Regulation

Government authorities 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 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, or biological products under Section 351 of the PHS Act (42 U.S.C. § 262) 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:

- It must be minimally manipulated;
- It must be intended for homologous use;
- 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
- 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 and OsteoTE qualify as 361 HCT/P tissue-based products, and believe that our core "TE" products in development (e.g., CartTE) 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. Our Salt Lake City manufacturing site was inspected in July 2018 and we received certain inspectional observations on Form FDA 483 following that inspection. We responded to those observations and are continuing a productive dialog with the FDA.

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, 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; 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 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 U.S. Department of Justice 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; 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 research, development and 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 research, development and 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 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. To better track utilization, we filed an application with CMS for a unique HCPCS SkinTE Q code. We were successful and received Q code 4200, which was effective January 1, 2019.

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. 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 or criminal penalties. Since we do not submit claims electronically to payers, we do not believe we are a covered entity under HIPAA.

Transparency Laws

The Patient Protection and Affordable Care Act imposes, among other things, 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 the FDA, and 361 HCT/P autologous tissue sources are not expressly addressed by this law.

USDA

The Company and its subsidiaries conduct preclinical research and development, which is regulated by the United States Department of Agriculture (USDA) Animal and Plant Health and Inspection Service (APHIS) and must be performed in compliance with the Animal Welfare Act, Animal Welfare Regulations, and Animal Care Policies. The Company and each of its subsidiaries that conduct preclinical research have in place Institutional Animal Care and Use Committees to oversee compliance with the animal care and use program and report accordingly to the USDA on an at least a semi-annual basis. All performance sites that maintain USDA-covered species are actively registered as USDA research facilities.

Employees

We had approximately 123 full-time employees as of October 31, 2018, all of whom are in the United States. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

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, changed its name to “PolarityTE MD, Inc.,” and remains a wholly-owned subsidiary of PolarityTE.

Prior to the acquisition of PolarityTE NV, Majesco DE developed and published a wide range of video games on digital networks through its Midnight City label. On May 2, 2017, Majesco Entertainment Company, a Nevada corporation and wholly owned subsidiary of PolarityTE (“Majesco NV Sub”), was formed, into which all 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 the right, title, and interest in and to Majesco NV Sub’s business of developing, publishing, and distributing video game products.

In May 2018 we acquired assets of a preclinical research and veterinary sciences business and related real estate, which we now operate through our subsidiary, Ibex Preclinical Research, Inc. The aggregate purchase price was $3.8 million, of which $2.3 million was paid at closing and the balance satisfied by a promissory note payable to the Seller with an initial fair value of $1.22 million and contingent consideration with an initial fair value of approximately $0.3 million. As a result, we have significant research facilities and a well-educated and skilled team of scientists and researchers that comprise the contract research segment of our business. These resources are highly beneficial to the work we are doing on our TE products and in RTD and ARC. We also offer research services to unrelated third parties on a contract basis, which we offer under the trademark POLARITYRD. Contract research services help us defray the costs of maintaining a first-rate research facility and allow us to meet companies pursuing new technologies that may be opportunities for collaborative or strategic relationships going forward.

Contact and Available Information

Our principal executive offices are located at 123 Wright Brothers Drive, Salt Lake City, UT 84116 and our telephone number is (385) 237-2279. Our website address is www.polarityte.com.

We file annual, quarterly, and current reports, as well as proxy statements and other information with the Securities and Exchange Commission, which is 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 Securities and Exchange Commission ("SEC") are available on the SEC's website as www.sec.gov free of charge.

Glossary– for ease of reference, the following provides simplified explanations for some of the terms used herein. This Glossary is not intended to define these terms as they may be used in other documents, authored by PolarityTE or otherwise

Allogeneic – relating to tissues or cells that are genetically dissimilar and hence immunologically incompatible, although from individuals of the same species.

Allogeneic tissue rejection – the rejection of foreign tissue after the body develops an immune response to it.

Allografts – tissue grafts derived from a donor of the same species as the recipient but not genetically identical, e.g. tissue grafts derived from cadavers.

Alloplast – an allogeneic material used to construct, reconstruct, or augment tissue.

Autologous tissue – tissue originating from one's own body.

Bioreactor - a vessel in which a biological process is carried out that involves organisms or biochemically active substances derived from organisms.

Compartment Syndrome - a condition caused by pressure build up from internal bleeding or tissue swelling.

Dermis – the middle layer of skin, that contains connective tissue, hair follicles, and sweat glands.

Epidermis – the outermost layer of skin, responsible for providing a waterproof barrier and creating skin tone.

Epithelium - the tissue that covers a free surface or lines a tube or cavity of an animal body, such as the alimentary canal.

Fibroblasts - cells in connective tissue that produce collagen and other fibers.

Full-thickness skin graft (FTSG) - a skin graft that contains both the epidermis and the entire dermis.

Growth factor – a substance that is required for the stimulation of growth in living cells.

HCT/Ps - human cells, tissues and cellular and tissue-based products regulated by the FDA under 21 C.F.R. Parts 1270 and 1271.

Homologous – when used in relation to tissue, skin, or tissue product means it is similar in position, structure, function, or characteristics to the corresponding patient tissue.

Hypodermis – the deep subcutaneous layer of skin, below the dermis, that is made of fat and connective tissue.

Inosculate - to connect or join to become continuous.

Integument – the enveloping membrane of the body, including the epidermis, dermis, and all derivatives of the epidermis (hair, sebaceous glands, etc.).

Interface - a region of contact between living and/or organic material and other biomaterial or organic/inorganic material.

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Interactome – the complete set of physical interactions between molecules within a cell that underlies most genotype-to-phenotype relationships and modulates nearly all complex biological pathways and cellular networks seen in living systems.

In Vitro - outside a living organism, for example laboratory vessel (e.g., a test tube) and under laboratory conditions.

In Vivo - in a living organism.

Ischemic damage - damage that causes a restriction in blood supply, thus causing diminished delivery of oxygen to the affected tissue.

MPFU - a minimally polarized functional unit.

Neovascularization - the formation of new vessels from pre-existing ones (angiogenesis) or from cellular precursors (vasculogenesis).

Osteoarthritis - a disease that occurs when the protective cartilage on the ends of bones wears down over time.

Parietal bone - a bone forming the central side and upper back part of each side of the skull.

Polarity – the asymmetric organization of cellular elements, which allows development of specialized tissue and downstream function.

Scaffold – a three dimensional material that has been engineered to cause desirable cellular interactions to contribute to the formation of new functional tissues.

Scar revision – minimizing a scar so that it is less conspicuous and blends in with the surrounding skin tone and texture.

SCIRM - self-complexing intelligent regenerative material.

Sebaceous glands – small glands in the skin that secrete lubricating oily matter (sebum) into the hair follicles to lubricate the skin and hair.

Skin graft - the transplantation of skin onto a damaged area of the body.

Split-thickness skin graft (STSG) – a skin graft that contains the epidermis and only part of the dermis.

Stem cell – an undifferentiated cell capable of renewing itself, and from which certain other kinds of cells arise by differentiation.

Stem cell niche - the microenvironment within a tissue that interacts with stem cells to signal cell growth, development, renewal, and differentiation.

Tissue engineering triad – the three components of tissue engineering, as historically taught, requiring the use of a scaffold, a signal such as a growth factor, and a cell component such as a stem cell.

Urethral stricture - the narrowing of the urethra caused by injury, infection etc.

Xenografts – a tissue graft or organ transplant from a donor of a different species from the recipient.

Item 1A. Risk Factors.

Our business and operations are subject to many 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 occur, our financial condition or results of operations could suffer.

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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 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 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 new business in an industry with many market participants and intense competition, and in the shift from development to commercialization of new product candidates based on innovative technologies.

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

We have incurred significant operating losses, and may continue to incur significant operating losses over the next several years. We incurred a net loss of $65.4 million for the year ended October 31, 2018. 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 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 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 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 research and development of our product candidates. Until we can 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, or clinical trials, we may elect to discontinue or delay further evaluations for certain product candidates or programs 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 because of unanticipated differences, regulatory requirements, or other obligations, or challenges arising during clinical development.

Our product development programs are based on novel technologies. As a 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 for all our product candidates. We also cannot at this stage be certain of the safety of all product candidates that may be developed from 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 regarding 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 or registered, for commercial sale. Consequently, the development and regulatory approval 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 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 regarding 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 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; 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 for 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 pricing, 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 by 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 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.

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"), 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 cash 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 following 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 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 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 these laws is uncertain and subject to rapid change, especially considering 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. 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 ReCell, Integra Bilayer Wound Matrix, EpiFix, Apligraf, Dermagraft, Grafix, Epicel, and others. 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 access to sensitive patient information is subject to complex regulations at multiple levels and we would be adversely affected if we fail to adequately protect this information.

We receive, maintain and utilize personal health and other confidential and sensitive data as part of the treatments we provide. 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 a 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 incorrect or incomplete disclosure of our uses of their information, or 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 or remediation costs, and compensatory, special, punitive, and statutory damages, consent orders, 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 our product candidates will face intense competition from existing or future products.

All our product candidates face intense competition from existing and future products marketed by large, well-established companies (including but not limited to Avita Medical, Integra LifeSciences, Wright Medical Group, MiMedx, Osiris, Organogenesis, Allosource, MTF Biologics 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 additional new research and development activities to establish new competitive 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 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 R&D 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.

If serious adverse or inappropriate side effects are identified during the development or use 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.

If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their use or development or limit them 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 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, 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 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. There is 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 able to determine the commercial viability of a new product, technology, material, or other innovation. In addition, even if we can successfully develop enhancements or new generations of our product candidates, these enhancements or new generations of product candidates may not produce sales more than 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, such as adopting the use of SkinTE as a substitute for 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; or
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 recently formed a sales and marketing team for SkinTE, which we intend to further develop. Nevertheless, our experience in the sale and marketing of SkinTE and other potential products is very limited, and we cannot predict whether or to what extent our internal sales effort may be successful. To achieve commercial success for any product candidate, we must either develop an effective internal sales and marketing team or outsource these functions to third parties.

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 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 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.

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 because of confusion concerning the scope of the recall or withdrawal, or because of the damage to our reputation for quality and safety.

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

Our strategy envisions a period of rapid growth. 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.

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 other stakeholders. 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. There is no assurance 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 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 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. If one or more of our future patents is challenged in U.S. or foreign courts or the United States Patent and Trademark Office ("USPTO") or foreign patent offices, the patent(s) may be found invalid 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 revenue and results of operations.

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, or 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. To protect these trade secrets, the information is restricted to our employees, consultants, collaborators, and advisors on a need-to-know basis. 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 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 could impair our competitive position and 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 regarding 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 or that do not currently contain claims of concern that may later result in issued patents that our product candidates, procedures, 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 have a present intention to obtain, any legal opinion regarding our freedom to practice our technology.

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 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 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 relating to 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 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 pre- and post-grant oppositions or 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 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, whose requirements are costly to comply with, 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, inspection, and enforcement.

We believe SkinTE and OsteoTE 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, or biological products, and we could be required to withdraw those products from the market until the required clinical trials are complete and the applicable premarket regulatory clearances or approvals are obtained.

Other products we 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 products may be marketed or to whom the products may be marketed, and may require warnings to accompany the product or impose additional restrictions on the sale 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, 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, 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, the 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 FDA-registered SkinTE and OsteoTE products 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 these 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, 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 that regulatory process, as well as data from preclinical 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 post marketing 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, the 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 SkinTE and OsteoTE, 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 these products 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 SkinTE or OsteoTE. 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 FDA could disagree with our belief that our product candidates, including but not limited to SkinTE and OsteoTE, are 361 HCT/Ps. The FDA conducted an inspection of our Salt Lake City, UT manufacturing facility in July 2018, and issued certain inspectional observations on Form FDA 483. We responded to those observations and are continuing a productive dialog with the FDA.

The Tissue Reference Group ("TRG") is a body within the FDA designed to provide recommendations regarding whether a 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 TRG or sought a formal opinion from the OCP.

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 provided limited 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, SkinTE and OsteoTE, 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 or OsteoTE, 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 certain products 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 products. If, however, after we commence marketing of any of our product candidates, including SkinTE or OsteoTE, the FTC or one or more states conclude that we lack adequate substantiation for our claims, we may be subject to significant penalties, 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.

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 Several of our products are, or will be, 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, those products.

If one of our products 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 products. 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 ("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 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 have established our own processing facility, which we believe is cGTP compliant. Any failure by us 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 products, as well as enforcement actions.

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

Our failure 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 or registration of any product candidates, or the commercialization of our product candidates.

We are subject to regulation and inspection by the FDA for cGTP, with respect to our 361 HCT/P products, and current Good Manufacturing Practice ("cGMP"), with respect to our product candidates that are not 361 HCT/Ps. Complying with cGTP or cGMP and 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.

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 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.

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 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 positive results of operations and cash flows.

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 or adversely affect our ability to sell products or conduct our clinical trials, and our business would be adversely impacted.

All the manufacturing of our product candidates takes place at our single U.S. facility. 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 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.

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

An active trading market for our common stock may not continue to develop or be sustained.

Although our common stock is listed on the NASDAQ Capital Market, or NASDAQ, we cannot assure you that an active, liquid trading market for our shares will continue to develop or be sustained. If an active market for our common stock does not continue to develop or is not sustained, it may be difficult for you to sell shares quickly or without depressing the market price for the shares or to sell your shares at all.

The trading price of the shares of our common stock has been and may continue to be volatile, and you may not be able to resell some or all your shares at a desired price.

Our stock price has been highly volatile during the fiscal year ended October 31, 2018, with closing stock prices ranging from a high of $38.97 per share to a low of $12.11 per share. The stock market in general, and the market for biotech companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. Because of this volatility, investors in our stock may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- actual or anticipated variations in our operating results;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- the timing and results of our product development plans
- failure or discontinuation of any of our development programs;
- conditions or trends in our industry;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biotech industry;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, or divestitures;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- capital commitments;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- announcements and expectations of additional financing efforts; and
- sales of our common stock, including sales by our directors and officers or specific stockholders.

In addition, in the past, stockholders have initiated class action lawsuits against biotechnology companies following periods of volatility in the market prices of these companies' stock. We are currently a party to such litigation and may be in the future due to price volatility. Such litigation could cause us to incur substantial costs and divert management's attention and resources from the operation of our business.

If equity research analysts do not continue to publish research or reports or publish unfavorable research or reports about us, our business or our industry, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. Presently we have only limited research coverage by equity research analysts. Equity research analysts may elect not to initiate or continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. We have no control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more

equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Sales of a substantial number of shares of our common stock could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

In addition, we have filed registration statements on Form S-8 registering the issuance of shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 are available for sale in the public market subject to vesting arrangements and exercise of existing options, the grant of new options in the future, and the restrictions of Rule 144 in the case of our affiliates.

The issuance of additional stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

Our amended and restated certificate of incorporation authorizes us to issue up to 250,000,000 shares of common stock and up to 25,000,000 shares of preferred stock with such rights and preferences as may be determined by our board of directors (the "Board"). Subject to compliance with applicable rules and regulations, we may issue our shares of common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investment, our stock incentive plans or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

Our executive officers and directors and their affiliates own a significant percentage of our issued and outstanding common stock and can exercise significant influence over matters submitted to stockholders for approval.

As of January 7, 2019, our executive officers and directors and their affiliates beneficially owned approximately 42.5% of our outstanding common stock. As a result, if these stockholders were to choose to act together, they could exert a significant degree of influence over matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, could have significant influence on the election of directors and approval of any merger, consolidation, or sale of all or substantially all our assets, including a transaction on terms that other stockholders may desire.

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:

- we have 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;
- our Board is authorized to issue up to 25,000,000 shares of preferred stock without stockholder approval, which 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;
- stockholders are not entitled to remove directors other than by a two-thirds vote and only for cause;
- stockholders cannot call a special meeting of stockholders;

we require all stockholder actions be taken at a meeting of our stockholders, and not by written consent; and stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

A material weakness in internal control over financial reporting could have a material adverse effect on our business, results of operations, financial condition and liquidity.

As discussed in Item 9A - *Controls and Procedures*, we have identified material weaknesses in internal control over financial reporting through our evaluation of our controls at October 31, 2018. Our material weaknesses consist of:

- insufficient internal controls related to information technology general controls in the areas of user access, user provisioning, and change management over certain systems that support the financial reporting process;
- inadequate documentation of period end financial disclosure and reporting processes;
- ineffective controls related to the documentation and completeness of the Company's stock-based compensation expense; and
- inadequate review procedures and segregation of duties over processing sales invoices.

A material weakness could result in a material misstatement of our annual or interim financial statements requiring a restatement of the affected financial statements. A material misstatement and resulting restatement entail numerous risks, including the following:

- We could be subject to civil litigation, including class action shareholder actions arising out of or relating to a restatement, which litigation, if decided against us, could require us to pay substantial judgments, settlements or other penalties;
- Negative publicity relating to a restatement may adversely affect our business and the market price of our common stock;
- Management's focus on achieving our business objectives may be diverted to addressing (i) the restatement (ii) customers', employees', investors' and regulators' questions and concerns regarding the restatement (iii) any negative impact on the Company's public image with our customers and in the financial market caused by the restatement, and (iv) any subsequent litigation that may result from the restatement;
- The SEC may review a restatement and require further amendment of our public filings; and
- We may incur significant expenses associated with preparing and filing a restatement.

Each of these risks described above could have a material adverse effect on our business, results of operations, financial condition, and liquidity.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date and have no plans to pay cash dividends in the foreseeable future. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

We incur costs and demands upon management because of being a public company.

As a public company listed in the United States, we are incurring, and will continue to incur, significant legal, accounting and other costs. These costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and stock exchanges, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management’s time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules also might make it more difficult for us to obtain some types of insurance, including directors' and officers' liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Effective July 15, 2018, we entered into a commercial lease agreement with Salt Lake City Corporation, pursuant to which we leased approximately 44,695 rentable square feet of office space at 123 Wright Brothers Drive in Salt Lake City, Utah. The initial term of the lease is two years, and may be extended for an additional term of five years by agreement of the parties. The base rent plus maintenance fees over the two-year term of the lease is $469,288 per year, or $39,108 per month.

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 at 1960 S. 4250 West, Salt Lake City, UT. 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.

In May 2018, we purchased two parcels of real property in Cache County, Utah, consisting of approximately 1.75 combined gross acres of land, together with the buildings, structures, fixtures, and personal property located at 1072 West RSI Drive, Logan, Utah. This facility is used for the operation of our pre-clinical contract services business.

On October 19, 2018, we entered into an office lease with Lefrak SBN Limited Partnership, a Georgia limited partnership, covering approximately 7,250 square feet of space in the building located at 40 West 57th Street, New York, New York City. The lease is for a term of three years. The annual lease rate is $60 per square foot. Initially we will occupy and pay for only 3,275 square feet of space, and we are not obligated under the lease to pay for the remaining 3,975 square feet covered by the lease unless we elect to occupy that additional space. We have a sublease

with the affiliate of one of our directors pursuant to which said affiliate will sublease 1,220 square feet at the same lease rate we pay to the landlord, and an option to expand the space occupied to an additional 2,753 square feet, which means we would be leasing 6,028 square feet from the landlord and subleasing 3,972 square feet to the affiliate of our director.

We lease office space in Hazlet, New Jersey at a cost of approximately $1,100 per month under a month to month lease agreement.

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

Item 3. Legal Proceedings.

On June 26, 2018, a class action complaint alleging violations of the Federal securities laws was filed in the United States District Court, District of Utah, by Jose Moreno against the Company and two directors of the Company, Case No. 2:18-cv-00510-JNP (the "Moreno Complaint"). On July 6, 2018, a similar complaint was filed in the same court against the same defendants by Yedid Lawi, Case No. 2:18-cv-00541-PMW (the "Lawi Complaint"). Both the Moreno Complaint and Lawi Complaint allege that the defendants made or were responsible for, disseminating information to the public through reports filed with the Securities and Exchange Commission and other channels that contained material misstatements or omissions in violation of Sections 10 and 20(a) of the Exchange Act and Rule 10b-5 adopted thereunder. Specifically, both complaints allege that the defendants misrepresented the status of one of the Company's patent applications while touting the unique nature of the Company's technology and its effectiveness. Plaintiffs are seeking damages suffered by them and the class consisting of the persons who acquired the publicly-traded securities of the Company between March 31, 2017, and June 22, 2018. Plaintiffs have filed motions to consolidate and for appointment as lead plaintiff. On November 28, 2018, the Court consolidated the *Moreno* and *Lawi* cases under the caption *In re PolarityTE, Inc. Securities Litigation* (the "Consolidated Securities Litigation"), and requested the appointment of the plaintiff in *Lawi* as the lead plaintiff. An order for appointment of the lead plaintiff has not been entered. After the lead plaintiff is appointed, the plaintiff will have 60 days to file an amended complaint. The Company believes the allegations in the Moreno Complaint and Lawi Complaint are without merit, and intends to defend the litigation, vigorously. The Company expects its first response will be to file a motion to dismiss after the first to occur of the plaintiff filing an amended complaint or the period for filing an amended complaint expires. At this early stage of the proceedings the Company is unable to make any prediction regarding the outcome of the litigation.

In November 2018, a shareholder derivative lawsuit was filed in the United States District Court, District of Utah, with the caption *Monther v. Lough, et al*., case no. 2:18-cv-00791-TC, alleging violations of the Exchange Act, breach of fiduciary duty, and unjust enrichment on the part of certain officers and directors based on the facts and circumstances recited in the Consolidated Securities Litigation. On November 26, 2018, the court issued an order staying all proceedings until after the disposition of motions to dismiss the Consolidated Securities Litigation.

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, a former subsidiary of the Company, 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 represented himself pro se in the litigation and sought 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 finding that the accused products did not literally infringe the asserted patent and that plaintiff was barred from pursing infringement under the doctrine of equivalents due to prosecution history estoppel. The plaintiff appealed that decision to the Court of Appeals for the Federal Circuit. On April 9, 2018, the Court of Appeals for the Federal Circuit affirmed the judgment of the District Court for the Western District of Washington. On May 7, 2018, the plaintiff filed a petition for panel rehearing and rehearing en banc by the Court of Appeals. The petition for rehearing was denied on June 8, 2018. The plaintiff subsequently filed a petition for a writ of certiorari with the Supreme Court of the United States, which was denied in November 2018. Consequently, this matter has been resolved without liability to the

Company.

In the ordinary course of business, we may become involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements, regulatory compliance, and other matters. Except as noted above, at October 31, 2018, we were not party to any legal or arbitration proceedings that may have significant effects on our financial position or results of operations. No governmental proceedings are pending or, to our knowledge, contemplated against us. We are not a party to any material proceedings in which any director, member of senior management or affiliate of ours is either a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

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 “PTE.”

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.

The following information should be read in conjunction with the consolidated financial statements and related notes thereto included in this Annual Report on Form 10-K.

In addition to historical information, this report contains forward-looking statements that involve risks and uncertainties that may cause our actual results to differ materially from plans and results discussed in forward-looking statements. We encourage you to review the risks and uncertainties discussed in the sections entitled Item 1A. "Risk Factors" and "Forward-Looking Statements" included at the beginning of this Annual Report on Form 10-K. The risks and uncertainties can cause actual results to differ significantly from those in our forward-looking statements or implied in historical results and trends. We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are 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 operate two segments; the regenerative medicine business segment and the contract research segment.

Segment Reporting

The regenerative medicine business segment over the last year has established and advanced our core “TE” program, which includes our first commercial product, SkinTE. The commercial launch of SkinTE has included the build out of commercial, manufacturing, and corporate structure to support the expected, significant growth of SkinTE revenue and deployments in 2019 and beyond. This includes equipment, personnel, systems, and leased properties. Research and development continues to expand to advance the product development pipeline.

In May 2018 we acquired assets of a preclinical research and veterinary sciences business and related real estate, which we now operate through our subsidiary, Ibex Preclinical Research, Inc. The aggregate purchase price was $3.8 million, of which $2.3 million was paid at closing and the balance satisfied by a promissory note payable to the Seller with an initial fair value of $1.22 million and contingent consideration with an initial fair value of approximately $0.3 million. As a result, we have significant research facilities and a well-educated and skilled team of scientists and researchers that comprise the contract research segment of our business. These resources are highly beneficial to the work we are doing on our TE products and in RTD and ARC. We also offer research services to unrelated third parties on a contract basis, which we offer under the trademark POLARITYRD. Contract research services help us defray the costs of maintaining a first-rate research facility and allow us to meet companies pursuing new technologies that may be opportunities for collaborative or strategic relationships going forward.

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.

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.

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.

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 financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities or the disclosure of gain or loss contingencies at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Among the more significant estimates included in these financial statements are the valuation of warrant liability, valuation of derivative liability, stock-based compensation, the valuation allowances for deferred tax benefits, and the valuation of tangible and intangible assets included in acquisitions. Actual results could differ from those estimates.

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.

Goodwill and Intangible Assets. Goodwill represents the excess acquisition cost over the fair value of net tangible and intangible assets acquired. Goodwill is not amortized and is subject to annual impairment testing or between annual tests if an event or change in circumstance occurs that would more likely than not reduce the fair value of a reporting unit below its carrying value. In testing for goodwill impairment, the Company has the option to first assess qualitative factors to determine whether the existence of events or circumstances lead to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If, after assessing the totality of events and circumstances, the Company concludes that it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is not required. If the Company concludes otherwise, it is required to perform the two-step impairment test. The goodwill impairment test is performed at the reporting unit level by comparing the estimated fair value of a reporting unit with its respective carrying value. If the estimated fair value exceeds the carrying value, goodwill at the reporting unit level is not

impaired. If the estimated fair value is less than carrying value, further analysis is necessary to determine the amount of impairment, if any, by comparing the implied fair value of the reporting unit's goodwill to the carrying value of the reporting unit's goodwill.

The fair value of reporting units is based on widely accepted valuation techniques that the Company believes market participants would use, although the valuation process requires significant judgment and often involves the use of significant estimates and assumptions. The Company utilizes a market cap approach in estimating the fair value of reporting units. The estimates and assumptions used in determining fair value could have a significant effect on whether or not an impairment charge is recorded and the magnitude of such a charge. Adverse market or economic events could result in impairment charges in future periods.

Intangible assets deemed to have finite lives are amortized on a straight-line basis over their estimated useful lives, which generally range from one to eleven years. The useful life is the period over which the asset is expected to contribute directly, or indirectly, to its future cash flows. Intangible assets are reviewed for impairment when certain events or circumstances exist. For amortizable intangible assets, impairment exists when the undiscounted cash flows exceed its carrying value. At least annually, the remaining useful life is evaluated.

Impairment of Long-Lived Assets. The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. No impairment loss has been recognized.

Income Taxes. The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company evaluates the potential for realization of deferred tax assets at each quarterly balance sheet date and records a valuation allowance for assets for which realization is not more likely than not.

Stock Based Compensation. The Company measures all stock-based compensation to employees using a fair value method and records such expense in general and administrative and research and development expenses. Compensation expense for stock options with cliff vesting is recognized on a straight-line basis over the vesting period of the award, based on the fair value of the option on the date of grant. For stock options with graded vesting, the Company recognizes compensation expense over the service period for each separately vesting tranche of the

award as though the award were in substance, multiple awards.

The fair value for options issued is estimated at the date of grant using a Black-Scholes option-pricing model. The risk-free rate is derived from the U.S. Treasury yield curve in effect at the time of the grant. The volatility factor is determined based on the Company's historical stock prices. Forfeitures are recognized as they occur.

The value of restricted stock grants is measured based on the fair market value of the Company's common stock on the date of grant and amortized over the vesting period of, generally, six months to three years.

The accounting for non-employee options and restricted stock is similar to that of employees, however, unlike employee options and restricted stock, the measurement date is not the grant date. The measurement date is when performance is complete. Until the options or shares vest, they are re-measured (re-valued) each reporting period and the expense marked up or marked down accordingly.

Accounting for Warrants. The Company accounts for the issuance of common stock purchase warrants issued in connection with the equity offerings in accordance with the provisions of ASC 815, Derivatives and Hedging ("ASC 815"). The Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) gives the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies as assets or liabilities any contracts that (i) require net-cash settlement (including a requirement to net-cash settle the contract if an event occurs and if that event is outside the control of the Company) or (ii) gives the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). In addition, under ASC 815, registered common stock warrants that require the issuance of registered shares upon exercise and do not expressly preclude an implied right to cash settlement are accounted for as derivative liabilities. The derivative warrant liabilities were settled during the year.

Change in Fair Value of Derivatives. The Company assessed the classification of common stock purchase warrants as of the date of each offering and determined that certain instruments met the criteria for liability classification. Accordingly, the Company classified the warrants as a liability at their fair value and adjusts the instruments to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until the warrants are exercised or expired, and any change in fair value is recognized as "change in fair value of warrant liability" in the consolidated statements of operations. The fair value of the warrants has as well as other derivatives, been estimated using a Monte-Carlo or Black-Scholes valuation model. The warrants were settled during the year.

Revenue Recognition. The Company recognizes revenue upon the shipment of products or the performance of services when each of the following four criteria is met: (i) persuasive evidence of an arrangement exists; (ii) products are delivered or services are performed; (iii) the sales price is fixed or determinable; and (iv) collectability is reasonably assured. Contract services recognizes revenue based on the proportional performance method over the term of the respective service contract which requires us to make reasonable estimates of the extent of progress toward completion of the contract. Under this method, revenue is recognized according to the percentage of cost completed for the study. As a result, unbilled receivables and deferred revenue are recognized based on payment timing and work completed. The Company has one significant customer which makes up approximately 19% of consolidated revenues.

Results of Operations

Year ended October 31, 2018 versus the year ended October 31, 2017

Net Revenues. For the year ended October 31, 2018, total net revenues were $1.6 million including net revenues from product sales of $0.7 million from the sale of the Company's core product SkinTE in the regenerative medicine business segment. As SkinTE was commercially launched in the 2018 fiscal year, there were no regenerative medicine revenues in the prior fiscal year. Net revenues from services sales were $0.9 million from the contract research segment operations driven primarily by the POLARITYRD preclinical research business, which was acquired in this

fiscal year.

Cost of Sales. For the year ended October 31, 2018, cost of sales was approximately $1.0 million and approximately 64% of net revenues. Product cost of sales were $0.5 million or 73% of product sales. Service cost of sales were $0.5 million or 57% of service sales.

Research and Development Expenses. Research and development expenses increased $12.3 million, or 173%, in the fiscal year ended October 31, 2018, compared to the fiscal year ended October 31, 2017. The increase was primarily due to additional personnel hired to advance the product development pipeline, and their associated costs, including stock-based compensation, salaries, and benefits, as well as, lab supplies and related expenses.

General and Administrative Expenses. General and administrative expenses increased $29.4 million, or 156%, in the fiscal year ended October 31, 2018 compared to the fiscal year ended October 31, 2017. During the fiscal year, the Company expanded its infrastructure to support the commercial launch of SkinTE, build out of an FDA manufacturing and R&D facility, and support increased corporate operations. The resulting increase in expenses is driven primarily by employee-related costs, including stock-based compensation, salaries, and benefits, and increased outside services expense, including legal and accounting fees and consulting expenses.

Sales and Marketing Expenses. For the year ended October 31, 2018, sales and marketing expenses were $2.4 million. This represents the sales personnel and marketing costs primarily driven by the initial regional release of SkinTE. There were no sales personnel and marketing costs during the year ended October 31, 2017.

Other (Expenses) Income. For the year ended October 31, 2018, other (expenses) income mainly included a change in fair value of derivatives of approximately a $3.8 million gain, interest income of $0.4 million and a loss on extinguishment of warrant liability of approximately $0.5 million. For the year ended October 31, 2017, other (expenses) income was insignificant.

Net loss from continuing operations. Net loss from continuing operations for the year ended October 31, 2018 was approximately $65.4 million, compared to a net loss of approximately $130.5 million for the year ended October 31, 2017, primarily reflecting the decrease of $104.7 million in research and development - intellectual property acquired expenses offset by the increase in operating expenses driven by expanding operations discussed above.

Liquidity and Capital Resources

As of October 31, 2018, our cash and cash equivalents balance was approximately $71.0 million and our working capital was approximately $68.0 million, compared to cash and cash equivalents of $17.7 million and working capital of $2.5 million at October 31, 2017.

As reflected in the consolidated financial statements, we had an accumulated deficit of approximately $324.4 million at October 31, 2018, a net loss of approximately $65.4 million and approximately $28.5 million net cash used in continuing operating activities for the year ended October 31, 2018.

On April 12, 2018, we completed a public offering of 2,335,937 shares of our common stock at an offering price of $16.00 per share, resulting in net proceeds of $34.6 million, after deducting offering expenses. On June 7, 2018, we completed an underwritten offering of 2,455,882 shares of our common stock at an offering price of $23.65 per share, resulting in net proceeds of approximately $58.0 million, after deducting offering expenses.

Based upon the current status of our product development and commercialization plans, we believe that our existing cash and cash equivalents will be adequate to satisfy our capital needs for at least the next 12 months from the date of filing. We anticipate needing substantial additional financing to continue clinical deployment and commercialization of our lead product SkinTE, development of our other product candidates, and scaling the manufacturing capacity for

our products and product candidates, and prepare for commercial readiness. We will continue to pursue fundraising opportunities when available, however, such financing may not be available on terms favorable to us, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our product development programs. We plan to meet our capital requirements primarily through issuances of equity securities, debt financing, revenue from product sales and future collaborations. Failure to generate revenue or raise additional capital would adversely affect our ability to achieve our intended business objectives.

Our actual capital requirements will depend on many factors, including among other things: our ability to scale the manufacturing for and to commercialize successfully our lead product, SkinTE; the progress and success of clinical evaluation and acceptance of SkinTE; our ability to develop our other product candidates; and the costs and timing of obtaining any required regulatory registrations or approvals. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. The foregoing factors, along with the other factors described in the section, Item 1A, “Risk Factors” in Part I of this Report on Form 10-K will impact our future capital requirements and the adequacy of our available funds. If we are required to raise additional funds, any additional equity financing may be highly dilutive, or otherwise disadvantageous, to existing stockholders, and debt financing, if available, may involve restrictive covenants. If we elect to pursue collaborative arrangements, the terms of such arrangements may require us to relinquish rights to certain of our technologies, products or marketing territories. Our failure to raise capital when needed, and on acceptable terms, would require us to reduce our operating expenses and would limit our ability to respond to competitive pressures or unanticipated requirements to develop our product candidates and to continue operations, any of which would have a material adverse effect on our business, financial condition and results of operation.

Off-Balance Sheet Arrangements

As of October 31, 2018, 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 $71.0 million and $68.0 million, respectively, as of October 31, 2018 compared to cash and cash equivalents and working capital of approximately $17.7 million and $2.5 million at October 31, 2017, respectively.

Operating Cash Flows

Cash used in continuing operating activities for the year ended October 31, 2018 amounted to approximately $28.5 million compared to approximately $7.6 million for the 2017 period. The increase in net cash used in continuing operating activities mostly relates to the increases in both research and development, sales and marketing, and general and administrative expenses.

Cash used in discontinued operating activities in the year ended October 31, 2018, amounted to $0 compared to approximately $33,000 for the same period in 2017.

Investing Cash Flows

Cash used in continuing investing activities for the year ended October 31, 2018 amounted to approximately $11.5 million compared to $2.5 million for the 2017 period. For the year ended October 31, 2018, the activity relates to the acquisition of IBEX and the purchase of property and equipment. For the year ended October 31, 2017, the activity only relates to the purchase of property and equipment.

Financing Cash Flows

Net cash provided by financing activities for the year ended October 31, 2018 amounted to approximately $93.3 million compared to approximately $21.2 million for the 2017 period. The $92.7 million in net proceeds from the sale of common stock in the year ended October 31, 2018, accounts for the majority of that period's financing activity and accounts for the majority of the increase in net cash provided by financing activities as compared to the comparable prior year period.

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, and 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.

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on the evaluation of the effectiveness of our disclosure controls and procedures as of October 31, 2018, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, were not effective due to the material weaknesses identified below. To address the material weaknesses, management performed additional analyses and other procedures to determine whether the financial statements included herein fairly present our financial results. 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.

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.

As permitted by the SEC, management's assessment did not include the internal controls over financial reporting of the acquired IBEX operations which is included in our consolidated financial statements as of October 31, 2018 and for the period from the acquired date through October 31, 2018. IBEX represented approximately 53% of consolidated revenue for the year ended October 31, 2018 and approximately 6% of total assets as of October 31, 2018.

Our management does not expect that our disclosure controls and procedures or our internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. 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 the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls is also 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 the degree of compliance with the policies or procedures may deteriorate. 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. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Management assessed the effectiveness of our internal control over financial reporting as of October 31, 2018. 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, 2018.

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 weaknesses, which have caused management to conclude that as of October 31, 2018 our internal control over financial reporting was not effective at the reasonable assurance level:

(1) insufficient internal controls related to information technology general controls in the areas of user access, user provisioning, and change management over certain systems that support the financial reporting process;

(2) inadequate documentation of period end financial disclosure and reporting processes;

(3) ineffective controls related to the documentation and completeness of the Company's stock-based compensation expense; and

(4) inadequate review procedures and segregation of duties over processing sales invoices.

EisnerAmper, LLP has provided an attestation report on the Company's internal control over financial reporting as of October 31, 2018.

Changes in Internal Control over Financial Reporting

We have taken several steps to remediate the material weaknesses identified above. These steps include the following:

Period End Reporting – The Company implemented period end checklists and other procedures to ensure proper documentation. Management believes that preparing and implementing sufficient period end documentation will improve financial disclosure and reporting processes.

Stock-Based Compensation System – The Company is in the process of implementing a systemic solution to our stock-based compensation accounting, including internal processes and an external compensation account management tool. Management expects the tool to be in production in early 2019. The system implementation and additional procedures enable the Company to properly document the stock-based compensation expense.

IT Systems & Controls – The Company has hired additional IT personnel and adopted access restrictions and protocols to prevent unauthorized access and unauthorized changes to data and records.

Processing Revenue Transactions – The Company has hired additional accounting staff. The additional headcount will result in the proper segregation of duties and provide more checks and balances within the department. During the fourth quarter, the Company implemented processes and procedures to remediate the issue.

In addition to the steps taken to address the material weaknesses listed above, the Company has implemented the following material changes to its internal controls during the third and fourth quarters of the year ended October 31, 2018:

Enterprise Resource Planning System – The Company implemented a phased approach to a company-wide enterprise resource planning system to further enhance our internal control environment. Management continues to monitor the impact of this implementation on our processes as well as the impact to the internal controls over financial reporting.

Changes to Personnel – The Company hired nine additional people to its accounting and finance staff as of the year ended October 31, 2018. Four of the staff additions were hired during the last fiscal quarter of the year. These personnel have improved the financial reporting and control environment.

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

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders

PolarityTE, Inc.

Opinion on the Internal Control over Financial Reporting

We have audited PolarityTE, Inc. and Subsidiaries' (the "Company") internal control over financial reporting as of October 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). In our opinion, because of the effect of the material weaknesses described in the following paragraph on the achievement of the objectives of the control criteria, PolarityTE, Inc. and Subsidiaries has not maintained effective internal control over financial reporting as of October 31, 2018, based on criteria established in the Internal Control - Integrated Framework (2013) issued by COSO.

The Company acquired IBEX during the year ended October 31, 2018, and management excluded this entity from its assessment of the effectiveness of the Company's internal control over financial reporting as of October 31, 2018, which represented approximately 53% of consolidated revenue for the year ended October 31, 2018 and approximately 6% of total assets as of October 31, 2018. Our audit of internal control over financial reporting of the Company also excluded an evaluation of the internal control over financial reporting of this entity.

A material weakness is a control deficiency, or combination of deficiencies, 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. The following material weaknesses have been identified and included in management's assessment.

(1) insufficient internal controls related to information technology general controls (ITGC) in the areas of user access, user provisioning, and change management over certain systems that support the financial reporting process;
(2) inadequate documentation over period end financial disclosure and reporting processes;
(3) ineffective controls related to the documentation and completeness of the Company's stock-based compensation expense; and
(4) inadequate review procedures and segregation of duties over processing sales invoices.

These material weaknesses were considered in determining the nature, timing, and extent of the audit tests applied in our audit of the October 31, 2018 financial statements, and this report does not affect our report dated January 14, 2019, on those financial statements.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the consolidated balance sheets of PolarityTE, Inc. and Subsidiaries as of October 31, 2018 and 2017, and the related consolidated statements of operations, stockholders’ equity, and cash flows for each of the years then ended, and the related notes, and our report dated January 14, 2019 expressed an unqualified opinion.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

An entity's internal control over financial reporting is a process 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. An entity's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the entity; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the entity are being made only in accordance with authorizations of management and directors of the entity; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the entity's 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.

/s/ EisnerAmper LLP

EISNERAMPER LLP

Iselin, NJ

January 14, 2019

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Item 9B. Other Information.

Change in Fiscal Year

Pursuant to authority conferred on the Board under the Company's Restated Bylaws, on January 11, 2019, the Board approved a change in the Company's fiscal year end from October 31 to December 31. The change in fiscal year is effective December 31, 2018, and the Company will file an Annual Report on Form 10-K for the two-month transition period ended December 31, 2018. The change is fiscal year is reflected in an amendment to Article IX, Section 4 of the Company's Restated Bylaws to read as follows:

Section 4. Fiscal Year

Except as otherwise determined by the Board of Directors from time to time, the fiscal year of the Corporation shall end on the last day of December of each year.

PART III

Item 10 - Directors, Executive Officers and Corporate Governance.

The following table sets forth the names and ages of all our directors.

Denver Lough	36	Class III Director
Steve Gorlin	80	Class II Director
Jeff Dyer	59	Class I Director
Jon Mogford	50	Class I Director
Willie C. Bogan	69	Class II Director

Peter A. Cohen	71	Class III Director
Rainer Erdtmann	54	Class III Director
David Seaburg	47	Class II Director
Minnie Baylor-Henry	71	Class I Director

The following is a summary of the background and qualifications of each of our directors.

Dr. Denver Lough, was appointed our Chairman and Chief Executive Officer and Chief Scientific Officer on December 1, 2016 and has continued to serve in this capacity throughout 2018. He also served as Chief Scientific Officer from December 2016 to May 2018, when he became Chief R&D Officer. Prior to December 2016, Dr. Lough served both clinical and research roles at multiple institutions. From 2012 until 2016 Dr. Lough was a Plastic & Reconstructive Surgery House Staff Officer at Johns Hopkins University School of Medicine, Department of Plastic & Reconstructive Surgery. Dr. Lough has received numerous accolades and awards by national societies related to basic and translational science applications in tissue engineering, regenerative medicine, and immunology as well as within solid organ and reconstructive transplantation. We believe that Dr. Lough is qualified to serve as a member of our Board because of his experience in clinical medicine, surgery, research as well as the development and innovation of technologies related to regenerative medicine and related patent applications and intellectual property which the Company has reviewed for potential development. Dr. Lough holds an M.D. and PhD in Biochemistry, Molecular and Cell Biology from Georgetown University, which he earned in 2012. Dr. Lough has served within the Department of Surgery and Institute for Plastic Surgery Southern Illinois University School of Medicine and Translational Research Director at Laboratory for Regenerative Medicine and Applied Sciences. He has served within the Laboratories for Craniomaxillofacial Regenerative Medicine at the Johns Hopkins Hospital Department of Plastic and Reconstructive Surgery. In addition, Dr. Lough was a lead research associate in the Vascularized Composite Allotransplantation Laboratory at the Johns Hopkins Hospital Department of Plastic and Reconstructive Surgery and has been a research consultant to the Johns Hopkins Hendrix Burn Research Center. He has also served within the Brady Urological Institute at the Johns Hopkins School of Medicine. Dr. Lough was assembled as a member among other burn experts as a Taiwanese presidential disaster response team following the largest civilian burn disaster in 2015.

Steve Gorlin joined the Board in February 2017. Mr. Gorlin helped found several biotechnology and pharmaceutical companies over the past 40 years, including Hycor Biomedical, Inc. (acquired by Agilent), Theragenics Corporation (NYSE: TGX), CytRx Corporation (NASDAQ: CYTR), Medicis Pharmaceutical Corporation (acquired by Valeant), EntreMed, Inc. (NASDAQ: ENMD), MRI Interventions, DARA BioSciences, Inc. (NASDAQ: DARA), MiMedx Group, Inc. (NASDAQ: MDXG), and Medivation, Inc. (NASDAQ: MDVN). Since December 2014, Mr. Gorlin has served as a director of Catasys, Inc. and Co-Chairman of the board of directors of Medovex, Inc., and since May 2011 he has served on the board of directors of NTC China, Inc. In addition, since 2011, Mr. Gorlin has served as a member of the board of directors of DemeRX, Inc. (“DemeRX”) and from 2011 until 2012 he served as Chairman of the board of DemeRX. Since July 2015, he has also served as Vice Chairman of the board of NantKwest, Inc. and from July 2013 until May 2015 he served on various executive committees and the board of directors of Conkwest, Inc., a private company, which is now NantKwest, Inc. From November 2006 until June 2013, Mr. Gorlin served as a member of the board of directors of MiMedx Group, Inc. From 2010 until 2014 Mr. Gorlin served on the Business Advisory Council to the Johns Hopkins School of Medicine, from 2011 until 2013 he served on The Johns Hopkins BioMedical Engineering Advisory Board and from 2007 until 2011 he served on the Board of the Andrews Institute. He is

presently a member of the Research Institute Advisory Committee (RIAC) of Massachusetts General Hospital. Mr. Gorlin founded several non-medical related companies, including Perma-Fix, Inc., Pretty Good Privacy, Inc. (sold to Network Associates), Judicial Correction Services, Inc. (sold to Correctional Healthcare) and NTC China, Inc. He started The Touch Foundation, a nonprofit organization for the blind and was a principal financial contributor to the founding of Camp Kudzu for diabetic children. Mr. Gorlin is qualified to serve as a member of the Company's Board because of his experience in regenerative medicine and pharmaceutical drug and medical device research and development.

Jeff Dyer was appointed to our Board of Directors on March 2, 2017. Mr. Dyer has served as the Horace Beesley Professor of Strategy at Brigham Young University since September 1999. From August 1993 until September 1999 he served as an Assistant Professor at Wharton School, University of Pennsylvania, and from July 1984 until September 1988 he served as Management Consultant and Manager of Bain & Company. Mr. Dyer received his Bachelor of Science degree in psychology and MBA from Brigham Young University and his PhD in management from University of California, Los Angeles. Mr. Dyer is qualified to serve as a member of the Company's Board because of his extensive business and management expertise and knowledge of capital markets.

Dr. Jon Mogford was appointed to our Board of Directors on February 8, 2017. Dr. Mogford has served in various capacities for the Texas A&M University System ("Texas A&M"). Since May 2013, Dr. Mogford has served as the Vice Chancellor for Research, from August 2012 until April 2013 he served as the Chief Research Officer and from November 2011 until August 2012 he served as Associate Vice Chancellor for Strategic Initiatives at Texas A&M. Prior to joining Texas A&M in 2011, from February 2010 until October 2011, Dr. Mogford served as Deputy Director of the Defense Sciences Office (DSO) of the Defense Advanced Research Projects Agency (DARPA) in the U.S. Department of Defense. From July 2005 until January 2009, Dr. Mogford served as Program Manager of DSO of DARPA. In addition, since November 2016, Dr. Mogford has served as a member of the board of directors of Medovex Corp. Dr. Mogford is the recipient of the Secretary of Defense Medal for Outstanding Public Service. Dr. Mogford obtained his bachelor's degree in Zoology from Texas A&M University and doctorate in Medical Physiology from the Texas A&M University Health Science Center, College Station, Texas. His research in vascular physiology continued at the University of Chicago as a Postdoctoral fellow from 1997 until 1998. Dr. Mogford transitioned his research focus to the field of wound healing at Northwestern University, both as a Research Associate and as a Research Assistant Professor from 1998 until 2003. He then served as a Life Sciences Consultant to DARPA on the Revolutionizing Prosthetics program from December 2003 until June 2005. Dr. Mogford is qualified to serve as a member of the Company's Board because of his experience and research in regenerative medicine.

Willie C. Bogan joined the Board in April 2018. Mr. Bogan served as Associate General Counsel and Corporate Secretary of McKesson Corporation ("McKesson"), a San Francisco-based healthcare services and information technology company (relocating to Las Colinas, TX in 2019) currently ranked 6th on the Fortune 500, from July 2009 until his retirement from McKesson in November 2015. He joined McKesson in November 2006 as Associate General Counsel and Assistant Secretary. Before joining McKesson, Mr. Bogan held senior advisory positions at the following public companies in the San Francisco Bay Area: Bank of America; Safeway; Charles Schwab; and Catellus Development Corporation, a real estate development company. Prior to becoming in-house counsel, he was a partner at Steinberg Miller Bogan & Goldstein in Manhattan Beach, California. He started his law career as a law firm associate in Los Angeles, California. Mr. Bogan graduated Phi Beta Kappa and Summa Cum Laude from Dartmouth College where he majored in Spanish. He received an M.A. degree in Politics and Economics from Oxford University where he studied as a Rhodes Scholar. He earned his J.D. degree from Stanford Law School. Mr. Bogan is qualified to serve as a member of the Board because of his knowledge of the healthcare industry and his experience as an advisor to public companies and their boards of directors on securities law and corporate governance matters.

Peter A. Cohen joined the Board in June 2018. Mr. Cohen has served as Vice Chairman of the Board of Scientific Games Corporation since September 2004. Mr. Cohen was Chairman of Cowen Inc. (formerly known as Cowen Group, Inc.), a diversified financial services company, from November 2009 through June 2018, and served as Chief Executive Officer from November 2009 through December 2017. Mr. Cohen was a founding partner and principal of Ramius LLC, a private investment management firm formed in 1994 that was combined with Cowen in late 2009. Mr. Cohen served as a member of the board of directors of Chart Acquisition Corp. (which, because of a business combination, is now known as Tempus Applied Solutions Holdings, Inc.) from September 2011 to November 2016. From November 1992 to May 1994, Mr. Cohen was Vice Chairman of the Board and a director of Republic New York Corporation, as well as a member of its executive management committee. Mr. Cohen was Chairman and Chief Executive Officer of Shearson Lehman Brothers from 1983 to 1990. Mr. Cohen is currently a Trustee of Mount Sinai Medical Center and has served on its board for approximately thirty years. Mr. Cohen is qualified to serve as a member of the Board because of his knowledge of the capital markets and corporate finance, and his experience as a public company director.

Rainer Erdtmann joined the Board in August 2018. He has 26 years of experience in finance and investment banking. For the past three years Mr. Erdtmann has been a portfolio manager and general partner of Point Sur Investors LLC, specializing in identifying innovative biotech companies. Prior to Point Sur Investors, from February 2009 until September 2015, Mr. Erdtmann was with Pharmacyclics, Inc., a Nasdaq-listed company. He began as Vice President, Finance & Administration, Corporate Secretary and acted as the Principal Financial and Accounting Officer. In that capacity he was responsible for accounting, SEC reporting, audits, and investor relations. He built and had operational responsibility for Finance, IT, HR, Legal, Facilities, and Events. He later served as Executive Vice President of Corporate Affairs including Corporate Communications. Additionally, he structured and administered the international revenue for Pharmacyclics into a swiss-based subsidiary. Mr. Erdtmann began his career at Commerzbank, Germany, where he was an investment banker and portfolio manager for institutional international accounts. Mr. Erdtmann earned the Diplom Kaufmann degree, with honors, in Finance and Banking from the Westfaelische Wilhelms Universitaet, Muenster, Germany. Mr. Erdtmann is qualified to serve as a member of the Board because of his knowledge of the biotech industry, his deep experience in capital markets and finance, and his knowledge of commercial and business practices in Europe and North America.

David Seaburg joined the Board in August 2018. David Seaburg is a Managing Director and Head of Sales Trading at Cowen & Company, a diversified financial services company. Over the course of his 20+ year career at Cowen in both Equity Sales Trading and Trading, Mr. Seaburg has advanced to increasingly senior level roles at the firm. In 2006, Mr. Seaburg was named Head of Sales Trading and appointed to the firm’s Equity Operating Committee. Mr. Seaburg is a CNBC Fast Money Contributor and provides regular on-air market commentary for the network. Mr. Seaburg holds a Bachelor of Arts degree in Business Finance and Economics from Northeastern University. Mr. Seaburg is qualified to serve as a member of the Board because of his knowledge of financial management, marketing, investor relations, acquisition transactions, and capital markets.

Minnie Baylor-Henry joined the Board in December 2018. She is a regulatory affairs leader who provides regulatory strategic support services to life sciences companies through her consulting firm, B-Henry & Associates. Before starting her consulting company, Ms. Baylor-Henry was employed by Johnson & Johnson (“J&J”) and members of the

J&J health care group in a number of positions, including: Worldwide Vice President Regulatory Affairs - Medical Devises for J&J from January 2011 to March 2015; Vice President - Medical & Regulatory Affairs – Specialty Pharmaceuticals, and Vice President-Regulatory Affairs – Over-the-Counter Products for McNeil Consumer Health Care from August 2003 to October 2008; and, Senior Director, Regulatory Affairs for RW Johnson Pharmaceutical Research & Development Corporation from July 1999 to August 2003. From October 2008 to October 2010, Ms. Baylor-Henry served as the National Director Regulatory Affairs Life Sciences for Deloitte. For eight years prior to August 1999, Ms. Baylor-Henry served in several positions with the U.S. Food & Drug Administration, including Director/Branch Chief – Division of Drug Marketing, Advertising and Communications, National Health Fraud Coordinator – Office of Regulatory Affairs/ Federal/ State Relations, and Regulatory Review Officer. From July 2018, to the present Ms. Baylor-Henry has served as a director of scPharmaceuticals, Inc., a publicly-held company engaged in the business of developing technologies that enable the subcutaneous administration of therapies that have previously been limited to intravenous delivery. Ms. Baylor-Henry received her pharmacy degree from Howard University’s College of Pharmacy and a law degree from Catholic University’s Columbus School of Law. Ms. Baylor-Henry is qualified to serve as a member of the Board because of her knowledge of the healthcare industry and experience with the regulatory regimen applicable to biologic and pharmaceutical products.

The following table sets forth the names, and positions of our executive officers.

Name	Position(s)
Denver Lough	Chief Executive Officer, Chief R&D Officer, Chairman and Class III Director
Edward Swanson	Chief Operating Officer
Paul E. Mann	Chief Financial Officer
Cameron Hoyler	General Counsel, Secretary, EVP Corporate Development & Strategy

The following is a summary of the background of each of our executive officers, except for Dr. Lough, which is presented above with our director information.

Dr. Edward Swanson, 33, was appointed as Chief Operating Officer and Director of the Company on December 1, 2016. Following completion of his undergraduate degree in Applied Sciences in Biomedical Sciences at the School of Engineering and Applied Sciences at the University of Pennsylvania, Dr. Swanson received his medical degree from Harvard Medical School, where he attended as a student from August 2008 to May 2012, graduating with honors for his thesis researching surgical outcomes within craniofacial and plastic surgery. From July 2012 until December 2016, Dr. Swanson was a Surgical Resident in Plastic & Reconstructive Surgery in the Department of Plastic and Reconstructive Surgery at The Johns Hopkins University School of Medicine. During his time at Johns Hopkins, he served in a leadership role within the residency, sitting on the Program Evaluation Committee from July 2015 to December 2016, and The Johns Hopkins Hospital House staff Patient Safety and Quality Council from July 2014 to June 2015. Dr. Swanson has extensive experience in basic and translational biomedical research, including as a research associate in Wound Healing in the Division of Plastic Surgery at the Brigham and Women's Hospital and Harvard Medical School from May 2004 to August 2004, thesis student in Traumatic Brain Injury at the University of Pennsylvania from August 2006 to May 2007, research fellow in Pancreatic Cancer Cellular Biology at the Brigham and Women's Hospital and Harvard Medical School from July 2007 to July 2008, research fellow in Nanomedicine at Harvard Medical School and MIT from May 2008 to August 2008, and research fellow in Vascularized Composite Allotransplantation at the Massachusetts General Hospital and Harvard Medical School during his final year of medical school. In addition, Dr. Swanson directed large animal translational research as a lead research associate in the Vascularized Composite Allotransplantation Laboratory in the Department of Plastic and Reconstructive Surgery at The Johns Hopkins University School of Medicine from July 2014 to June 2015, overseeing experimental projects funded by multimillion dollar grants. Furthermore, Dr. Swanson has demonstrated national and international leadership throughout the field of plastic and reconstructive surgery at a young age, with greater than 40 peer-reviewed publications, five book chapters, and 30 national/international conference presentations. We believe that Dr. Swanson is qualified to serve as a member of our Board because of his experience in technology related to regenerative medicine and related technologies and their clinical applications, which the Company has reviewed for potential development.

Paul E. Mann, age 42, served as the Healthcare Portfolio Manager for Highbridge Capital Management from August 2016 until he joined the Company as Chief Financial Officer in June 2018. From August 2013 to March 2016, Mr.

Mann served as an analyst with Soros Fund Management. Prior to joining Soros Fund Management, Mr. Mann was an analyst and portfolio manager with Lodestone Natural Resources and UBS from September 2011 to March 2013. Prior to moving to the buy-side, Mr. Mann spent 11 years as a sell-side analyst at Morgan Stanley and Deutsche Bank. He started his career as a research scientist at Proctor and Gamble and he has an MA (Cantab) and an MEng in Chemical Engineering from Cambridge University. Mr. Mann is a CFA charter holder.

Cameron Hoyler, 35, was appointed General Counsel in April 2017, EVP Corporate Development & Strategy in May 2018, and Secretary in September 2018. Prior to joining the Company, Mr. Hoyler was an attorney at King & Spalding LLP, where he practiced in the Life Sciences and Product Liability groups from September 2012 to April 2017. Mr. Hoyler represented and counseled clients involved in disputes and transactions in a variety of settings, including product liability, employment, commercial, trademark, real estate, and insurance coverage. While at King & Spalding LLP, Mr. Hoyler devoted the vast majority of his practice to representing clients in the pharmaceutical and medical device industries, including Bristol-Myers Squibb Company, AstraZeneca Pharmaceuticals LP, and McKesson Corporation, in addition to working for clients in other highly-regulated industries, such as Chevron U.S.A. Inc. and Monsanto Company. From September 2010 to September 2012, Mr. Hoyler practiced at the law firm of Filice, Brown, Eassa & McLeod, where his practice included product liability, premises liability, employment, and insurance-related matters. He earned his Bachelor of Arts from the University of Pennsylvania, and his Juris Doctor from the University of San Francisco School of Law.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires the Company's directors, executive officers, and stockholders who own more than 10% of the Company's stock to file forms with the SEC to report their ownership of the Company's stock and any changes in ownership. The Company assists its directors and executives by identifying reportable transactions of which it is aware and preparing and filing the forms on their behalf. All persons required to file forms with the SEC must also send copies of the forms to the Company. We have reviewed all forms provided to us. Based on that review and on written information given to us by our executive officers and directors, we believe that all Section 16(a) filings during the past fiscal year were filed on a timely basis and that all directors, executive officers and 10% beneficial owners have fully complied with such requirements during the past fiscal year, except that immediately following his election to the Board Peter A. Cohen did not report on a timely basis the restricted stock units awarded to him in consideration for joining the Board due to a delay in obtaining his EDGAR filer codes.

Code of Ethics

We have adopted Code of Business Ethics and Practices that applies to every employee, officer, and director. Our Code of Business Ethics and Practices is publicly available, and can be found on our website at http://www.polarityte.com/ by clicking on the link to "Investor Relations" and the link to "Corporate Governance."

Procedure for Recommending Directors

There has not been a material change to the procedures by which security holders may recommend nominees for election to our board of directors since August 17, 2018, the date we filed our Proxy Statement for the annual meeting of stockholders held on September 20, 2018.

Audit Committee

Our board of directors has a standing Audit Committee. The board of directors has affirmatively determined the Audit Committee is composed of independent directors, as independence is defined for members of an audit committee in the rules of The NASDAQ Stock Market and Rule 10A-3(b)(1) adopted under the exchange Act. The members of the Audit Committee at October 31, 2018, were Jeff Dyer, Steve Gorlin, and Jon Mogford. The Board has determined that Jeff Dyer meets the qualification requirements of an audit committee financial expert as defined in Item 407 of Regulation S-K.

Item 11 - Executive Compensation.

Summary Compensation Table

The following Summary Compensation Table sets forth summary information as to compensation paid or accrued to our named executive officers during the last two fiscal years ended October 31, 2018 and 2017. Our named executive officers include our principal executive officer and the two most highly compensated executive officers other than the principal executive officer who were serving as executive officers at the end of the last completed fiscal year. There is no individual who was not serving as an executive officer at the end of the last completed fiscal year who served as an executive officer during the last completed fiscal year and would have been one of the two most highly compensated executive officers had the individual been serving at the end of the fiscal year.

Name and Principal Position	Year	Salary ($)	Bonus ($)	**Stock Awards ($)(1)**	**Option Awards ($)(1)**	Total ($)
Denver Lough	2018	448,462	1,010,000	2,395,050(2)	9,860,825(5)	13,714,337
Chairman of the Board,	2017	315,000	100,000	-0-	2,121,250(6)	2,536,250
Chief Executive Officer, Chief R&D Officer						
Edward Swanson	2018	338,462	650,000	798,350 (3)	2,738,775(7)	4,525,587
Chief Operating Officer	2017	270,000	100,000	-0-	1,794,578(8)	2,164,578
Paul E. Mann	2018	133,846	75,666	3,971,124(4)	9,682,330(9)	13,862,967
Chief Financial Officer	2017	-	-	-	-	-

(1) The figures in these columns represent the aggregate grant date fair value for restricted stock and option awards, respectively, granted during fiscal years 2018 and 2017 computed in accordance with FASB ASC Topic 718. See Note 11 to our consolidated financial statements presented in this Annual Report for details as to the assumptions used to determine the grant date fair value of the restricted stock and option awards.

(2) Represents 105,000 shares at a grant date fair value of $22.81 per common share.

(3) Represents 35,000 shares at a grant date fair value of $22.81 per common share.

(4) Represents 100,000 shares at a grant date fair value of $37.05 per common share and 11,667 shares at a grant date fair value of $22.81 per common share.

(5) Represents stock options to purchase 400,000 common shares at an exercise price of $24.95 per common share and 195,000 common shares at an exercise price of $20.12.

(6) Represents stock options to purchase 1,000,000 common shares at an exercise price of $3.15 per common share.

(7) Represents stock options to purchase 100,000 common shares at an exercise price of $24.95 and 65,000 common shares at an exercise price of $20.12.

(8) Represents stock options to purchase 846,000 common shares at an exercise price of $3.15 per common share.

(9) Represents stock options to purchase 350,000 common shares at an exercise price of $31.88 per common share and 21,666 common shares at an exercise price of $20.12.

Narrative Disclosure to Summary Compensation Table

Denver Lough's Employment Agreement

We have a written employment agreement with Dr. Lough dated November 10, 2017. We paid Dr. Lough a bonus of $150,000 when we signed the agreement. The agreement has an initial term of three years and automatically renews for successive one-year periods unless either party provides the other party with written notice of his or its intention not to renew at least three months prior to the expiration of the current term.

Dr. Lough's base salary is $530,000 per year. He is eligible to receive a bonus in the amount of 100% of annual salary, as may be determined from time to time by the Board of Directors in its discretion, and is eligible to participate in any equity- based incentive compensation plan or program we adopt. During 2018, Dr. Lough was awarded:

- cash bonuses totaling $1,010,000,
- restricted stock units representing the right to receive a total of 105,000 shares of common stock that vest in four equal installments every six months beginning six months following the grant date, and
- options to purchase 400,000 common shares at an exercise price of $24.95 and 195,000 common shares at an exercise price of $20.12, both exercisable for a term of 10 years that vest in 24 equal monthly installments beginning one month after the grant date.

Dr. Lough, if terminated while not in material breach of the agreement, shall also have the right to participation payments paid to the Company (or any affiliate) from commercial transactions associated with U.S. Patent Application No. 14/954,335 and PCT International Patent Application No. PCT/US2015/063114, and any and all patents and patent applications, whether domestic or foreign, claiming priority thereto or arising therefrom, and intellectual property rights associated with the patents (sales or licenses to third parties).

Edward Swanson's Employment Agreement

We have a written employment agreement with Dr. Swanson dated November 10, 2017. We paid Dr. Swanson a bonus of $100,000 when we signed the agreement. The agreement has an initial term of two years and automatically renews for successive one-year periods unless either party provides the other party with written notice of his or its intention not to renew at least three months prior to the expiration of the current term.

Dr. Swanson's base salary is $400,000 per year. He is eligible to receive a bonus in the amount of 100% of annual salary, as may be determined from time to time by the Board of Directors in its discretion, and is eligible to participate in any equity- based incentive compensation plan or program we adopt. During 2018, Dr. Swanson was awarded:

- cash bonuses totaling $650,000,
- restricted stock units representing the right to receive a total of 35,000 shares of common stock that vest in four equal installments every six months beginning six months following the grant date, and
- options to purchase 100,000 common shares at an exercise price of $24,95 and 65,000 common shares at an exercise price of $20.12, both exercisable for a term of 10 years that vest in 24 equal monthly installments beginning one month after the grant date.

Paul E. Mann's Employment Agreement

Mr. Mann's employment agreement (the "Mann Agreement") provides for an annual base salary of $400,000 and a discretionary annual bonus up to 100% of his base salary as determined at the discretion of the board of directors. Mr. Mann was granted options under the Company's 2017 Equity Incentive Plan to purchase 350,000 and 21,666 shares of the Company common stock at a price equal to fair value as determined under the Plan exercisable over a period of 10 years, which vests subject to continued employment in 24 equal monthly installments beginning one month after the effective date of his engagement, and restricted stock awards equivalent to 100,000 and 11,667 shares of Company common stock that vests, subject to continued employment, in four installments every six months beginning on the date six months following the effective date of his engagement. At the discretion of the Board, Mr. Mann may be granted additional equity compensation awards. Mr. Mann is also entitled to certain payments and benefits if the Company terminates his employment without "cause" or he terminates his employment for "good reason". Benefits are also provided if Mr. Mann is terminated because of a change in control. The benefit levels under the employment

agreements generally include continued payment of base salary, a bonus for the year of termination, accelerated vesting of equity awards and continued welfare benefits, and are described in more detail under the “Potential Payments Upon Termination or Change-In-Control” below. Mr. Mann is entitled to participate in the Company’s insurance and benefit plans on the same basis as other employees of the Company.

Potential Payments Upon Termination or Change-In-Control

Under our employment agreements with Dr. Lough, Dr. Swanson, and Mr. Mann, we are obligated to make payments or provide benefits to them in the event of a termination of employment or a change of control. If employment of one of these officer is terminated for any reason, then the officer is entitled to receive:

- the sum of his then base salary from the date of termination,
- reasonable expenses incurred by the officer relating to the performance of his duties,
- accrued but unused vacation time through the date of termination,
- the sum of his then annual bonus, and
- all equity awards earned and vested prior to the date of termination.

Furthermore, if the officer is terminated for any reason other than "cause," by the officer for "good reason," or because of a change in control, then the officer is entitled to receive the greater of:

- a cash amount equal to the sum of the officer's base salary, annual bonus, and equity awards earned during the year immediately preceding the date of termination, or
- the amount payable (including base salary, annual bonus, and equity awards) for the remainder of the term of the employment agreement;

subject to the officer delivering to us a written release agreement.

Under the agreements, "cause" means: the willful and continued failure of the officer to perform substantially his duties and responsibilities (other than due to death or disability) and such failure is not cured within 30 days following a written demand for performance; conviction of, or plea of guilty or *nolo contendere* to, a felony; or fraud, dishonesty, or gross misconduct that is materially and demonstratively injurious to the Company. "Good reason" means the occurrence of any of the following events without the officer's consent: the assignment to the officer of duties that are significantly different from, or that result in a substantial diminution of, the duties that he assumed on at the beginning of the employment agreement; the assignment to the officer of a title that is different from and subordinate to the title at the beginning of the employment agreement; or material breach of the employment agreement by the Company. Should the officer be required to serve in a diminished capacity in a division or unit of another entity (including the acquiring entity), after a change in control, such event constitutes good reason regardless of the title of the officer.

Dr. Lough, if terminated while not in material breach of his employment agreement, is entitled to receive participation payments on amounts paid to us from commercial transactions associated with U.S. Patent Application No. 14/954,335, and PCT International Patent Application No. PCT/US2015/063114, and any and all patents and patent applications, whether domestic or foreign, claiming priority thereto or arising therefrom, and intellectual property rights associated with the patents, such as sales or licenses to third parties.

Outstanding Equity Awards at Fiscal Year-End

The following table shows grants of stock options and grants of unvested stock awards outstanding on the last day of the fiscal year ended October 31, 2018, to each of the executive officers named in the Summary Compensation Table.

	Option Awards					Stock Awards	
Name	Option Grant Date	Number of Securities	Number of Securities	Option Exercise	**Option**	Number	Market Value of

		Underlying Unexercised Options Exercisable (#)(1)	Underlying Unexercised Options Unexercisable (#)(1)	Price ($)	**Expiration Date**	of Shares or Units of Stock That Have Not Vested (#)	Shares or Units of Stock That Have Not Vested ($)(2)
Denver Lough	11-30-2016	958,333	41,667	$ 3.15	11-30-2026	105,000	$1,600,200
	11-10-2017	183,333	216,667	$ 24.59	11-10-2027	-	-
	9-20-2018	8,125	186,875	$ 20.12	9-20-2028	-	-
Edward Swanson	11-30-2016	810,750	35,250	$ 3.15	11-30-2026	35,000	$533,400
	11-10-2017	45,833	54,167	$ 24.59	11-10-2027	-	-
	9-20-2018	2,708	62,292	$ 20.12	9-20-2028	-	-
Paul E. Mann	6-20-2018	58,333	291,667	$ 31.88	6-20-2028	100,000	$1,524,000
	9-20-2018	903	20,763	$ 20.12	9-20-2028	11,667	$177,805

(1) All stock option listed vest in 24 monthly installments beginning one month following the grant date.
(2) Market value based on closing stock price of $15.24 on October 31, 2018

Director Compensation

The following table shows the total compensation paid or accrued during the fiscal year ended October 31, 2018, to each of our directors, current and former.

Name	**Fees Earned or Paid in Cash ($)**	**Stock Awards ($)(1)**	**Option Awards ($)(1)**	**All Other Compensation ($)**	Total ($)
Steve Gorlin	38,000	119,500 (2)	82,225 (6)	-0-	239,775
Jeff Dyer	45,000	119,500 (2)	82,225 (6)	-0-	246,775
Jon Mogford	40,000	119,500 (2)	82,225 (6)	-0-	241,775
Willie C. Bogan	20,000	777,300 (3)	-0-	-0-	797,300
Peter A. Cohen	10,000	706,200 (4)	-0-	-0-	716,200
Rainer Erdtmann	-0-	-0-	800,542 (7)	-0-	800,542
David Seaburg	-0-	1,347,600 (5)	-0-	-0-	1,347,600
Minnie Baylor-Henry(8)	-0-	-0-	-0-	-0-	-0-

(1) The figures in these columns represent the aggregate grant date fair value for restricted stock and option awards, respectively, granted during fiscal years 2018 and 2017 computed in accordance with FASB ASC Topic 718. See Note [ ] to our consolidated financial statements presented in this Annual Report for details as to the assumptions used to determine the grant date fair value of the restricted stock and option awards.

(2) Represents 5,000 shares at a grant date fair value of $23.91 per common share.

(3) Represents 30,000 shares at a grant date fair value of $25.91 per common share.

(4) Represents 30,000 shares at a grant date fair value of $23.54 per common share.

(5) Represents 60,000 shares at a grant date fair value of $22.46 per common share.

(6) Represents stock options to purchase 5,000 common shares at an exercise price of $24.59 per common share.

(7) Represents stock options to purchase 50,000 common shares at an exercise price of $20.47 per common share.

(8) Minnie Baylor-Henry became a director in December 2018. At that time, she received the initial director compensation previously approved by resolution of the Board in September 2018 for all new directors. The compensation included a grant to her of 8,975 restricted stock units for an equal number of common shares that vest in three annual installments commencing December 10, 2019, subject to continued service as a director, and an option to

purchase 19,329 shares of the Company's common stock exercisable over a term of 10 years that vest in three annual installments commencing December 10, 2019, subject to continued service as a director. The restricted stock units and option were issued under the Company's 2019 Equity Incentive Plan, and the option exercise price is $13.65 per share, which is fair value determined under the Plan. The fair value of the compensation determined in accordance with FASB ASC Topic 718 is $350,000. Ms. Baylor-Henry will also be entitled to participate in the annual compensation package the Company provides to its non-employee directors.

During the fiscal year ended October 31, 2017, our non-employee directors were compensated in accordance with the following terms.

Each non-employee director receives a quarterly cash retainer of $10,000. The Company's Audit Committee Chairman receives a $15,000 annual Service Fee, the Compensation Committee Chairman receives a $10,000 annual service fee, and the Nominating and Corporate Governance Committee Chairman receives an $8,000 annual service fee.

Each non-employee director is entitled to receive 10-year options under the Company equity incentive plan to purchase that number of shares of the Company's Common Stock valued at $150,000, calculated by dividing $150,000 by the Black-Scholes value of the stock options based on the closing stock price the day the stock options are awarded.

Each non-employee director is entitled to a fee of $1,500 for each Board of Directors meeting at which the director is present in person, and each member of our Board committees is entitled to a fee of $800 for each committee meeting at which the director is present in person. Each non-employee director is entitled to a fee of $500 for each teleconference called by either the Chairman of the Board of Directors, the President of the Company or the Chairman of a Board of Directors committee.

Effective November 1, 2018, non-employee directors will be compensated as follows:

- Each non-employee director receives an annual cash retainer of $45,000 paid quarterly;
- Our Audit Committee Chairman will receive an annual fee of $20,000, our Compensation Committee Chairman will receive an annual fee of $15,000, and our Nominating and Governance Committee Chairman will receive an annual fee of $10,000;
- Non-chair members of our Audit Committee will receive an annual fee of $9,000, of our Compensation Committee will receive an annual fee of $7,000, and of our Nominating and Governance Committee Chairman will receive an annual fee of $5,000; and
- Each non-employee director is entitled to receive an annual equity award with a value of $175,000 determined under the Black-Scholes formula, which may be issued entirely in stock options exercisable over 10 Years that vest, subject to continuing service, in 12 monthly installments beginning one month after the grant date, or 65% in stock options and 35% restricted stock units that vest, subject to continuing service, in a lump sum one year after the grant date.

David Seaburg

In August 2018 David Seaburg was elected by the Board of Directors to serve as a director of the Company. Subsequently the Company entered into a written consulting agreement with Mr. Seaburg pursuant to which he will provide investor relations and other services to the Company over a period of two years for a fee consisting of (i) quarter-annual cash payment of $10,000, (ii) 60,000 restricted stock units issued under the Company equity incentive plan that vest in four equal installments every six months during the term of the agreement subject to continued service, and (iii) an annual award under the Company equity incentive plan of options exercisable over a term of 10 years to purchase common stock in number equal to the number of shares of common stock with a value of $150,000 at the time of the award based on a Black-Scholes calculation.

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

The following table sets forth information regarding the beneficial ownership of our common stock as of January 7, 2019, by

- each person known to us to be the beneficial owner of more than 5% of the common stock,
- each of our current directors,
- each officer named in the Summary Compensation Table presented in Item 11, above, and
- all our directors and executive officers as a group.

The number of shares of common stock beneficially owned by each person is determined under applicable SEC rules. Under such rules, beneficial ownership includes any shares as to which the person has sole or shared voting power or investment power, and any shares that the person has the right to acquire within 60 days of the date as of which the beneficial ownership determination is made. Applicable percentages are based upon 21,456,643 voting shares issued and outstanding as of January 7, 2019, and treating any shares that the holder has the right to acquire within 60 days as outstanding for purposes of computing their percent ownership. Except as otherwise indicated, each of the stockholders listed below has sole voting and investment power over the shares beneficially owned, subject to community property laws where applicable, and addresses are c/o PolarityTE, Inc., 123 Wright Brothers Drive, Salt Lake City, Utah 84116.

	Number of Shares of Common Stock Beneficially Owned	Percentage of Common Stock
Executive Officers and Directors (1):		
Denver Lough	8,357,292	36.7
Edward Swanson	927,898	4.1
Paul Mann	166,181	0.7
Cameron Hoyler	215,417	1.0
Steve Gorlin	111,209	0.5
Jon Mogford	112,757	0.5
Jeff Dyer	173,731	0.8
Willie C. Bogan	10,376	nil
Peter A. Cohen	60,376	0.3
Rainer Erdtmann (2)	163,187	0.8
David Seaburg	25,000	0.1
Minnie Baylor-Henry	-0-	-0-
Executive Officers and Directors as a Group (12 persons)	10,323,424	42.5
Greater that 5% Holders:		
Barry Honig (3) 555 S. Federal Hwy, #450, Boca Raton, FL 33432	1,927,388	9.0
Michael Brauser (4) 4400 Biscayne Blvd., Suite 850, Miami, FL 33137	1,431,638	6.7

(1) Includes the following number of shares of options that were exercisable or restricted share awards expected to vest within 60 days of January 14, 2019: Dr. Lough, 1,037,292; Dr. Swanson 927,898; Mr. Hoyler, 125,417; Mr. Gorlin, 56,208, Dr. Mogford, 57,756; Mr. Dyer, 147,208; Mr. Bogan, 10,375; Mr. Cohn, 10,375; Mr. Erdtmann, 19,005; and Mr. Seaburg, 15,000.

(2) Includes 94,180 shares owned by Point Sur Investors Fund I. Mr. Erdtmann is Managing Director and General Partner of Point Sur Investors LLC, the general partner of Point Sur Investors Fund I, and as a result may be deemed to have shared voting and investment control over the shares held by Point Sur Investors Fund I.

(3) The stock information for Mr. Honig is based on information contained in an amendment to Schedule 13G filed with the Securities and Exchange Commission on July 23, 2018, reflecting the stockholder’s beneficial ownership as of July 23, 2018.

(4) The stock information for Mr. Brauser is based on information contained in an amendment to Schedule 13G filed with the Securities and Exchange Commission on June 28, 2018, reflecting the stockholder's beneficial ownership as of June 27, 2018.

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

Director Independence

Our Board is currently comprised of nine members. The Board has reviewed the materiality of any relationship that each of our directors has with the Company, either directly or indirectly. Based upon this review, the Board has determined that Steve Gorlin, Jeff Dyer, Dr. Jon Mogford, Willie C. Bogan, Peter A. Cohen, Rainer Erdtmann,and Minnie Baylor-Henry are "independent directors" as defined by the rules of The NASDAQ Stock Market.

Certain Relationships and Related Transactions

In October 2018, we entered into an office lease covering approximately 7,250 square feet of rental space in the building located at 40 West 57th Street in New York City. The lease is for a term of three years. The annual lease rate is $60 per square foot. Initially we will occupy and pay for only 3,275 square feet of space, and we are not obligated under the lease to pay for the remaining 3,975 square feet covered by the lease unless we elect to occupy that additional space. Comparable annual lease rates for similar office space in the area range between $67 and $110 per square foot. We believe the terms of the lease are very favorable to us, and we obtained these favorable terms through the efforts of Peter A. Cohen, a director, which he provided so that the company he owns, Peter A. Cohen, LLC ("Cohen LLC"), could sublease a portion of the office space.

Initially, we are using three offices and two work stations in the office and share common areas representing approximately 2,055 square feet. Cohen LLC is using approximately 1,220 square feet. The monthly lease payment for 3,275 square feet is $16,377. Of this amount $6,103 is allocated pro rata to Cohen LLC based on square footage occupied. Additional lease charges for operating expenses and taxes are allocated under the sublease based on the ratio of rent paid by us and Cohen LLC to total rent.

Cohen LLC identified two associated entities that may wish to occupy an additional 2,753 square feet of space in the office. Under the terms of the sublease Cohen LLC can add this additional space to the 1,220 square feet occupied, which would bring the total space occupied by us and Cohen LLC to 6,028 square feet. Because a portion of the additional space subleased to Cohen LLC is less private and attractive, we agreed to reduce the overall annual lease rate for the Cohen LLC space to $58.60 per square foot, which means we will be paying an annual lease rate for the space we use of $62.70. Assuming Cohen LLC subleases the additional office space, our annual lease payment to the lessor would be $361,680, and Cohen LLC would pay to us $232,830 under the sublease.

Item 14 - Principal Accountant Fees and Services.

The following table sets forth the fees billed by EisnerAmper LLP ("EisnerAmper"), for each of our last two fiscal years for the categories of services indicated.

	2018 ($)	2017 ($)
Audit Fees	485,210	198,540
Audit Related Fees	—	—
Tax Fees	—	—
Other Fees	—	—
Total Fees	485,210	198,540

Audit fees consist of fees billed for professional services rendered for the audit of our financial statements and review of interim consolidated financial statements included in quarterly reports and services that are normally provided by the principal accountants relating to statutory and regulatory filings or engagements.

Audit related fees consist of fees billed for assurance and related services that are reasonably related to the performance of the audit or review of our consolidated financial statements and are not included in audit fees.

Tax fees consist of fees billed for professional services for tax compliance, tax advice, and tax planning. These services include preparation of federal and state income tax returns.

Other fees consist of fees for product and services other than the services reported in the categories described above.

Audit Committee Pre-Approval Policies and Procedures

Our Audit Committee assists the Board in overseeing and monitoring the integrity of our financial reporting process, our compliance with legal and regulatory requirements, and the quality of our internal and external audit processes. The role and responsibilities of the Audit Committee are set forth in a written charter adopted by the Board, which is available on our website at *www.polarityte.com.* The Audit Committee is responsible for selecting, retaining, and determining the compensation of our independent public accountant, approving the services they will perform, and reviewing the performance of the independent public accountant. The Audit Committee reviews with management and our independent public accountant our annual financial statements on Form 10-K and our quarterly financial statements on Forms 10-Q. The Audit Committee reviews and reassesses the charter annually and recommends any changes to the Board for approval. The Audit Committee is responsible for overseeing our overall financial reporting process. In fulfilling its responsibilities for the financial statements for fiscal year 2018, the Audit Committee took the following actions:

- reviewed and discussed the audited financial statements for the fiscal year ended October 31, 2018, with management and EisnerAmper;
- discussed with EisnerAmper the matters required to be discussed in accordance with the rules set forth by the Public Company Accounting Oversight Board (“PCAOB”), relating to the conduct of the audit;
- received written disclosures and the letter from EisnerAmper regarding its independence as required by applicable requirements of the PCAOB regarding EisnerAmper’s communications with the Audit Committee and the Audit Committee further discussed with EisnerAmper its independence; and
- considered the status of pending litigation, taxation matters, and other areas of oversight relating to the financial reporting and audit process that the Audit Committee determined appropriate.

Our Audit Committee approved all services that our independent accountants provided to us in the past two fiscal years.

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)
3.13	Amendment No. 1 to Restated Bylaws dated January 11, 2019, Changing Fiscal Year
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).
#10.01	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)
10.02	Stockholders Agreement (incorporated by reference to Exhibit 10.4 to our Form 8-K filed with the Commission on December 7, 2016)
10.03	Voting Agreement (incorporated by reference to Exhibit 10.5 to our Form 8-K filed with the Commission on December 7, 2016)
10.04	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)
10.05	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)
10.06	Form of Subscription Agreement (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the Commission on December 16, 2016)
10.07	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)
10.08	Form of First Amendment to Agreement and Plan of Reorganization (incorporated by reference to Exhibit 10.3 to our Form 8-K filed with the Commission on December 16, 2016)
10.09	Form of Exchange Agreement (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the Commission on January 19, 2017)
10.10	Purchase Agreement by and Among the Company and Zift Interactive LLC (incorporated by reference to our Form 10-Q filed with the Commission on September 14, 2017)
10.11	Form of Subscription Agreement (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the Commission on September 20, 2017)
10.12	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the Commission on September 20, 2017)
#10.13	Employment Agreement with Denver Lough (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the Commission on November 16, 2017)
#10.14	Employment Agreement with Edward Swanson (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the Commission on November 16, 2017)
#10.15	

	Employment Agreement with John Stetson (incorporated by reference to Exhibit 10.3 to our Form 8-K filed with the Commission on November 16, 2017)
#10.16	Employment Agreement with Cameron Hoyler (incorporated by reference to Exhibit 10.4 to our Form 8-K filed with the Commission on November 16, 2017)
10.17	Commercial Lease Agreement by and Between the Company and Adcomp LLC (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the Commission on December 29, 2017)
#10.18	Executive Employment Agreement with Paul Mann (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the Commission on September 14, 2018)
#*10.19	Consulting Agreement with David Seaburg dated August 8, 2018

#*10.20	Form of Restricted Stock Unit Agreement – 2017 Equity Incentive Plan
#*10.21	Form of Stock Option Agreement – 2017 Equity Incentive Plan
#*10.22	Form of Restricted Stock Unit Agreement – 2019 Equity Incentive Plan
#*10.23	Form of Stock Option Agreement – 2019 Equity Incentive Plan
#10.24	PolarityTE 2019 Equity Incentive Plan (incorporated by reference to Exhibit 99.1 to our Form S-8 registration Statement filed with the Commission on October 5, 2018)
#10.25	PolarityTE 2019 Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.2 to our Form S-8 registration Statement filed with the Commission on October 5, 2018
*10.26	Agreement of Lease by and between the Company and Lefrak Sbn Limited Partnership for office space at 40 West 57th Street, New York, New York 10019
*10.27	Sublease Agreement by and between the Company and Peter Cohen LLC for office space at 40 West 57th Street, New York, New York 10019
*21.1	Subsidiaries
*23.1	Consent of EisnerAmper LLP
*31.1	Certification of Principal Executive Officer
*31.2	Certification of Principal Financial Officer
*32.1	Section 1350 Certificate of Chief Executive Officer and Chief Financial Officer

*101.INS	XBRL Instance Document
*101.SCH	XBRL Taxonomy Extension Schema Document
*101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
*101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
*101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
*101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

#Constitutes a management contract, compensatory plan or arrangement.
*Filed herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

POLARITYTE, INC. AND SUBSIDIARIES

By: */s/ Denver Lough*
Chief Executive Officer (Principal Executive Officer)

Date: January 14, 2018

By: */s/ Paul Mann*
Chief Financial Officer (Principal Financial and Accounting Officer)

Date: January 14, 2019

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	**Title**	**Date**
/s/ Denver Lough Denver Lough	Chief Executive Officer and Chairman of the Board of Directors	January 14, 2019
/s/ Steven Gorlin Steven Gorlin	Director	January 14, 2019
/s/ Jeffery Dyer Jeffery Dyer	Director	January 14, 2019
/s/ Jon Mogford Jon Mogford	Director	January 14, 2019
/s/ Willie C. Bogan Willie C. Bogan	Director	January 14, 2019
/s/ Peter A. Cohen Peter A. Cohen	Director	January 14, 2019
/s/ Rainer Erdtmann Rainer Erdtmann	Director	January 14, 2019
/s/ David Seaburg David Seaburg	Director	January 14, 2019
/s/ Minnie Baylor-Henry Minnie Baylor-Henry	Director	January 14, 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

PolarityTE, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of PolarityTE, Inc. and Subsidiaries (the "Company") as of October 31, 2018 and 2017, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of October 31, 2018 and 2017, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of October 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated January 14, 2019 expressed an adverse opinion.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates

made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2010. Partners of Amper, Politziner & Mattia LLP joined EisnerAmper LLP in 2010. Amper, Politziner & Mattia LLP had served as the Company's auditor since 2009.

EISNERAMPER LLP

Iselin, New Jersey

January 14, 2019

POLARITYTE, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)

	October 31, 2018	October 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$70,961	$17,667
Accounts receivable	940	–
Inventory	238	–
Prepaid expenses and other current assets	1,163	297
Total current assets	73,302	17,964
Non-current assets:		
Property and equipment, net	12,927	2,173
Intangible assets, net	957	–
Goodwill	278	–
Other assets	378	15
Total non-current assets	14,540	2,188
TOTAL ASSETS	$87,842	$20,152
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$4,363	$1,939
Other current liabilities	286	–
Current portion of long-term note payable	519	–
Deferred revenue	150	–
Warrant liability and embedded derivative	–	13,502
Total current liabilities	5,318	15,441
Long-term note payable, net	736	–
Other long-term liabilities	126	–
Total liabilities	6,180	15,441
Commitments and Contingencies		
Redeemable convertible preferred stock - 0 and 6,455 shares authorized, issued and outstanding at October 31, 2018 and 2017; liquidation preference - $0 and $17,750.	–	4,541
STOCKHOLDERS' EQUITY:		
Convertible preferred stock - 25,000,000 shares authorized, 0 and 3,230,655 shares issued and outstanding at October 31, 2018 and 2017, aggregate liquidation preference $0 and $2,140, respectively	–	109,995

Common stock - $.001 par value; 250,000,000 shares authorized; 21,423,999 and 6,515,524 shares issued and outstanding at October 31, 2018 and 2017, respectively	21	7
Additional paid-in capital	406,087	149,173
Accumulated deficit	(324,446)	(259,005)
Total stockholders' equity	81,662	170
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$87,842	$20,152

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

POLARITYTE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share amounts)

	For the Years Ended October 31,	
	2018	2017
Net revenues		
Products	$689	$–
Services	874	–
Total net revenues	1,563	–
Cost of sales:		–
Products	500	–
Services	502	–
Total costs of sales	1,002	–
Gross profit	561	–
Operating costs and expenses		
Product research and development	19,376	7,107
Research and development - intellectual property acquired	–	104,693
General and administrative	48,252	18,812
Sales and marketing	2,365	–
Total operating costs and expenses	69,993	130,612
Operating loss	(69,432)	(130,612)
Other income (expense)		
Interest income	395	23
Change in fair value of derivatives	3,814	109
Loss on extinguishment of warrant liability	(520)	–
Net loss from continuing operations before income taxes	(65,743)	(130,480)
Benefit for income taxes	302	–
Net loss from continuing operations	(65,441)	(130,480)
Loss from discontinued operations	–	(449)
Gain on sale of discontinued operations	–	100
Loss from discontinued operations, net	–	(349)
Net loss after income taxes	(65,441)	(130,829)
Deemed dividend – accretion of discount on Series F preferred stock	(1,290)	(369)
Deemed dividend – exchange of Series F preferred stock	(7,057)	–
Cumulative dividends on Series F preferred stock	(373)	(124)
Net loss attributable to common stockholders	$(74,161)	$(131,322)
Net loss per share, basic and diluted:		
Loss from continuing operations	$(4.29)	$(26.50)
Loss from discontinued operations	–	(0.07)

Net loss	(4.29)	(26.57)
Deemed dividend – accretion of discount on Series F preferred stock	(0.09)	(0.07)
Deemed dividend – exchange of Series F preferred stock	(0.46)	-
Cumulative dividends on Series F preferred stock	(0.02)	(0.03)
Net loss attributable to common stockholders	$(4.86)	$(26.67)
Weighted average shares outstanding, basic and diluted:	15,259,731	4,923,327

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

POLARITYTE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share and per share amounts)

	Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Number	Amount	Number	Amount	Capital	Deficit	Equity
Balance - October 31, 2016	7,374,454	$10,153	2,782,963	$ 3	$123,417	$ (128,176)	$ 5,397
Issuance of common stock in connection with:							
Conversion of Series A preferred stock to common stock	(3,991,487)	(976)	761,798	1	975	–	–
Conversion of Series B preferred stock to common stock	(6,512)	(549)	108,543	–	549	–	–
Conversion of Series C preferred stock to common stock	(23,185)	(1,809)	504,184	1	1,808	–	–
Conversion of Series D preferred stock to common stock	(129,665)	(1,517)	216,106	–	1,517	–	–
Issuance of Series E preferred stock for research and development intellectual property	7,050	104,693	–	–	–	–	104,693
Stock option exercise	–	–	268,847	–	1,301	–	1,301
Warrants exchanged for common stock	–	–	56,250	–	78	–	78
Stock-based compensation expense	–	–	1,057,500	1	17,744	–	17,745
Common stock issued for cash	–	–	759,333	1	2,277	–	2,278
Deemed dividend – accretion of discount on Series F preferred stock	–	–	–	–	(369)	–	(369)
Cumulative dividends on Series F preferred stock	–	–	–	–	(124)	–	(124)
Net loss	–	–	–	–	–	(130,829)	(130,829)
Balance as of October 31, 2017	3,230,655	$109,995	6,515,524	$ 7	$149,173	$ (259,005)	$ 170
Issuance of common stock in connection with:							
	(3,146,671)	(769)	713,036	1	768	–	–

Conversion of Series A preferred stock to common stock							
Conversion of Series B preferred stock to common stock	(47,689)	(4,020)	794,820	1	4,019	–	–
Conversion of Series C preferred stock to common stock	(2,578)	(201)	59,950	–	201	–	–
Conversion of Series D preferred stock to common stock	(26,667)	(312)	44,445	–	312	–	–
Conversion of Series E preferred stock to common stock	(7,050)	(104,693)	7,050,000	7	104,686	–	–
Exchange of Series F preferred stock and dividends to common stock	–	–	1,003,393	1	13,060	–	13,061
Extinguishment of warrant liability	–	–	151,871	–	3,045	–	3,045
Stock option exercises	–	–	161,433	–	687	–	687
Proceeds received from issuance of common stock, net of issuance costs of $2,785	–	–	4,791,819	4	92,672	–	92,676
Stock-based compensation expense	–	–	126,000	–	38,821	–	38,821
Deemed dividend – accretion of discount on Series F preferred stock	–	–	–	–	(1,290)	–	(1,290)
Cumulative dividends on Series F preferred stock	–	–	–	–	(373)	–	(373)
Series F preferred stock dividends paid in common stock	–	–	11,708	–	306	–	306
Net loss	–	–	–	–	–	(65,441)	(65,441)
Balance as of October 31, 2018	–	$–	21,423,999	$ 21	$406,087	$ (324,446)	$ 81,662

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

POLARITYTE, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	For the Years Ended October 31,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(65,441)	$(130,829)
Loss from discontinued operations	–	349
Loss from continuing operations	(65,441)	(130,480)
Adjustments to reconcile net loss from continuing operations to net cash used in continuing operating activities:		
Stock based compensation expense	38,821	16,627
Change in fair value of derivatives	(3,814)	(109)
Depreciation and amortization	1,394	432
Loss on extinguishment of warrant liability	520	–
Amortization of intangible assets	100	-
Amortization of debt discount	35	–
Change in fair value of contingent consideration	20	–
Research and development - intellectual property acquired	–	104,693
Changes in operating assets and liabilities:		
Accounts receivable	(940)	–
Inventory	(238)	–
Prepaid expenses and other current assets	(911)	(190)
Other assets	(378)	–
Accounts payable and accrued expenses	2,136	1,411
Deferred revenue	150	–
Other long-term liabilities	–	–
Net cash used in continuing operating activities	(28,546)	(7,616)
Net cash provided by discontinued operating activities	–	33
Net cash used in operating activities	(28,546)	(7,583)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(9,221)	(2,544)
Acquisition of IBEX	(2,258)	–
Net cash used in continuing investing activities	(11,479)	(2,544)
Net cash provided by discontinued investing activities	60	25
Net cash used in investing activities	(11,419)	(2,519)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from stock options exercised	687	1,301
Net proceeds from the sale of preferred stock and warrants	–	17,667
Net proceeds from the sale of common stock	92,676	2,278

Payment of contingent consideration liability	(30)	–
Payments on capital leases	(74)	–
Net cash provided by financing activities	93,259	21,246
Net increase in cash and cash equivalents	53,294	11,144
Cash and cash equivalents - beginning of period	17,667	6,523
Cash and cash equivalents - end of period	$70,961	$17,667
Supplemental schedule of non-cash investing and financing activities:		
Conversion of Series A preferred stock to common stock	$769	$976
Conversion of Series B preferred stock to common stock	$4,020	$549
Conversion of Series C preferred stock to common stock	$201	$1,809
Conversion of Series D preferred stock to common stock	$312	$1,517
Conversion of Series E preferred stock to common stock	$104,693	$–
Exchange of Series F preferred stock for common stock	$13,061	$–
Extinguishment of warrant liability	$2,525	$–
Unpaid liability for acquisition of property and equipment	$300	$54
Warrants exchanged for common stock shares	$–	$78
Establishment of warrant liability in connection with Series F Preferred Stock issuance	$–	$4,299
Establishment of derivative liability in connection with Series F Preferred Stock issuance	$–	$9,319
Deemed dividend – accretion of discount on Series F preferred stock	$1,290	$369
Cumulative dividends on Series F preferred stock	$373	$124
Series F preferred stock dividends paid in common stock	$306	$–
Contingent consideration for IBEX acquisition	$278	$–
Contingent consideration earned and recorded in accounts payable	$33	$–
Note payable issued as partial consideration for IBEX acquisition	$1,220	$–
Property and equipment additions through capital leases	$251	$–

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

POLARITYTE, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. PRINCIPAL BUSINESS ACTIVITY AND BASIS OF PRESENTATION

PolarityTE, Inc. and subsidiaries (the "Company") 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.

Asset Acquisition and Name Change. On December 1, 2016, Majesco Entertainment Company (*n/k/a* PolarityTE, Inc.), a Delaware corporation entered into an agreement to acquire the assets of Polarity NV, 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."

On April 7, 2017, the Company issued 7,050 shares of its newly authorized Series E Preferred Stock (the "Series E Preferred Shares") to Dr. Denver Lough, the developer of the Company's tissue regeneration technology who became the Company's Chief Executive Officer, for the purchase of Polarity NV's assets. The Series E Preferred Stock was convertible into an aggregate of 7,050,000 shares of the Company's common stock with a fair value of approximately $104.7 million based on 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 with no alternative future use, the total purchase price was immediately expensed as research and development - intellectual property acquired.

The Company adopted ASU 2017-01, *Business Combinations (Topic 805), Clarifying the Definition of a Business*, during the first quarter of fiscal 2017. In accordance with ASU 2017-01 the Company analyzed the above transaction noting that substantially all the fair value of the gross assets acquired were concentrated in a single intellectual property asset and Polarity NV had no employees on the acquisition date. The Company further considered that Polarity NV's intellectual property did not generate any revenue and never had any employees or workforce. In December 2016, the Company established a clinical advisory board and added three members in December 2016 and three more in January 2017. Establishing the clinical advisory board and hiring a COO are critical to establishing a workforce that has the knowledge and experience to obtain regulatory approval of the Company's intellectual property. Therefore, the acquisition of an intellectual property asset and no employees from Polarity NV on April 7, 2017 did not represent the acquisition of an organized workforce with the necessary skills and experience to create outputs and, therefore, did not represent a business combination.

Discontinued Operations. On June 23, 2017, the Company sold Majesco Entertainment Company, a Nevada corporation and wholly-owned subsidiary of the Company ("Majesco Sub") to Zift Interactive LLC ("Zift"), a Nevada limited liability company pursuant to a purchase agreement. Pursuant to the terms of the agreement, the Company sold 100% of the issued and outstanding shares of common stock of Majesco Sub to Zift, including all of the right, title and interest in and to Majesco Sub's business of developing, publishing and distributing video game products through 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 with a fair value of $0. As of October 31, 2018, the Company has received $85,000 in cash consideration and $15,000 remains receivable and is included in prepaid expenses and other current assets.

In May 2018, the Company purchased the assets of a preclinical research sciences business and related real estate from Ibex Group, L.L.C., a Utah limited liability company, and Ibex Preclinical Research, Inc., a Utah corporation (collectively, "IBEX"). The Company acquired these assets to accelerate research and development of its TE product candidates, and now operate the business as IBEX to advance its product development and deliver preclinical research services to third parties. The business consists of a "good laboratory practices" (GLP) compliant preclinical research facility that is USDA registered and includes vivarium, operating rooms, preparation rooms, storage facilities, and surgical and imaging equipment. The real property includes two parcels in Logan, Utah, consisting of approximately 1.75 combined gross acres of land, together with the buildings, structures, fixtures, and personal property located on the real property. The aggregate purchase price was $3.8 million, of which $2.3 million was paid at closing and the balance satisfied by a promissory note payable to the Seller with an initial fair value of $1.2 million and contingent consideration with an initial fair value of approximately $0.3 million.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation. The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Significant intercompany accounts and transactions have been eliminated in consolidation.

Segments. The Company's operations are based in the United States and involve products and services which are managed separately. Accordingly, it operates in two segments: 1) regenerative medicine products and 2) contract services. The Chief Operating Decision Maker (CODM) is our Chief Executive Officer (CEO). The CODM allocates resources to and assesses the performance of each operating segment using information about its revenue and operating income (loss). Prior to the acquisition of IBEX, the Company operated in one segment.

Use of estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities or the disclosure of gain or loss contingencies at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Among the more significant estimates included in these financial statements are the valuation of warrant liability, valuation of derivative liability, proportional performance method, stock-based compensation, the valuation allowances for deferred tax benefits, and the valuation of tangible and intangible assets included in acquisitions. Actual results could differ from those estimates.

Reclassifications. Certain reclassifications have been made to our prior period financial statements to conform with the current period presentation. On our consolidated balance sheet, we have combined the Receivable from Zift current and non-current with prepaid expenses and other current assets and other assets, respectively.

Cash and cash equivalents. Cash equivalents consist of highly liquid investments with original maturities of three months or less at the date of purchase. At various times, the Company has deposits in excess of the Federal Deposit Insurance Corporation limit. The Company has not experienced any losses on these accounts.

Accounts Receivable. Accounts receivable consists of amounts due to the Company related to the sale of the Company's core product SkinTE and contract services. Accounts that are outstanding longer than the contractual payment terms are considered past due. The Company determines its allowance for doubtful accounts by considering a number of factors, including the length of time trade accounts receivable are past due and the customer's current ability to pay its obligation to the Company. The Company writes off accounts receivable when they become uncollectible. As of October 31, 2018, an allowance for doubtful accounts was not considered necessary.

Accounts Payable and Accrued Expenses. The carrying amounts of accounts payable and accrued expenses approximate fair value as these accounts are largely current and short term in nature.

Inventory. Inventory comprises raw materials, which are valued at the lower of cost or net realizable value, on a first-in, first-out basis. The Company evaluates the carrying value of its inventory on a regular basis, taking into account anticipated future sales compared with quantities on hand, and the remaining shelf life of goods on hand.

Property and Equipment. Property and equipment is stated at cost. Depreciation is being provided for by the straight-line method over the estimated useful lives of the assets, generally ranging from three to eight years. Amortization of leasehold improvements is provided for over the shorter of the term of the lease or the life of the asset.

Capitalized Software. We capitalize certain internal and external costs incurred to acquire or create internal use software. Costs to create internal software are capitalized during the application development period. Capitalized software is included in property and equipment and is depreciated over three years once development is complete.

Goodwill and Intangible Assets. Goodwill represents the excess acquisition cost over the fair value of net tangible and intangible assets acquired. Goodwill is not amortized and is subject to annual impairment testing or between annual tests if an event or change in circumstance occurs that would more likely than not reduce the fair value of a reporting unit below its carrying value. In testing for goodwill impairment, the Company has the option to first assess qualitative factors to determine whether the existence of events or circumstances lead to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If, after assessing the totality of events and circumstances, the Company concludes that it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is not required. If the Company concludes otherwise, it is required to perform the two-step impairment test. The goodwill impairment test is performed at the reporting unit level by comparing the estimated fair value of a reporting unit with its respective carrying value. If the estimated fair value exceeds the carrying value, goodwill at the reporting unit level is not impaired. If the estimated fair value is less than carrying value, further analysis is necessary to determine the amount of impairment, if any, by comparing the implied fair value of the reporting unit’s goodwill to the carrying value of the reporting unit’s goodwill.

The fair value of reporting units is based on widely accepted valuation techniques that the Company believes market participants would use, although the valuation process requires significant judgment and often involves the use of significant estimates and assumptions. We performed a qualitative assessment and concluded that it is more likely than not that the fair value of the reporting unit is more than its carrying value. Accordingly, there was no indication of impairment, and further quantitative testing was not required. Adverse market or economic events could result in impairment charges in future periods.

Intangible assets deemed to have finite lives are amortized on a straight-line basis over their estimated useful lives, which generally range from one to eleven years. The useful life is the period over which the asset is expected to contribute directly, or indirectly, to its future cash flows. Intangible assets are reviewed for impairment when certain events or circumstances exist. For amortizable intangible assets, impairment exists when the undiscounted cash flows exceed its carrying value. At least annually, the remaining useful life is evaluated.

Impairment of Long-Lived Assets. The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. No impairment loss has been recognized.

Income Taxes. The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company evaluates the potential for realization of deferred tax assets at each quarterly balance sheet date and records a valuation allowance for assets for which realization is not more likely than not.

Stock Based Compensation. The Company measures all stock-based compensation to employees using a fair value method and records such expense in general and administrative and research and development expenses. Compensation expense for stock options with cliff vesting is recognized on a straight-line basis over the vesting period of the award, based on the fair value of the option on the date of grant. For stock options with graded vesting, the Company recognizes compensation expense over the service period for each separately vesting tranche of the award as though the award were in substance, multiple awards.

The fair value for options issued is estimated at the date of grant using a Black-Scholes option-pricing model. The risk-free rate is derived from the U.S. Treasury yield curve in effect at the time of the grant. The volatility factor is determined based on the Company’s historical stock prices. Forfeitures are recognized as they occur.

The value of restricted stock grants is measured based on the fair market value of the Company’s common stock on the date of grant and amortized over the vesting period of, generally, six months to three years.

The accounting for non-employee options and restricted stock is similar to that of employees, however, unlike employee options and restricted stock, the measurement date is not the grant date. The measurement date is when performance is complete. Until the options or shares vest, they are re-measured (re-valued) each reporting period and the expense marked up or marked down accordingly.

Loss Per Share. Basic loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share since the effects of potentially dilutive securities are antidilutive.

Commitments and Contingencies. We are subject to claims and litigation in the ordinary course of our business. We record a liability for contingencies when the amount is both probable and reasonably estimable. We record associated legal fees as incurred.

Accounting for Warrants. The Company accounts for the issuance of common stock purchase warrants issued in connection with the equity offerings in accordance with the provisions of ASC 815, Derivatives and Hedging ("ASC 815"). The Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) gives the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies as assets or liabilities any contracts that (i) require net-cash settlement (including a requirement to net-cash settle the contract if an event occurs and if that event is outside the control of the Company) or (ii) gives the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). In addition, under ASC 815, registered common stock warrants that require the issuance of registered shares upon exercise and do not expressly preclude an implied right to cash settlement are accounted for as derivative liabilities. The derivative warrant liabilities were settled during the year.

Change in Fair Value of Derivatives. The Company assessed the classification of common stock purchase warrants as of the date of each offering and determined that certain instruments met the criteria for liability classification. Accordingly, the Company classified the warrants as a liability at their fair value and adjusts the instruments to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until the warrants are exercised or expired, and any change in fair value is recognized as "change in fair value of derivatives" in the consolidated statements of operations. The fair value of the warrants has as well as other derivatives, been estimated using a Monte-Carlo or Black-Scholes valuation model. The warrants were settled during the year ended October 31, 2018.

Revenue Recognition. The Company recognizes revenue upon the shipment of products or the performance of services when each of the following four criteria is met: (i) persuasive evidence of an arrangement exists; (ii) products are delivered or services are performed; (iii) the sales price is fixed or determinable; and (iv) collectability is reasonably assured. Contract services revenue is recognized on the proportional performance method over the term of the

respective service contract which requires us to make reasonable estimates of the extent of progress toward completion of the contract. Under this method, revenue is recognized according to the percentage of cost completed for the study. As a result, unbilled receivables and deferred revenue are recognized based on payment timing and work completed. As of October 31, 2018 and 2017, the Company had unbilled receivables of $160,000 and $0 and deferred revenue of $150,000 and $0. The unbilled receivables balance is included in consolidated accounts receivable.

The Company has one significant customer which made up approximately 19% of 2018 consolidated revenues. The customer was in the contract services segment. The Company also has four customers which made up approximately 47% of consolidated accounts receivable as of October 31, 2018. Two of the customers were in the regenerative medicine segment and each made up 10% of the consolidated balance and two of the customers were in the contract services segment and made up 14% and 13% of the consolidated balance.

Recent Accounting Pronouncements.

In May 2014, the FASB issued ASU 2014-09, “Revenue from Contracts with Customers (Topic 606)”, a new accounting standard that requires recognition of revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which an entity expects to be entitled in exchange for those goods or services. The FASB has also issued several updates to ASU 2014-09. The new standard supersedes U.S. GAAP guidance on revenue recognition and requires the use of more estimates and judgments than the present standards. It also requires additional disclosures regarding the nature, amount, timing and uncertainty of cash flows arising from contracts with customers. Topic 606 is effective for our fiscal year 2019 beginning on November 1, 2018 and the Company plans to adopt using the full retrospective approach. As of October 31, 2018, the Company has completed and documented an assessment of the impact of the new revenue standard on its contracts with customers with an expected immaterial impact to the financial statements.

In February 2016, FASB issued ASU No. 2016-02, *Leases (Topic 842),* which supersedes FASB ASC Topic 840, *Leases (Topic 840)* and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. The standard is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. When adopted, the Company expects this guidance to have a material impact on its consolidated balance sheet.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments*, which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The adoption of this update is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles - Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment.* ASU No. 2017-04 removes Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. A goodwill impairment will now be the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. This standard will be applied prospectively and is effective for the Company beginning November 1, 2020. Early adoption is permitted for annual and interim goodwill impairment testing dates after January 1, 2017. The Company is currently evaluating the impact this standard will have on its financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting.* ASU 2017-09 provides clarity and reduces both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718, to a change to the terms or conditions of a share-based payment award. The amendments in ASU 2017-09 should be applied prospectively to an award modified on or after the adoption date. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. . The Company does not believe the adoption of this standard will have a significant impact on its financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-based Payment Accounting*. The standard expands the scope of Topic 718 to include share-based payments issued to nonemployees for goods or services, simplifying the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal

years with early adoption permitted, including adoption in an interim period. The Company does not believe the adoption of this standard will have a significant impact on its financial statements given the limited number of nonemployee stock-based awards outstanding.

3. LIQUIDITY

The Company has experienced recurring losses and cash outflows from operating activities. For the year ended October 31, 2018, the Company's net loss and cash used in operating activities were $65.4 million and $28.5 million, respectively. On April 12, 2018, the Company completed a public offering of 2,335,937 shares of the Company's common stock, par value $0.001 per share, at an offering price of $16.00 per share resulting in net proceeds of approximately $34.6 million, after deducting offering expenses payable by the Company (see Note 10).

On June 7, 2018, the Company completed an underwritten offering of 2,455,882 shares of the Company's common stock, par value $0.001 per share, at an offering price of $23.65 per share resulting in net proceeds of approximately $58.0 million, after deducting offering expenses payable by the Company (see Note 11).

Based upon the current status of our product development and commercialization plans, we believe that our existing cash and cash equivalents will be adequate to satisfy our capital needs for at least the next 12 months from the date of filing. We anticipate needing substantial additional financing to continue clinical deployment and commercialization of our lead product SkinTE, development of our other product candidates, and scaling the manufacturing capacity for our products and product candidates, and prepare for commercial readiness. We will continue to pursue fundraising opportunities when available, but such financing may not be available in the future on terms favorable to us, if at all. If adequate financing is not available, we may be required to delay, reduce the scope of, or eliminate one or more of our product development programs. We plan to meet our capital requirements primarily through issuances of equity securities, debt financing, revenue from product sales and future collaborations. Failure to generate revenue or raise additional capital would adversely affect our ability to achieve our intended business objectives.

4**. IBEX ACQUISITION**

On March 2, 2018, the Company, along with its wholly owned subsidiary, Utah CRO Services, Inc., a Nevada corporation ("Acquisition Co."), entered into agreements with Ibex Group, L.L.C., a Utah limited liability company, and Ibex Preclinical Research, Inc., a Utah corporation (collectively, the "Seller" or "IBEX") for the purchase of the assets and rights to the Seller's preclinical research and contract services business and related real estate. The Company acquired this preclinical biomedical research facility in order to accelerate research and development of PolarityTE pipeline products. The business consists of a "good laboratory practices" (GLP) compliant preclinical research facility, including vivarium, operating rooms, preparation rooms, storage facilities, and surgical and imaging equipment. The real property includes two parcels in Cache County, Utah, consisting of approximately 1.75 combined gross acres of land, together with the buildings, structures, fixtures, and personal property located on the real property. The above was accounted for as a business combination.

The acquisition closed on May 3, 2018. The aggregate purchase price was $3.8 million, of which $2.3 million was paid at closing and the balance satisfied by a promissory note payable to the Seller with an initial fair value of $1.2 million (see Note 9, for a description of the promissory note) and contingent consideration with an initial fair value of approximately $0.3 million. During the year ended October 31, 2018, the Company recorded approximately $38,000 of direct and incremental costs associated with acquisition-related activities. These costs were incurred primarily for banking, legal, and professional fees associated with the IBEX acquisition. These costs were recorded in general and administrative expenses in the consolidated statement of operations.

During the year ended October 31, 2018, IBEX contributed approximately $831,000 to net revenues and approximately $331,000 to gross profit.

Purchase Price Allocation

The following table summarizes the purchase price allocation for the IBEX acquisition (in thousands):

Equipment	$430
Land and buildings	2,000
Intangible assets	1,057
Goodwill	278
Accrued property taxes	(9)
Aggregate purchase price	$3,756
Less: Promissory note to seller	1,220
Contingent consideration	278
Cash paid at closing	$2,258

As part of the acquisition of IBEX, the Company recorded a contingent consideration liability of $0.3 million in current liabilities in the condensed consolidated balance sheets. The contingent consideration represents the estimated fair value of future payments due to the Seller of IBEX based on IBEX's revenue generated from studies quoted prior to but completed after the transaction. Contingent consideration is initially recognized at fair value as purchase consideration and subsequently remeasured at fair value through earnings. The initial fair value of the contingent consideration was based on the present value of estimated future cash flows using a 20% discount rate. The contingent consideration is the payment of 15% of the actual revenues received for work on any study initiated within 18 months following the closing of the purchase on the basis of certain specific customer prospects that received service proposals prior to the closing, provided that the total payments will not exceed $650,000. The subsequent increase in fair value of contingent consideration from acquisition to October 31, 2018 of approximately $20,000 was recognized in general and administrative expense in the Company's consolidated statement of operations for the year ended October 31, 2018. The excess of the fair value of purchase consideration over the fair values of identifiable assets and liabilities acquired is recorded as goodwill, including the value of the assembled workforce.

Disclosure of pro-forma revenues and earnings attributable to the acquisition is excluded because it is impracticable to obtain complete historical financial records for IBEX Preclinical Research, Inc.

The following table shows the valuation of the individual identifiable intangible assets acquired along with their estimated remaining useful lives (in thousands):

	Approximate Fair Value	Remaining Useful Life (in years)
Non-compete agreement	$ 410	4
Customer contracts and relationships	534	7 to 8
Trade names and trademarks	101	10 to 11
Backlog	12	Less than 1
Total intangible assets	$ 1,057	

5. FAIR VALUE

In accordance with *ASC 820, Fair Value Measurements and Disclosures*, financial instruments were measured at fair value using a three-level hierarchy which maximizes use of observable inputs and minimizes use of unobservable inputs:

Level 1: Observable inputs such as quoted prices in active markets for identical instruments

Level 2: Quoted prices for similar instruments that are directly or indirectly observable in the market

Level 3: Significant unobservable inputs supported by little or no market activity. Financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, for which determination of fair value requires significant judgment or estimation.

In connection with the offering of Units in September 2017 (see Note 10), the Company issued warrants to purchase an aggregate of 322,727 shares of common stock. These warrants were exercisable at $30.00 per share and expire in two years. The warrants were liabilities pursuant to ASC 815. The warrant agreement provided for an adjustment to the number of common shares issuable under the warrant 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); or (c) the Company issues new securities for consideration less than the exercise price. Under ASC 815, warrants that provide for down-round exercise price protection are recognized as derivative liabilities.

The Series F Preferred Shares contained an embedded conversion feature that was not clearly and closely related to the identified host instrument and, as such, was recognized as a derivative liability measured at fair value. The Company classified these derivatives on the consolidated balance sheet as a current liability.

As noted in Note 10, both the warrants and the Series F Preferred Shares were exchanged for common stock on March 6, 2018.

The fair value of the bifurcated embedded conversion feature was estimated to be approximately $7.2 million and $9.3 million, respectively, at March 5, 2018 and October 31, 2017 as calculated using the Monte Carlo simulation with the following assumptions:

	Series F Conversion Feature	
	March 5, 2018	October 31, 2017
Stock price	$20.05	$25.87
Exercise price	$27.50	$27.50
Risk-free rate	2.2 %	1.6 %
Volatility	88.2 %	96.0 %
Term	1.5	1.9

The fair value of the warrant liability was estimated to be approximately $2.5 million and $4.3 million, respectively, at March 5, 2018 and October 31, 2017 as calculated using the Monte Carlo simulation with the following assumptions:

	Warrant Liability	
	March 5, 2018	October 31, 2017
Stock price	$20.05	$25.87
Exercise price	$30.00	$30.00
Risk-free rate	2.2 %	1.6 %
Volatility	88.2 %	96.0 %
Term	1.5	1.9

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The fair value hierarchy of financial instruments, measured at fair value on a recurring basis on the consolidated balance sheets as of October 31, 2018 and 2017 is as follows (in thousands):

	Fair Value Measurement as of October 31, 2018

	Level 1	Level 2	Level 3	Total
Liabilities				
Contingent consideration	$–	$ –	$235	$235
Total	$–	$ –	$235	$235

	Fair Value Measurement as of October 31, 2017			
	Level 1	Level 2	Level 3	Total
Liabilities				
Warrant liability	$–	$ –	$4,256	$4,256
Derivative liability	–	–	9,246	9,246
Total	$–	$ –	$13,502	$13,502

The following table sets forth the changes in the estimated fair value for our Level 3 classified contingent consideration (in thousands) which is included in other current liabilities:

	Contingent Consideration
Fair value – October 31, 2017	$ –
IBEX acquisition – May 3, 2018	$ 278
Change in fair value	20
Earned and paid in cash	(30)
Earned and moved to accounts payable	(33)
Fair value - October 31, 2018	$ 235

6. PROPERTY AND EQUIPMENT, NET

The following table presents the components of property and equipment, net (in thousands):

	October 31, 2018	October 31, 2017
Machinery and equipment	$8,134	$ 2,418
Land and buildings	2,000	–
Computers and software	1,337	211
Leasehold improvements	1,137	–
Construction in progress	1,587	–
Furniture and equipment	566	30
Total property and equipment, gross	14,761	2,659
Accumulated depreciation	(1,834)	(486)
Total property and equipment, net	$12,927	$ 2,173

Depreciation expense for property and equipment, including assets acquired under capital leases for the years ended October 31, 2018 and 2017 is as follows (in thousands):

	For the Years Ended October 31,	
	2018	2017
General and administrative expense:		
Continuing operations	$223	$1
Discontinued operations	–	11
	223	12
Research and development expense:		
Continuing operations	1,171	431
Total depreciation expense	$1,394	$443

7. INTANGIBLE ASSETS AND GOODWILL

Intangible assets, net, consist of the following (in thousands):

	October 31, 2018	October 31, 2017
Non-compete agreement	$ 410	$ –
Customer contracts and relationships	534	–
Trade names and trademarks	101	–
Backlog	12	–
Total intangible assets, gross	1,057	–
Accumulated amortization	(100)	–
Total intangible assets, net	$ 957	$ –

Amortization expense for the year ended October 31, 2018 was approximately $100,000.

The future amortization of these intangible assets is expected to be as follows (in thousands):

Year ended October 31, 2019	$ 195
Year ended October 31, 2020	189
Year ended October 31, 2021	189
Year ended October 31, 2022	138
Year ended October 31, 2023	87
Thereafter	159
	$ 957

The changes in the carrying amount of goodwill for fiscal year 2018 is as follows (in thousands):

	Regenerative Medicine	Contract Services	Total
October 31, 2017	$ –	$ –	$–
Additions due to acquisitions and current year acquisitions' purchase price adjustments (1)	–	278	278
October 31, 2018			$278

(1) On May 3, 2018, the Company acquired the preclinical research and contract services business and related real estate from IBEX L.L.C.

8. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

The following table presents the major components of accounts payable and accrued expenses (in thousands):

	October 31, 2018	October 31, 2017
Accounts payable	$2,007	$441
Salaries and other compensation	933	574
Other accruals	792	369
Legal and accounting	631	555
Total accounts payable and accrued expenses	$4,363	$1,939

Salaries and other compensation includes accrued payroll expense, accrued bonus, and estimated employer 401K plan contributions.

9. LONG TERM NOTE PAYABLE

In connection with the IBEX Acquisition, described in Note 4, the Company issued a promissory note payable to the Seller with an initial fair value of $1.22 million. The promissory note has a principal balance of $1,333,333 and bears interest at a rate of 3.5% interest per annum. Principal and interest are payable in five equal installments beginning on November 3, 2018 and continuing on each six-month anniversary thereafter ("Payment Date"). The promissory note

may be prepaid by the Company at any time and becomes due and payable at the earlier of the maturity date of November 3, 2020 or upon an event of default, which includes failure to pay any installment on each Payment Date, breach of any negative covenants, insolvency or bankruptcy. Upon the occurrence of an event of default, the promissory note will bear an accelerated interest rate of 7% per annum from the date of the event of default.

The Company initially recognized the promissory note at its fair value, using an estimated market rate of interest for the Company, which was higher than the promissory note's stated rate. The result of imputing a market rate of interest resulted in an initial discount to the principal balance of approximately $113,000, which is being amortized to interest expense over the term of the promissory note using the effective interest method. The unamortized debt discount was $78,000 at October 31, 2018. Amortization of debt discount of $35,000 was included in interest expense for the year ended October 31, 2018.

10. PREFERRED SHARES AND COMMON SHARES

Common Stock Issuance

On April 12, 2018, the Company completed a public offering of 2,335,937 shares of the Company's common stock, par value $0.001 per share, at an offering price of $16.00 per share resulting in net proceeds of approximately $34.6 million, after deducting offering expenses payable by the Company.

On June 7, 2018, the Company completed an underwritten offering of 2,455,882 shares of the Company's common stock, par value $0.001 per share, at an offering price of $23.65 per share resulting in net proceeds of approximately $58.0 million, after deducting offering expenses payable by the Company.

Exchange of 100% of Outstanding Series F Preferred Stock Shares and Warrants

On September 20, 2017, the Company sold an aggregate of $17,750,000 worth of units of the Company's securities (the "Units") to accredited investors at a purchase price of $2,750 per Unit. Each Unit consisted 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 Shares"), convertible into one hundred (100) shares of the Company's common stock, and (ii) a two-year warrant to purchase up to 322,727 shares of the Company's common stock, at an exercise price of $30.00 per share.

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

On the two-year anniversary of the initial issuance date, any Series F Preferred Shares outstanding and not otherwise already converted, would, 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 Series F Preferred Shares.

The warrants issued in connection with the Series F Preferred Shares were determined to be liabilities pursuant to ASC 815. The warrant agreement provided for an adjustment to the number of common shares issuable under the warrant or adjustment to the exercise price, including but not limited to, if: (a) the Company issued shares of common stock as a dividend or distribution to holders of its common stock; (b) the Company subdivided or combined its common stock (i.e., stock split); or (c) the Company issues new securities for consideration 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 Shares was determined to not be clearly and closely related to the identified host instrument and, as such, was 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 Shares. The resulting discount to the aggregate stated value of the Series F Preferred Shares of approximately $13.6 million was recognized as accretion using the effective interest method similar to preferred stock dividends, over the two-year period prior to optional redemption by the holders.

On March 6, 2018, the Company entered into separate exchange agreements (the “Exchange Agreements”) with holders (each a “Holder”, and collectively the “Holders”) of 100% of the Company’s outstanding Series F Preferred Shares, and the Company’s warrants to purchase shares of the Company’s common stock issued in connection with the Series F Preferred Shares (such “Warrants” and Series F Preferred Shares collectively referred to as the “Exchange Securities”) to exchange the Exchange Securities and unpaid dividends on the Series F Preferred Shares for common stock (the “Exchange”).

The Exchange resulted in the following issuances: (A) all outstanding Series F Preferred Shares were converted into 972,070 shares of restricted common stock at an effective conversion price of $18.26 per share of common stock (the closing price of Common Stock on the NASDAQ Capital Market on February 26, 2018); (B) the right to receive 6% dividends underlying Series F Preferred Shares was terminated in exchange for 31,321 shares of restricted common stock; (C) 322,727 Warrants to purchase common stock were exchanged for 151,871 shares of restricted common stock; and (D) the Holders of the Warrants relinquished any and all other rights pursuant to the Warrants, including exercise price adjustments.

As part of the Exchange, the Holders also relinquished all other rights related to the issuance of the Exchange Securities, the respective governing agreements and certificates of designation, including any related dividends, adjustment of conversion and exercise price, and repayment option. The existing registration rights agreement with the holders of the Series F Preferred Shares was also terminated and the holders of the Series F Preferred Shares waived the obligation of the Company to register the common shares issuable upon conversion of Series F Preferred Shares or upon exercise of the warrants, and waived any damages, penalties and defaults related to the Company failing to file or have declared effective a registration statement covering those shares.

The exchange of all outstanding Series F Preferred Shares, and the holders' right to receive 6% dividends, for common stock of the Company was recognized as follows:

Fair market value of 1,003,393 shares of common stock issued at $20.05 (Company's closing stock price on March 5, 2018) in exchange for Series F Preferred Shares and accrued dividends	$20,117,990
Carrying value of Series F Preferred Shares at March 5, 2018, including dividends	(5,898,274)
Carrying value of bifurcated conversion option at March 5, 2018	(7,162,587)
Deemed dividend on Series F Preferred Shares exchange	$7,057,129

As the Warrants were classified as a liability, the exchange of the Warrants for common shares was recognized as a liability extinguishment. As of March 5, 2018, the fair market value of the 151,871 common shares issued in the Exchange was $3,045,034 and the fair value of the common stock warrant liability was $2,525,567 resulting in a loss on extinguishment of warrant liability of $519,467 during the year ended October 31, 2018.

The Company recognized accretion of the discount to the stated value of the Series F Preferred Shares of approximately $1,290,000 during the year ended October 31, 2018, as a reduction of additional paid-in capital and an increase in the carrying value of the Series F Preferred Shares. 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 Stock Conversion and Elimination

On February 6, 2018, 15,756 shares of Series B Convertible Preferred Stock ("Series B Preferred Shares") were converted into 262,606 shares of common stock.

On March 6, 2018, the Company received conversion notices (in accordance with original terms) from holders of 100% of the outstanding shares of Series A Convertible Preferred Stock (the "Series A Preferred Shares"), Series B Preferred Shares and Series E Convertible Preferred Stock (the "Series E Preferred Shares") and issued an aggregate of 7,945,250 shares of common stock to such holders.

The shares of Series E Preferred Stock were held by Dr. Denver Lough, the Company's Chief Executive Officer. On March 6, 2018, the Company entered into a new registration rights agreement (the "Lough Registration Rights Agreement") with Dr. Lough, pursuant to which the Company agreed to file a registration statement to register the resale of 7,050,000 shares of Common Stock issued upon conversion of the Series E Preferred Shares within six months, to cause such registration statement to be declared effective by the Securities and Exchange Commission as promptly as possible following its filing and, with certain exceptions set forth in the Lough Registration Rights

Agreement, to maintain the effectiveness of the registration statement until all of such shares have been sold or are otherwise able to be sold pursuant to Rule 144 under the Securities Act without restriction. Any sales of shares under the registration statement were subject to certain limitations as specified with more particularity in the Lough Registration Rights Agreement. In April 2018, Dr. Lough entered into a lock up agreement for 180 days, which prohibited him from selling any shares that may be registered until October 2018. The registration statement was not filed as of October 31, 2018. Dr. Lough has not made a demand for filing a registration statement and the Company does not propose to file a registration statement at the present time.

On March 7, 2018, the Company filed a Certificate of Elimination with the Secretary of State of the State of Delaware terminating the Company's Series A, Series B, Series C, Series D, Series E and Series F Preferred Stock. As a result, the Company has 25,000,000 shares of authorized and unissued preferred stock as of October 31, 2018 with no designation as to series.

Convertible preferred stock activity for the year ended October 31, 2018 consisted of the following:

	Shares Outstanding - October 31, 2017	Year to Date 2018 -Preferred Stock Conversions and Series F Exchange	Year to Date 2018 - Common Stock Shares Issued
Series A	3,146,671	(3,146,671)	713,036
Series B	47,689	(47,689)	794,820
Series C	2,578	(2,578)	59,950
Series D	26,667	(26,667)	44,445
Series E	7,050	(7,050)	7,050,000
Series F	6,455	(6,455)	972,070
Total	3,237,110	(3,237,110)	9,634,321

There was no convertible preferred stock outstanding as of October 31, 2018. Convertible preferred stock as of October 31, 2017 consisted of the following (in thousands, except share amounts):

	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	Aggregate Liquidation Preference	Common Shares Issuable Upon Conversion
Series A	8,830,000	3,146,671	$ 769	$ 2,140	713,245
Series B	54,250	47,689	4,020	–	794,806
Series C	26,000	2,578	201	–	59,953
Series D	170,000	26,667	312	–	44,445
Series E	7,050	7,050	104,693	–	7,050,000
Series F	6,455	6,455	4,541	17,750	645,455
Other authorized, unissued	15,906,245	–	–	–	–
Total	25,000,000	3,237,110	$ 114,536	$ 19,890	9,307,904

11. STOCK-BASED COMPENSATION

In the years ended October 31, 2018 and 2017, the Company recorded stock-based compensation expense related to restricted stock awards and stock options as follows (in thousands):

	For the Years Ended October 31,	
	2018	2017
General and administrative expense:		
Continuing operations	$31,982	$14,869
Discontinued operations	–	1,118
	31,982	15,987
Research and development expense:		
Continuing operations	6,322	1,758
Sales and marketing expense:		
Continuing operations	517	–
Total stock-based compensation expense	$38,821	$17,745

Incentive Compensation Plans

2017 Plan

On December 1, 2016, the Company's Board of Directors (the "Board") approved the Company's 2017 Equity Incentive Plan (the "2017 Plan"). The purpose of the 2017 Plan is to promote the success of the Company and to increase stockholder value by providing an additional means through the grant of awards to attract, motivate, retain and reward selected employees, consultants and other eligible persons. The 2017 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights and other types of stock-based awards to the Company's employees, officers, directors and consultants. The Compensation Committee of the Board will administer the 2017 Plan, including determining which eligible participants will receive awards, the number of shares of common stock subject to the awards and the terms and conditions of such awards. Up to 7,300,000 (increased from 3,450,000 in October 2017) shares of common stock are issuable pursuant to awards under the 2017 Plan. Unless earlier terminated by the Board, the 2017 Plan shall terminate at the close of business on December 1, 2026. As of October 31, 2018, the Company had approximately 65,015 shares available for future issuances under the 2017 Plan.

2016 Plan

In the fiscal year ended October 31, 2016, the Company adopted the 2016 Plan, an omnibus equity incentive plan administered by the Company's board of directors, or by one or more committees of directors appointed by the Board, pursuant to which the Company may issue up to 4,000,000 shares of the Company's common stock under equity-linked awards to certain officers, employees, directors and consultants. The 2016 Plan permits the grant of stock options, including incentive stock options and nonqualified stock options, stock appreciation rights, restricted shares, restricted share units, cash awards, or other awards, whether at a fixed or variable price, upon the passage of time, the occurrence of one or more events, or the satisfaction of performance criteria or other conditions, or any combination thereof. As of October 31, 2018, the Company had 3,333,336 shares available for future issuances under the 2016 Plan.

2014 Plan

In the fiscal year ended October 31, 2015, the Company adopted the 2014 Plan, an omnibus equity incentive plan administered by the Company's board of directors, or by one or more committees of directors appointed by the Board, pursuant to which the Company may issue up to 2,250,000 shares of the Company's common stock under equity-linked awards to certain officers, employees, directors and consultants. The 2014 Plan permits the grant of stock options, including incentive stock options and nonqualified stock options, stock appreciation rights, restricted

shares, restricted share units, cash awards, or other awards, whether at a fixed or variable price, upon the passage of time, the occurrence of one or more events, or the satisfaction of performance criteria or other conditions, or any combination thereof. As of October 31, 2018, the Company had approximately 1,927,453 shares available for future issuances under the 2014 Plan.

Stock Options

Employee stock-option activity in the fiscal years ended October 31, 2018 and 2017:

	Number of shares	**Weighted-Average Exercise Price**
Outstanding, October 31, 2016	383,210	$ 5.74
Granted	3,482,000	$ 6.29
Exercised	(268,847)	$ 4.84
Forfeited	(70,833)	$ 6.42
Outstanding - October 31, 2017	3,525,530	$ 6.34
Granted	2,638,769	$ 23.55
Exercised	(161,810)	$ 4.31
Forfeited	(217,984)	21.89
Outstanding - October 31, 2018	5,784,505	$ 13.68
Options exercisable, October 31, 2018	3,505,407	$ 8.53
Weighted-average grant date fair value of options granted during the year ended October 31, 2018		$ 17.56

Non-employee stock option activity in the fiscal year ended October 31, 2018 and 2017:

	Number of shares	Weighted-Average Exercise Price
Outstanding - October 31, 2016	–	$ –
Granted	293,000	$ 19.61
Outstanding - October 31, 2017	293,000	$ 19.61
Granted	3,000	$ 18.63
Outstanding - October 31, 2018	296,000	$ 19.60
Options exercisable - October 31, 2018	174,625	$ 17.65

Stock options are generally granted to employees or non-employees at exercise prices equal to the fair market value of the Company's stock of the day prior to the grant. Stock options generally vest over one to three years and have a term of five to ten years. The total fair value of employee options granted during the year ended October 31, 2018 was approximately $46.3 million. The grant date fair value of non-employee options granted during the year ended October 31, 2018 was approximately $39,000. The intrinsic value of options outstanding at October 31, 2018 was $33.7 million. The intrinsic value of options exercised during the fiscal year ended October 31, 2018 was $1.8 million. The weighted average remaining contractual term of outstanding and exercisable options at October 31, 2018 was 8.7 years and 8.3 years, respectively.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following range of assumptions for the years ended October 31:

	October 31,	
	2018	2017
Risk free annual interest rate	2.0%-3.2%	1.6%-2.3 %
Expected volatility	80.9%-96.5%	71.7%-86.5 %
Expected term of options (years)	5.0-6.0	5.0-6.0
Assumed dividends	–	–

The fair value of employee and non-employee stock option grants is recognized over the vesting period of, generally, one to three years. As of October 31, 2018, there was approximately $22.4 million of unrecognized compensation cost related to non-vested employee and non-employee stock option awards, which is expected to be recognized over a remaining weighted-average vesting period of 0.8 years.

Restricted-stock activity for employees and non-employees in the fiscal year ended October 31, 2018:

	Number of shares	Weighted-Average Grant-Date Fair Value
Unvested, October 31, 2016	274,829	$ 6.00
Granted	1,057,500	$ 4.80
Vested	(1,105,197)	$ 4.47
Unvested - October 31, 2017	227,132	$ 7.83
Granted	712,034	$ 25.27
Vested	(242,819)	$ 11.74
Forfeited	(22,387)	$ 20.62
Unvested - October 31, 2018	673,960	$ 24.52

The total fair value of restricted stock vested during the year ended October 31, 2018 was approximately $2.9 million.

The value of restricted stock grants is measured based on the fair market value of the Company’s common stock on the date of grant and recognized over the vesting period of, generally, six months to three years. As of October 31, 2018, there was approximately $11.9 million of unrecognized compensation cost related to unvested restricted stock awards, which is expected to be recognized over a remaining weighted-average vesting period of 1.2 years.

12. INCOME TAXES

The Company calculates its provision for federal and state income taxes based on current tax law. The Tax Cuts and Jobs Act (tax reform) was enacted on December 22, 2017 ("Enactment Date"), and has several key provisions impacting accounting for and reporting of income taxes. The most significant provision reduces the U.S. corporate statutory tax rate from 35% to 21% beginning on January 1, 2018. Although most provisions of tax reform are not effective until 2018, the Company is required to record the effect of a change in tax law as of the Enactment Date on its deferred tax assets. As the Company maintains a full valuation allowance against its deferred tax assets, there is no income tax expense recorded related to this change other than the Federal AMT credit which are refundable due to the passage of tax reform. As of the Enactment Date, the Company estimated that its deferred tax asset and related valuation allowance were each reduced by approximately $2.6 million.

In accordance with Staff Accounting Bulletin 118 ("SAB 118"), income tax effects of the Tax Act may be refined upon obtaining, preparing, or analyzing additional information during the measurement period and such changes could be material. During the measurement period, provisional amounts may be adjusted for the effects, if any, of interpretative guidance issued after December 31, 2017, by U.S. regulatory and standard-setting bodies. While we are able to make reasonable estimates of the impact of the reduction in corporate rate and the deemed repatriation transition tax, the final impact of the Tax Act may differ from these estimates, due to, among other things, changes in our interpretations and assumptions, additional guidance that may be issued by the I.R.S., and actions we may take. We are continuing to gather additional information to determine the final impact.

Due to the Company's history of losses and uncertainty of future taxable income, a valuation allowance sufficient to fully offset net operating losses and other deferred tax assets has been established. The valuation allowance will be maintained until sufficient positive evidence exists to support a conclusion that a valuation allowance is not necessary. The issuance of the Series E Preferred Stock in connection with its original acquisition of the PolarityTE, Inc., a Nevada corporation in April 2017, will likely result in limitations on the utilization of the Company's net operating loss carryforwards under IRS section 382. The effect of this is being analyzed now.

The provision (benefit) for income taxes for the years ended October 31, 2018 and 2017 consisted of (in thousands):

	2018	2017
Current:		
Federal	$(302)	$–
State		–
Deferred:		
Federal	(11,561)	(2,679)
State	(475)	(304)
Impact of change in effective tax rates on deferred taxes	–	–

Change in: valuation allowance	12,036	2,983
	$(302)	$–

The difference between income taxes computed at the statutory federal rate and the provision for income taxes for 2018 and 2017 related to the following (in thousands, except percentages):

	2018		2017	
	Amount	**Percent of Pretax Income**	Amount	**Percent of Pretax Income**
Tax (benefit) at federal statutory rate	$(22,325)	34 %	$(44,283)	34 %
State income taxes, net of federal income taxes	(475)	(1)%	(304)	- %
Effect of warrant liability	(1,120)	2 %	(74)	- %
Effect of other permanent items	30	- %	(82)	- %
Effect of Acquisition of intangible assets	–	- %	35,595	(27)%
Effect of stock compensation	–	- %	3,147	(3)%
Change in valuation allowance	12,036	(18)%	2,983	(2)%
Reduction of NOL's due to Section 382 Limitations	11,552	(17)%	3,018	(2)%
	$(302)	– %	$–	- %

The components of deferred income tax assets (liabilities) were as follows (in thousands):

	October 31,	
	2018	2017
Impairment of development costs	$7	$–
Depreciation and amortization	(546)	95
Compensation expense not deductible until options are exercised	10,529	4,553
All other temporary differences	382	248
Net operating loss carry forward	8,455	3,158
Less valuation allowance	(18,827)	(8,054)
Deferred tax asset (liability)	$–	$–

Realization of deferred tax assets, including those related to net operating loss carryforwards, are dependent upon future earnings, if any, of which the timing and amount are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. Based upon the Company's current operating results management cannot conclude that it is more likely than not that such assets will be realized.

Utilization of the net operating loss 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 net operating loss carryforwards before utilization. Due to the change in tax law, all losses post 2018 will have an unlimited carryforward period (but can only utilize 80% max per year). All prior net operating losses still have the

same carryforward limit of 20 years. The net operating loss carryforwards available for income tax purposes at October 31, 2018 amounts to approximately $37.8 and expires between 2037 and 2038 for federal income taxes, and approximately $20.4 for state income taxes, which primarily expires between 2032 and 2033.

The Company files income tax returns in the U.S. and various states As of October 31, 2017, the Company had no unrecognized tax benefits, which would impact its tax rate if recognized. As of October 31, 2018, the Company had no accrual for the potential payment of penalties. As of October 31, 2018, the Company was not subject to any U.S. federal, and state tax examinations. The Company’s U.S. federal tax returns have been examined for tax years through 2011 with the results of such examinations being reflected in the Company’s results of operations as of October 31, 2013. The Company does not anticipate any significant changes in its unrecognized tax benefits over the next 12 months.

13. LOSS PER SHARE

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	October 31,	
	2018	2017
Shares issuable upon conversion of preferred stock	–	9,307,904
Shares issuable upon exercise of warrants	–	322,727
Shares issuable upon exercise of stock options	6,080,505	3,818,530
Non-vested shares under restricted stock grants	673,960	227,132

14. COMMITMENTS AND CONTINGENCIES

Contingencies

On June 26, 2018, a class action complaint alleging violations of the Federal securities laws was filed in the United States District Court, District of Utah, by Jose Moreno against the Company and two directors of the Company, Case No. 2:18-cv-00510-JNP (the "Moreno Complaint"). On July 6, 2018, a similar complaint was filed in the same court against the same defendants by Yedid Lawi, Case No. 2:18-cv-00541-PMW (the "Lawi Complaint"). Both the Moreno Complaint and Lawi Complaint allege that the defendants made or were responsible for, disseminating information to the public through reports filed with the Securities and Exchange Commission and other channels that contained material misstatements or omissions in violation of Sections 10 and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 adopted thereunder. Specifically, both complaints allege that the defendants misrepresented the status of one of the Company's patent applications while touting the unique nature of the Company's technology and its effectiveness. Plaintiffs are seeking damages suffered by them and the class consisting of the persons who acquired the publicly-traded securities of the Company between March 31, 2017, and June 22, 2018. Plaintiffs have filed motions to consolidate and for appointment as lead plaintiff. On November 28, 2018, the Court consolidated the *Moreno* and *Lawi* cases under the caption *In re PolarityTE, Inc. Securities Litigation* (the "Consolidated Securities Litigation"), and requested the appointment of the plaintiff in *Lawi* as the lead plaintiff. An order for appointment of the lead plaintiff has not been entered. After the lead plaintiff is appointed, the plaintiff will have 60 days to file an amended complaint. The Company believes the allegations in the Moreno Complaint and Lawi Complaint are without merit, and intends to defend the litigation, vigorously. The Company expects its first response will be to file a motion to dismiss after the first to occur of the plaintiff filing an amended complaint or the period for filing an amended complaint expires. At this early stage of the proceedings the Company is unable to make any prediction regarding the outcome of the litigation.

In November 2018, a shareholder derivative lawsuit was filed in the United States District Court, District of Utah, with the caption *Monther v. Lough, et al*., case no. 2:18-cv-00791-TC, alleging violations of the Securities Exchange Act of 1934, breach of fiduciary duty, and unjust enrichment on the part of certain officers and directors based on the facts and circumstances recited in the Consolidated Securities Litigation. On November 26, 2018, the court issued an order staying all proceedings until after the disposition of motions to dismiss the Consolidated Securities Litigation.

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, a former subsidiary of the Company, 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 represented himself pro se in the litigation and sought 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 finding that the accused products did not literally infringe the asserted patent and that plaintiff was barred from pursing infringement under the doctrine of equivalents due to prosecution history estoppel. The plaintiff appealed that decision to the Court of Appeals for the Federal Circuit. On April 9, 2018, the Court of Appeals for the Federal Circuit affirmed the judgment of the District Court for the Western District of Washington. On May 7, 2018, the plaintiff filed a petition for panel rehearing and rehearing en banc by the Court of Appeals. The petition for rehearing was denied on June 8, 2018. The plaintiff subsequently filed a petition for a writ of certiorari with the Supreme Court of the United States, which was denied in November 2018. Consequently, this matter has been finally resolved without liability to the Company.

In the ordinary course of business, we may become involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements, regulatory compliance, and other matters. Except as noted above, at October 31, 2018, we were not party to any legal or arbitration proceedings that may have significant effects on our financial position or results of operations. No governmental proceedings are pending or, to our knowledge, contemplated against us. We are not a party to any material proceedings in which any director, member of senior management or affiliate of ours is either a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

Commitments

The Company leases facilities and certain equipment under noncancelable leases that expire at various dates through November 2022. Leases are classified as capital leases when the terms of the lease transfer substantially all the risk and rewards of ownership to the lease. Other leases are classified as operating leases.

Property and equipment under capital leases are initially recorded at the lower of asset fair value or the present value of the minimum lease payments on the consolidated balance sheet. The corresponding liability to the lessor is included in the balance sheet as a capital lease obligation. Lease payments under capital leases are treated as debt-service payments and recognized as a reduction of the capital lease obligation and an increase in interest expense.

The following schedule summarizes the future minimum lease payments for operating and capital leases at October 31, 2018 (*in thousands*):

	Operating leases	Capital leases
Year ended October 31, 2019	$ 1,887	$ 61
Year ended October 31, 2020	1,895	52
Year ended October 31, 2021	1,481	49
Year ended October 31, 2022	1,323	36
Year ended October 31, 2023	111	–
Thereafter	–	–
	$ 6,697	$ 198

Rent expense for the years ended October 31, 2018 and 2017 was $1.4 million and $222,000, respectively.

The Company has entered into employment agreements with key executives that contain severance terms and change of control provisions.

15. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

In October 2018, the Company entered into an office lease covering approximately 7,250 square feet of rental space in the building located at 40 West 57th Street in New York City. The lease is for a term of three years. The annual lease

rate is $60 per square foot. Initially the Company will occupy and pay for only 3,275 square feet of space, and the Company is not obligated under the lease to pay for the remaining 3,975 square feet covered by the lease unless we elect to occupy that additional space. Comparable annual lease rates for similar office space in the area range between $67 and $110 per square foot. The Company believes the terms of the lease are very favorable to us, and the Company obtained these favorable terms through the assistance of Peter A. Cohen, a director, which he provided so that the company he owns, Peter A. Cohen, LLC ("Cohen LLC"), could sublease a portion of the office space.

Initially, the Company is using three offices and two work stations in the office and share common areas representing approximately 2,055 square feet. Cohen LLC is using approximately 1,220 square feet. The monthly lease payment for 3,275 square feet is $16,377. Of this amount $6,103 is allocated pro rata to Cohen LLC based on square footage occupied. Additional lease charges for operating expenses and taxes are allocated under the sublease based on the ratio of rent paid by the Company and Cohen LLC to total rent.

Cohen LLC identified two associated entities that may wish to occupy an additional 2,753 square feet of space in the office. Under the terms of the sublease Cohen LLC can add this additional space to the 1,220 square feet occupied, which would bring the total space occupied by us and Cohen LLC to 6,028 square feet. Because a portion of the additional space subleased to Cohen LLC is less private and attractive, the Company agreed to reduce the overall annual lease rate for the Cohen LLC space to $58.60 per square foot, which means the Company will be paying an annual lease rate for the space the Company uses of $62.70. Assuming Cohen LLC subleases the additional office space, our annual lease payment to the lessor would be $361,680, and Cohen LLC would pay to the Company $232,830 under the sublease. Sublease income and amounts due from the related party for the year ended and as of October 31, 2018 were de minimis.

In August 2018 David Seaburg was elected by the Board of Directors to serve as a director of the Company. Subsequently the Company entered into a written consulting agreement with Mr. Seaburg pursuant to which he will provide investor relations and other services to the Company over a period of two years for a fee consisting of (i) quarter-annual cash payment of $10,000, (ii) 60,000 restricted stock units issued under the Company equity incentive plan that vest in four equal installments every six months during the term of the agreement subject to continued service, and (iii) an annual award under the Company equity incentive plan of options exercisable over a term of 10 years to purchase common stock in number equal to the number of shares of common stock with a value of $150,000 at the time of the award based on a Black-Scholes calculation. As of the year ended October 31, 2018, the Company has made no payments to Mr. Seaburg for consulting services. The total value of Mr. Seaburg's agreement is approximately $1.7 million, which will be recognized as expense over the 24-month consulting period. Approximately $324,221 was recognized as expense during the year ended October 31, 2018.

16. DISCONTINUED OPERATIONS

On June 23, 2017, the Company sold Majesco Entertainment Company, a Nevada corporation and wholly-owned subsidiary of the Company ("Majesco Sub") to Zift Interactive LLC ("Zift"), a Nevada limited liability company pursuant to a purchase agreement. The results of operations from the discontinued business for the years ended October 31, 2018 and 2017 are as follows (in thousands):

	For the Years Ended October 31, 2018	2017
Revenues	$–	$558
Expenses	–	1,007
Loss from discontinued operations	$–	$(449)
Gain on sale of discontinued operations	$–	$100

The cash flows from the discontinued business for the years ended October 31, 2018 and 2017 are as follows (in thousands):

	For the Years Ended October 31, 2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss from discontinued operations	$–	$(349)
Adjustments to reconcile net loss from discontinued operations to net cash used in discontinued operating activities:		
Depreciation and amortization	–	11
Stock based compensation expense	–	1,118
Amortization of capitalized software development costs and license fees	–	50
Gain on sale of Majesco Sub	–	(100)
Changes in operating assets and liabilities:		
Accounts receivable	–	113
Accounts payable and accrued expenses	–	(810)
Net cash provided by discontinued operating activities	$–	$33
CASH FLOWS FROM INVESTING ACTIVITIES		
Cash received from sale of Majesco Sub	$60	$25

Net cash provided by discontinued investing activities	$60	$25

17. SEGMENT REPORTING

The Company’s operations involve products and services which are managed separately. Accordingly, it operates in two segments: 1) regenerative medicine and 2) contract services.

Certain information concerning our segments for the years ended October 31, 2018 and 2017 is presented in the following table (in thousands):

	For the Years Ended October 31,	
	2018	2017
Net Revenues:		
Reportable Segments:		
Regenerative medicine	$689	$–
Contract services	874	–
Total net revenues	$1,563	$–
Net loss:		
Reportable Segments:		
Regenerative medicine	$(65,219)	$(130,480)
Contract services	(222)	–
Discontinued operations	–	(349)
Total net loss	$(65,441)	$(130,829)

	As of October 31, 2018	As of October 31, 2017
Identifiable assets employed:		
Reportable segments:		
Regenerative medicine	$82,512	$20,152
Contract services	5,330	–
Discontinued operations	–	–
Total assets	$87,842	$20,152

18. SUBSEQUENT EVENTS

On January 11, 2019, the Board approved an amendment to the Restated Bylaws of the Company changing the Company’s fiscal year end from October 31 to December 31. The change in fiscal year is effective December 31, 2018, and the Company will file an Annual Report on Form 10-K for the two-month transition period ended December 31, 2018.