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 December 31, 2019

OR

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

For the Transition Period from _____

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 (800) 560-3983

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001	PTE	NASDAQ Capital Market
Preferred Stock Purchase Rights		NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [ ] No [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 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 June 30, 2019, was $79,393,237.

The outstanding number of shares of common stock as of March 6, 2020, was 38,358,450.

Documents incorporated by reference: None.

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

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," "seek," "should," "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

Overview

PolarityTE, Inc., headquartered in Salt Lake City, Utah, is a biotechnology company developing and commercializing regenerative tissue products and biomaterials. Our regenerative SkinTE product is commercially available for the repair, reconstruction, replacement, and supplementation 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 intend to continue to focus on the SkinTE product offering and to enhance that offering with the development of SkinTE Cryo and other products.

Our Goals and Objectives

We aspire to deliver products from our platform technologies that provide superior results to patients, while reducing costs and promoting improved health economics for patients, providers, and payors. During the past three years we pursued the attainment of that goal through the development and commercialization of SkinTE. Our current plan is to:

- Expand the commercial sales team and increase productivity through improved hiring and training and by executing on a clearly defined sales and marketing strategy;
- Focus on positioning SkinTE for broader adoption as an established treatment for specific wounds;
- Complete the clinical trials we have in process;
- Continue development of SkinTE Cryo and other products; and
- to pursue strategic relationships that enhance our technology offerings through joint development or licensing arrangements or acquisitions.

SkinTE

The Importance of Skin

Skin has several functions. It provides a barrier to water loss and pathogens and protects against diverse forms of trauma, including thermal, chemical and ultraviolet radiation. Skin keeps us in touch with our environment through a host of nerve endings, regulates body temperature and enhances metabolic functions, as well as synthesizing vitamin D.

- The importance of the skin as a barrier is illustrated by the mortality associated with large surface area burns, where increased transepidermal water loss culminates in dehydration, renal failure and shock.
- Skin is an active immune organ, and dysfunctional innate defenses have significant clinical implications. Products of the stratum corneum, including free fatty acids, polar lipids, and glycosphingolipids accumulate in the intercellular spaces and horny layer, exhibiting antimicrobial properties, and functioning as a first line of defense. Antimicrobial peptides exhibit potent and targeted resistance against a wide spectrum of common pathogens, and when this barrier is breached, second lines of protection are provided by an inflammatory cascade in the subepithelial tissue.
- Biosynthesis of melanin involves a complex pathway that occurs in melanocytes, within membrane-bound organelles called melanosomes. Melanocytes are present in the basal and suprabasal layers of the skin and in the hair follicles and transfer melanosomes through dendritic processes where they form melanin caps that reduce the harmful effects of ultraviolet light.
- The skin is a ready source of vitamin D following sun exposure. It is a fat-soluble prohormone steroid primarily acknowledged for its endocrine role in calcium homeostasis maintaining levels of serum calcium through control of calcium and phosphate absorption from the intestine, and resorption of bone.
- The skin controls body temperature. The underlying adipose tissue insulates against conductive heat loss, whereas loss of heat is facilitated actively by evaporation of sweat from the skin surface and by increased blood flow through the rich vascular network of the dermis.

The clinical significance of skin is illustrated by the morbidity associated with burns and cutaneous defects. According to statistics collected by the Nation Burn Repository, the mortality rate from 2008 to 2017 among burn patients treated at surveyed burn centers is approximately 3%. A 12-month prospective observational study of diabetic foot ulcers first published in October 2017 reported that out of a group of 299 patients, 17.4% had some sort of amputation of the foot and 6.0% of the 299 patients underwent revascularization surgery. A report published on Medscape in June 2018 states that pressure injuries are listed as the direct cause of death in 7-8% of all patients with paraplegia. We believe that the regeneration of full-thickness skin with all the processes and appendages that enable it to perform its vital functions is critical to long-term, positive patient outcomes following serious skin injury.

Limitations of Other Skin Treatment Therapies

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 autograft (using the patient's own skin in a skin graft), an allograft (using human skin from a donor), or a variety of skin substitutes to provide a skin-like barrier while the margin of the wound heals through secondary intention and contraction. Historically, 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 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 commonly 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 components and structures required for the regeneration of normal skin.

After the failure to harvest all the necessary skin structures and components 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, the 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 cultured epithelial autograft (a form of manipulated autograft), allograft (tissue grafts derived from a donor of the same species as the recipient but not genetically identical), xenograft (a tissue graft or organ transplant from a donor of a different species from the recipient), and engineered skin substitutes. None of these substitutes have been able to regenerate the cutaneous appendages (e.g., hair follicle, sweat gland, sebaceous glands, etc.), which are necessary for the development of full-thickness, normal skin.

Our Solution - SkinTE

Many organs have a series of layered interfaces: an avascular cellular epithelium that spontaneously regenerates, a basement membrane zone, and stroma or vascular supporting connective tissue that does not regenerate. In skin, these layers are referred to as an epidermis of stratified squamous epithelium and a fibrous neurovascular dermis, which rests on a hypodermis or subcutaneous fat. We believe there is something powerful, reactive, and dynamic controlling regeneration of tissues such as skin, 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; instead, tissues have functionally organized cellular aggregates called appendages, which run, and even regenerate, the composite tissues they are a part of when altered, stimulated, and processed in certain ways.

The core technology of SkinTE is minimally polarized functional units ("MPFUs"). MPFUs are multi-cellular micro-aggregates that act as an intrinsic, regenerative bio-reactor capable of expanding, proliferating, and synthesizing cells, materials, factors, and systems necessary for regenerating full-thickness, three-dimensional tissue. In the application of SkinTE to date we have been able, when applicable to a particular case, to collect from a patient a skin tissue sample 5 cm^2 in size or less and produce enough SkinTE to treat a wound 30x greater in size than the skin collected. SkinTE allows the patient to regenerate full-thickness, three-dimensional skin (similar to a FTSG) by contributing a much smaller skin sample, while reducing the scarring and morbidities associated with STSGs, and producing results we believe to be superior to STSGs and synthetic skin substitutes.

SkinTE can be utilized by a variety of health care providers in an operating room, wound clinic, or doctor's office. When a new health care facility or practice begins using our SkinTE product, we ship harvest boxes to the facility so that the procedure for treating a patient with SkinTE can begin immediately when the need arises. Each harvest box includes a container for the skin sample collected, labels for shipping the sample to our facility, and a temperature-controlled shipping box that maintains an appropriate environment for the sample as it is delivered to our FDA regulated biomedical manufacturing facility.

The harvested skin is used in its entirety to manufacture SkinTE, which is returned for application to the patient's wound as early as 48 hours after harvest and is viable for use up to 14 days after harvest. Processing of the skin creates cellular micro-aggregates that are optimized for grafting and expansion, which retain the progenitor cells within the hair follicles. The product is not cultured or expanded ex-vivo, and no enzymes, growth factors, or serum derivatives are utilized during manufacturing. The final product, SkinTE, is delivered in a syringe and has the consistency of a paste. Following wound bed preparation, SkinTE is spread evenly across the entire surface of the wound and adheres (or "takes") to the wound in a similar manner to traditional skin grafts. Once integrated with the wound bed, the product expands and regenerates full-thickness skin across the entire surface.

SkinTE was registered with the United States Food and Drug Administration (FDA) in August 2017, and is 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.

Clinical Trials

Burns and Traumatic Wounds

We initiated a head-to-head trial comparing SkinTE to the STSG, the clinical standard of care, in the first quarter of 2018. Eight patients were enrolled in the trial and the primary endpoint for the trial is graft take. The results of the interim analysis were accepted for a podium presentation at the American Burn Association 52nd Annual Meeting that was scheduled to begin March 17, 2020, but the meeting was canceled as a coronavirus preventative measure and we have not received any word on rescheduling. We continue to accumulate clinical results on non-trial patients from our commercial sales of SkinTE for various indications, including acute burn, burn reconstruction, surgical reconstruction, scar revision, and chronic wounds. Some of these cases have been presented independently by, or in collaboration with, providers at national conferences, such as the American Society of Plastic Surgery – The Meeting in September 2019.

Diabetic Foot Ulcer (DFU) Trials

DFUs are chronic wounds and represent one of the most costly and medically significant health related morbidities encountered during a patient's lifetime. The estimated annual US payor burden of DFU ranges from $9.1 billion to $13.2 billion according to a 2014 article in *Diabetes Care*, a publication of the American Diabetes Association. The outpatient management of diabetic foot ulcers represents the major contributing cost to the health care system. Inadequate assessment and management with chronicity of treatment is one of the primary cost drivers and failures of care.

SkinTE was used to treat 10 patients (11 DFUs) in a pilot trial completed in June 2019, and first reported at the Symposium on Advanced Wound Care Fall 2019. The following are the results as determined by independent review:

- 10 of 11 (90.9%) DFUs healed within eight weeks of a single application of SkinTE
- Median time to closure was 25 days
- DFU sizes ranged from 1.0 to 21.7 cm^2
- One patient was removed from the study at week three due to adverse events not related to the study or SkinTE procedure
- No SkinTE-related adverse reactions were observed

We are now engaged in a multicenter, randomized controlled trial evaluating SkinTE versus standard of care in treatment of DFU. The size of the study is 102 patients and the trial is actively enrolling patients. The primary endpoint is percentage of ulcers closed at 12 weeks. Secondary endpoints include quality of life, return of function, pain, and cost-effectiveness. We are hopeful that we will have initial data from the trial that we can make public in the second quarter of 2020.

Venous Leg Ulcer (VLU) Trials

VLUs are a type of chronic wound and constitute a significant burden on the worldwide health care system and are often refractory to treatment. Up to one-third of treated patients experience four or more episodes of recurrence. Delivering all the elements of native skin can potentially reduce the recurrence rate.

SkinTE was used to treat 10 patients in a pilot trial completed in September 2019, and first reported at the Symposium on Advanced Wound Care Fall 2019, where we received recognition as Best Abstract. The following are the results as determined by independent review:

- 8 of 10 (80%) VLUs closed within 12 weeks of a single application of SkinTE
- Of the two VLUs not deemed closed within 12 weeks: one VLU was the largest in the study ($12.2cm^2$), and closed within 13.5 weeks post a single application of SkinTE; one VLU was previously deemed closed, and reopened prior to the two-week durability visit as a result of external factors unrelated to the SkinTE procedure
- Median time to closure was 21 days
- No SkinTE-related adverse reactions were observed

We are now engaged in a multicenter, randomized controlled trial evaluating SkinTE versus standard of care in treatment of VLU. The size of the study is 102 patients and the trial is actively enrolling patients. Secondary endpoints include quality of life, return of function, pain, and cost-effectiveness. An interim analysis is planned at 50 patients, and based on current enrollment we are hopeful this analysis may be available in the second half of 2020.

Market Opportunity

The primary markets for SkinTE are chronic wounds (including DFUs, VLUs, and pressure ulcers), burn wounds, wounds from surgical procedures, and wounds from traumatic injury.

- The American Burn Association reported the estimated number of burn injuries in 2016 was 486,000, and that approximately 40,000 of these resulted in hospitalization.
- The Centers for Disease Control reported in 2017 there are approximately 30.3 million diabetes sufferers in the United States. The American Diabetes Association report on the economic costs of diabetes in 2017 states that the direct medical cost of diabetes in that year was $237 billion. A 2005 article estimated the number of DFUs at between 1.2 and 3.0 million, and a 2003 article estimated the prevalence of unhealed DFUs after 12 weeks of conventional treatment at between 1.0 and 2.5 million. The estimated annual US payor burden of DFU ranges from $9.1 billion to $13.2 billion according to a 2014 article in *Diabetes Care*.
- A 2010 article reports the prevalence of venous ulcers at approximately 600,000 annually, and a subsequent 2014 article reports that on average between 33% and 66% of these ulcers persist for six weeks and are, therefore, referred to as chronic, resulting in approximately 200-360 thousand patients per year that we believe would be potential candidates for treatment with SkinTE.
- Pressure Ulcers are common in hospital systems, increase patient morbidity and mortality, and are costly for patients and the healthcare system. According to the Agency for Healthcare Research & Quality (AHRQ) there are more than 2.5 million individuals that develop pressure ulcers annually, and approximately 600-700 thousand people are admitted to hospitals with one or more pressure ulcers. Of these ulcers, approximately 77% are treated with both topical therapies and excisional surgical debridement.
- We believe SkinTE is suitable for treating a number of acute wounds. In 2017 the results of a 2010 survey were published showing approximately 11.4 million musculoskeletal and integumentary in-patient surgeries occurred during the survey year, and the inpatient traumatic injury rate was 524.3 persons for every 100,000 people. A 2015 study reports the incidence of surgical wound dehiscence following different surgical procedures ranges between 1.3% and 9.3%. Of those dehiscence occurrences, a 2017 article recites the results of a survey of 187 patients with surgical wounds healing by secondary intention showing 77, or 41.2%, were wounds that had dehisced.

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 use by early adopters, often in the context of product evaluations, with the goal of securing 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 initial build out of our commercial organization. In 2019, we pushed to grow our SkinTE sales by increasing market awareness, positioning SkinTE for broader adoption as the treatment for specific wounds, and improving the productivity of our sales team by selective additional hiring and optimized training. We ended 2019 with approximately 25 salespeople and 10 clinical science staff that support the sales team.

We have observed that the sales process is affected by several factors, including the receptiveness of the physician to consider and then adopt a new therapeutic approach, facility administrative approval where required, the nature and type of wounds treated at a target account, and the incidence of wound care cases at target accounts. We also believe that the previous lack of SkinTE clinical trials, which we were not required to obtain before commercialization as a 361 HCT/P, has adversely affected the willingness of healthcare providers to use SkinTE.

In the hospital and large facility setting we begin the sales process with introductions to physicians whose patients may benefit from SkinTE. After a physician in the system is willing to use the product, the hospital or large facility usually requires an assessment by its Value Analysis Committee (VAC) prior to commencing commercial SkinTE use. This can be a formal and lengthy administrative process, and our experience shows the length of the process varies widely from one customer to the next. In some cases, the physician seeking to use our product can complete a product evaluation during the VAC process, but in others the test trial must wait until VAC approval. After VAC approval and any product evaluations are complete, we negotiate the terms of a final purchase agreement.

In clinics and smaller facility operations there is often no VAC and related approval process. The salesperson focuses more directly on the physician and the benefits SkinTE can provide to the physician's patients. In these facilities the process focuses on selling the physician on an evaluation use of SkinTE, and, after the evaluation, entering into a purchase agreement.

Once purchase agreements are in place, our sales team and clinical operations staff maintain close contact with the health care provider to support the initial therapeutic applications of SkinTE. This relationship enhances a provider's ability to effectively incorporate SkinTE into its existing patient treatment decisions.

SkinTE's pricing structure is designed to be competitive in the marketplace and reflects SkinTE's ability to deliver durable, functional full-thickness skin replacement with only one application, compared to the costly practice of regular wound care over a long period of time. We are working closely with our customers to ensure that pricing is not a barrier to broad adoption of SkinTE across a variety of wounds and points of care.

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 for procedures within Hospital Outpatient Departments (HOPDs) and Ambulatory Surgical Centers (ASCs). In these settings, bundled APC facility payments are dictated by the procedures 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.

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 HCPCS Q4200, which was effective January 1, 2019.

In November 2019, we made a business decision to no longer promote the use of Q4200 in office or clinic settings. We believe there are appropriate Level 1 CPT Codes within the Full Thickness Skin Graft code category, in addition to Surgical Preparation codes with appropriate modifiers (52 & 58) that are appropriate for SkinTE. We expect, however, that hospitals will continue to use Q4200 with alpha ‘N’ to denote zero value of the product along with Revenue Code 0636 when SkinTE is bundled within the payments hospitals receive for full thickness skin grafting CPTs. We will continue to report ASP and work with CMS within the respective framework because we believe that SkinTE can qualify as a high cost product based on current CMS guidance in place. The strategy will support projected commercial payer adoption moving forward, and we are developing evidence to support this objective.

Development Projects

Accelerating adoption and growth of SkinTE is a priority for us. The focus of our development projects reflects that priority.

SkinTE Cryo

SkinTE Cryo allows us to offer multiple deployments from one original harvest through a cryopreservation process. We believe this is a valuable offering that will enhance our SkinTE commercialization effort for several reasons. Using one harvest for multiple deployments improves patient treatment when:

- a patient is susceptible to multiple chronic wounds;
- the provider suspects a patient might require a second deployment of SkinTE due to past non-compliance with rehab protocols; or
- the provider elects to use a staged deployment on a patient with a large wound due to wound location or other therapeutic circumstances.

We believe we will complete our development work on SkinTE Cryo in the second quarter of 2020 and are evaluating options for commercializing SkinTE Cryo, which we believe we will be able to test in a limited market release during the second half of 2020.

SkinTE POC

Our SkinTE point-of-care device is intended to permit the processing and deployment of SkinTE immediately following the initial harvest at the point-of-care. SkinTE POC is in the development stage and we are now evaluating different designs for the device with a view to what users will find most conducive to application in a hospital or clinic. This is a long-term development project.

PTE 11000

PTE 11000 is an allogenic, biologically active dressing for use in wound care and aesthetics to accelerate healing of skin. It is a composition made using cadaveric tissue via a proprietary process. It is currently in the preclinical phase of development and we believe this development phase may be completed sometime in 2021.

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. We are pursuing additional pre-clinical testing and research to gather more information on potential markets for this product. This is a long-term development project.

Other Potential Products

We believe our innovative technologies may be platforms for developing therapies that address a variety of indications, including cartilage, muscle, blood vessels, and neural elements, as well as solid and hollow organ composite tissue systems. Accordingly, we will investigate and evaluate these product opportunities as time and resources permit given our focus on commercializing SkinTE and the product candidates described above.

- CartTE to deliver a cartilage construct for a variety of applications, including osteoarthritis therapies, facial reconstruction, facial aesthetics, hand reconstruction, as well as wrist reconstruction. Osteoarthritis of the hip or knee is estimated to affect 9% of the US population greater than 30 years of age, with costs of treatment totaling $28.6 billion in 2013, according to a review by Grande et al. Market projections by Krutz et al. in 2007 predict that the demand for primary (first-time) total hip and knee replacements will grow to 572,000 and 3.48 million procedures per year by 2030 in the US, respectively. We believe this demand for joint replacement demonstrates the substantial opportunity for alternative therapies that can delay or prevent traumatic joint replacement surgeries.
- 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.
- 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, 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 may deploy a commercialization strategy similar to that of SkinTE or we may commercialize the product through a licensing or strategic partnership arrangement. 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 preclinical and clinical testing and substantially extend the time of bringing the product to market.

Manufacturing

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 tissue product, and perform outgoing quality control and quality assurance work prior to shipping. We have validated our manufacturing process as being aseptic. All SkinTE is manufactured within an ISO 5 isolator located within an ISO 7 cleanroom. Our processes are designed and validated to prevent the spread of communicable disease, and to prevent cross-contamination between samples. Our quality systems comply with current Good Tissue Practices under 21 C.F.R. Part 1271.

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 have significant research facilities and this resource is beneficial to the work we are doing in our development projects. We also offer research services to third parties on a contract basis through our subsidiary, Arches Research and IBEX. Contract research services help us defray the costs of maintaining a research facility.

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. In April 2019, we leased 6,307 square feet of manufacturing, laboratory, and office space in the Doctors Hospital complex in Augusta, Georgia, where The Joseph M. Still Burn Center is located. We intend to establish at the Doctors Hospital a remote manufacturing facility to service the region, which we believe will be operational in the middle of 2020.

Suppliers

As part of our strategy of ensuring timely delivery of our products, we have avoided relying on any third-party supplier as a sole source vendor for any element of our production process. We have identified alternate suppliers and, where appropriate, supply alternatives for any sourcing challenges.

Intellectual Property

As we advance our platform technology, product and pipeline developments, 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 are actively seeking U.S. and international patent protection for a variety of technologies, including our MPFU technology, our Complex Living Interface Coordinated Self-Assembling Materials (“CLICSAM”) Technology, our Composite-Interfacing, Biomaterial Accelerant Substrate (“CIBAS”) Technology, as well as Biological Sample Harvest and Deployment Kits.

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.

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 and in other countries throughout the world. Additional registered trademarks in the United States include our logo, WELCOME TO THE SHIFT, and WHERE SELF REGENERATES SELF.

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, governmental agencies, and public and private research institutions. Our competition includes providers of FTSGs and STSGs, the current standards of care, as well as other companies developing and commercializing skin substitutes. Any advances in regenerative medicine by others may be used to develop therapies that compete against SkinTE. 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, and we face significant competition in the wound care space from multiple products, including ReCell, Integra Bilayer Wound Matrix, EpiFix, Apligraf, Dermagraft, Grafix, Epicel, and others.

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.

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 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.

Arches Research 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. Arches Research 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, and molecular biology assays.

Government Regulation

Government authorities, 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, laws, and regulations.

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) and the federal Food, Drug, and Cosmetic Act (the "FD&C Act"). Under this 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 investigational new drug application ("IND") or investigational device exemption ("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.

If, however, an HCT/P meets the criteria for regulation solely under Section 361 of the Public Health Service Act and Part 1271 of Title 21 of the Code of Federal Regulations (so-called "361 HCT/Ps"), no premarket FDA review for safety and effectiveness under a drug, device, or biological product marketing application is required. The processor of the 361 HCT/P 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 reactions 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/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 Federal Establishment Identification number ("FEI#") after submitting the Form FDA 3356 (registration form). 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. Part 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. Part 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 engaged in a productive dialog with the FDA. Following our responses, in or around February 2019, FDA classified the July 2018 inspection of our Salt Lake City Manufacturing site as "Voluntary Action Initiated," or "VAI." A VAI classification indicates that, although FDA found and documented objectionable conditions during its inspection, FDA will not take or recommend regulatory or enforcement action with respect to such inspectional observations at this time.

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, non-binding recommendations and formal, binding designations 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 designation from the OCP.

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 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, exempt 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 False Claims Act ("FCA") imposes civil liability on any person or entity that submits, or causes others to submit, a false or fraudulent claim for payment (e.g., by the Medicare or Medicaid programs) to the U.S. government. Damages under the FCA can be significant, and consist of the imposition of fines and penalties, as well as possible exclusion from Medicare, Medicaid and other federal healthcare programs. 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, in order to settle allegations under the FCA, 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 (such as Medicare and Medicaid), and commercial healthcare insurers, such as 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.

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 statute because our products are neither regulated as pharmaceuticals, biologics, nor medical devices by the FDA, and 361 HCT/Ps are not expressly addressed by this law. We do, however, voluntarily file annual reports because we believe it enhances our reputation in the medical industry to be transparent about what we do and how we do it.

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 sites that maintain USDA-covered species are actively registered as USDA research facilities.

Employees

We had approximately 153 full-time employees and four part-time employees as of December 31, 2019, 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

Majesco Entertainment Company, a Delaware corporation ("Majesco DE"), was incorporated in the state of Delaware on May 8, 1998. On December 1, 2016, Majesco Acquisition Corp., a Nevada corporation and wholly owned subsidiary of Majesco DE entered into an Agreement and Plan of Reorganization with PolarityTE, Inc., a Nevada corporation ("PolarityTE NV") and the sole shareholder 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 ("Zift"), 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 perform research on our development projects and comprise the contract research segment of our business.

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 http://www.polarityte.com. We have included our website address as an inactive textual reference only. We make available, free of charge through our website, our annual reports on Form 10-K, our quarterly reports on Form 10-Q, our current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") as soon as reasonably practicable after we electronically file such material, or furnish it to the SEC. We also similarly make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons.

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.

Risks Related to Our Business

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 $92.5 million for the year ended December 31, 2019, and $65.4 million for the 12-month period ended October 31, 2018. Our ability to achieve profitable operations in the future will depend in large part upon the successful commercialization of SkinTE, and we are unable to predict when, if ever, that may occur. Our continuing capital needs to support expansion of the marketing effort, clinical trials, and other costs of our business could cause us to seek additional funding through public or private equity offerings, debt financings or from other sources. The sale of additional equity may result in dilution to our stockholders. In these circumstances, there is no assurance that we would be able to secure funding on terms acceptable to us, or at all.

If the commercialization of our lead product candidate, SkinTE, is not successful, our results of operations and financial condition will be adversely affected.

Our near-term prospects depend upon our ability to effectively market our lead product candidate, SkinTE. Gaining market acceptance and market share depends on a number of factors, including favorable completion of pending clinical trials, obtaining certainty on reimbursement for different applications, and our ability to develop an effective sales team. If we are not successful in commercializing SkinTE or are significantly delayed in doing so, our operating results and financial condition will be adversely affected.

Our revenue growth for SkinTE depends on our ability to expand our sales force, increase distribution and sales to existing customers and develop new customers, and there can be no assurance that these efforts will result in significant increases in sales.

We are in the process of investing in development of our direct sales force to allow for the opportunity to increase sales to existing customers and reach new customers. There can be no assurance that this effort will result in a meaningful increase in revenues. We expect to incur substantial expense to expand our sales force, and there is no assurance that we will recoup this investment through increased sales or that any increase in sales will allow us to sustain our operations.

Meaningful revenue growth in the foreseeable future is dependent on one product – SkinTE.

While a contributor to revenues, we do not believe our contract services business offers a revenue growth opportunity substantial enough to sustain our operations. Meaningful revenue growth will come from sales of regenerative tissue products and biomaterials, and the only such product we will be selling for the foreseeable future is SkinTE. To the extent that sales of SkinTE lag behind our need to generate revenue to make up the gap between available capital and cash flow from operations or there is a disruption in our ability to generate revenue from the distribution of SkinTE, our results of operations, financial condition, and growth prospects would be materially, adversely affected.

Our ability to effectively sell SkinTE depends on a number of factors that we are still learning about.

Factors impacting our ability to successfully commercialize SkinTE include:

- obtaining data from clinical trials that supports the efficacy of SkinTE;
- our ability to educate and train physicians and hospitals on the benefits of our product;
- the rate at which providers adopt our product;
- our ability to scale up our commercialization of SkinTE in a way that generates positive results;
- our ability to obtain adequate reimbursement from third parties for our product; and
- other activities generally necessary to accelerate market acceptance of a relatively new product that represents a change from traditional treatment regimens.

We began marketing SkinTE on a regional level in the fourth quarter of 2018, so we are still learning about the market and how to approach it with our product. We have begun to identify important factors, such as the items listed above, that affect our sales effort and continue to gain insight as our experience with marketing SkinTE grows. As we are still in the learning stage, we cannot predict when, if ever, we will succeed in establishing a formula for selling SkinTE that will produce revenue at a level sufficient to sustain our operations.

We will incur substantial costs in terms of both money and corporate resources for clinical and preclinical trials, and the results of these trials is uncertain.

We are pursuing two clinical trials for DFUs and VLUs and are evaluating plans for additional clinical trials for SkinTE. Clinical trials entail substantial costs, and we will continue to incur substantial costs on clinical trials for SkinTE. In addition, we expect that we will pursue development work and pre-clinical trials on our product development projects, which will result in additional costs with no assurance that the research and development work will result in any marketable product or revenue for us. These expenditures are subject to numerous uncertainties in timing and cost of completion, and potentially detract from our effort to commercialize SkinTE. Finally, there is no assurance that the results of a clinical or preclinical trial will be helpful in advancing the marketability or development of any product, and to the extent the results are not helpful, it is unlikely we would be able to recoup our investment in these trials and development efforts.

Our success will be dependent on our ability to achieve a meaningful level of SkinTE acceptance by the medical community.

We believe the lack of SkinTE clinical trials, which we were not required to obtain before commercialization as a 361 HTC/P, has adversely affected the acceptance of SkinTE by the wound care segment of the medical community. While we hope that our clinical trials will provide positive results, which will help to advance acceptance of SkinTE, we cannot guarantee this outcome. Our ability to gain, and then maintain, acceptance depends on whether we can demonstrate that SkinTE is an attractive alternative to existing or wound care treatment options, including both surgical techniques and products. Our ability to do so will depend on physicians' evaluations of clinical safety, efficacy, ease of use, reliability, and cost-effectiveness, including insurance reimbursement. If the medical community and patients do not accept SkinTE as safe and effective, our ability to sell SkinTE and our results of operations may be materially and adversely affected.

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. Until established payment rates are set by payers, 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 or products in competitive markets, 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 products or 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 products 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 for any particular intended use or indication or in any particular jurisdiction, does not guarantee that such product will remain approved for reimbursement, will continue to be reimbursed at comparable rates, or that similar or additional products will be approved for reimbursement 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 limit or 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 successfully commercialize our product candidates. Our product and product candidates may receive negative assessments that may impact our ability to receive reimbursement for a product. We cannot be sure that reimbursement in the United States or elsewhere will be available for any of our products or product candidates in the future. If reimbursement is not available or is limited, our ability to commercialize our products and product candidates would be substantially impaired, which would adversely affect the viability of our commercial operations.

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 or payment that we would receive for any products in the future, which would limit our revenue and profitability. If we are unable to obtain or maintain reimbursement approval from commercial third-party payers and Medicare and Medicaid programs for our products and product candidates, or if the amount reimbursed is inadequate, our ability to generate revenues could be limited.

There may be significant fluctuations in our operating results.

We are at the beginning of the second year of our focused commercialization effort for SkinTE, so significant quarterly fluctuations in our results of operations are expected because our customer base, while growing, remains very small in relation to the overall wound care market. Fluctuations in quarterly results may also be caused by seasonal changes in wound care treatment demand, timing of sales force expansion, and general economic conditions. There can be no assurance that the level of revenues and profits, if any, we achieve in any particular fiscal period, will not be significantly lower than in other comparable fiscal periods. Our spending on operations is based, in part, on our expectations as to future revenues. As a result, if future revenues are below expectations, net income or loss may be disproportionately affected by a reduction in revenues, as any corresponding reduction in expenses may not be proportionate to the reduction in revenues.

The recent widespread outbreak of respiratory illness caused by a strain of coronavirus (Covid-19) has resulted in business closures and disruptions that may affect various suppliers of items we may use to produce and deliver SkinTE, notwithstanding the fact that we operate entirely within the United States. A significant outbreak of coronavirus and other contagious diseases could result in a widespread health crisis that might have a chilling effect on patients seeking treatment from healthcare providers for conditions where SkinTE may be suitable, and could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could affect demand for our products and impact our business, financial condition, and results of operations.

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 of the manufacturing of SkinTE takes place at our single U.S. facility. We are in the process of developing another manufacturing facility in Augusta, Georgia, but this facility is not yet operational. If regulatory, manufacturing, or other problems require us to discontinue production at our current facility, we will not be able to supply SkinTE to patients or have supplies for 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 quickly transfer manufacturing to our facility under development or 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 applicable cGTP or the FDA's current good manufacturing practices ("cGMP") 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.

Performance issues, service interruptions or price increases by our shipping carriers could negatively affect our business, financial condition and results of operations and harm our reputation and the relationship between us and the healthcare providers with which we work.

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of skin harvested from patients and the return of SkinTE manufactured for those patients, and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage, or destruction of any delivery systems, it could result in delays in delivering our product and spoilage of the SkinTE we produce for patients, which is viable for 14 days following the skin harvest date. Any such occurrences may damage our reputation and lead to decreased demand for our solution and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for SkinTE on a timely basis.

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

The manufacturing, marketing, and processing of our products and 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 products would be costly and would divert management resources. A recall or withdrawal of one of our products, or a similar product processed by another entity, also could impair sales of our products because of confusion concerning the scope of the recall or withdrawal, or because of the damage to our reputation for quality and safety.

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

We may pursue licensing or strategic partnership opportunities in the future to enhance and accelerate the development and commercialization of our existing products and potential product candidates. We may rely on such arrangements to assist in launching, marketing, and developing our products and product candidates. However, we may face significant competition in seeking appropriate arrangements and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a licensing, strategic partnership, or other alternative arrangements for any present or future proposed products and programs for a variety of reasons. Even if we are successful in our efforts to establish licensing agreements or strategic partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such arrangements if, for example, development or approval of a product candidate is delayed or sales of an approved or registered product are disappointing.

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 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 the 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 SkinTE is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to SkinTE, or if physicians switch to other new drug or biologic products, or choose to reserve SkinTE for use in limited circumstances.

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

SkinTE faces 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 in the wound care market, successfully identify product candidates or develop products earlier than we do, or develop products that are more effective or safe, or that cost less than SkinTE. These competitive factors could require us to conduct additional 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 SkinTE and achieve revenue and profits.

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

We are focused on employing our resources to commercialize SkinTE, and thus we expect to continue to use our capital to advance that objective rather than on research and development on product candidates that will take a long time to evaluate and develop. Until we can successfully commercialize our product candidates and achieve significant revenue, if any, it is unlikely we will be able to make a significant capital commitment to research and development of new product candidates.

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 potential product opportunities. 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 core 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.

Our potential 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 potential 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 potential product candidates creates significant challenges regarding product development and optimization, manufacturing, government regulation, and third-party reimbursement. As a result, the development pathway for any such product and its commercialization may be subject to increased scrutiny, as compared to the pathways 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.

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 SkinTE or other products we develop 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 products are used is determined to be unsafe, we may be required to delay, alter, or abandon our product development or commercialization.

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 products 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 products. Defending a lawsuit, regardless of merit, could be costly, divert management attention, and result in adverse publicity, which could result in the withdrawal, or reduced acceptance, of our products 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 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 depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees will negatively affect our business, financial condition and results of operations.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and other personnel. We are highly dependent upon our senior management and other key personnel. Although we have entered into employment agreements with all of our executive officers, each of them may terminate their employment with us at any time. The replacement of any of our key personnel likely would involve significant time and costs and may significantly delay or prevent the achievement of our business objectives and could therefore negatively affect our business, financial condition, and results of operations. In addition, we do not carry any key person insurance policies that could offset potential loss of service under applicable circumstances.

We have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than us. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages.

In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived value of our stock awards declines, it may harm our ability to recruit and retain highly skilled employees. Many of our employees have become or will soon become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, it will negatively affect our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

We do not currently own any issued patents in the United States 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 in the United States 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 in the United States. 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 current or 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 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, patent applications, 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 certain aspects of the manufacture of our products and potential 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 formal 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 patents or future patents or patent applications 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" or "cGTP"), labeling, record keeping, adverse-reaction reporting, inspection, and enforcement.

We believe SkinTE is appropriately regulated solely under Section 361 of the Public Health Service Act and Part 1271 of Title 21 of the Code of Federal Regulations (i.e., as a so-called "361 HCT/P") and that, as a result, no premarket review or approval by the FDA is required. If the FDA does not agree that SkinTE meets its regulatory criteria for regulation as a 361 HCT/P, it will be regulated as a drug, device, or biological product, and we could be required to withdraw SkinTE from the market until the required clinical trials are complete and the applicable premarket regulatory clearances or approvals are obtained. Manufacturers of new drugs, biologics, and some medical devices must complete extensive clinical trials, which must be conducted pursuant to an effective IND. In addition, the FDA must review and approve a BLA or NDA before a new drug or biologic may be marketed.

A determination by the FDA that SkinTE is not a 361 HCT/P would negatively impact our commercialization of the product and substantially increase the cost to us of regulatory compliance, all of which would adversely affect our results of operations and financial condition. This same risk applies to any other product we may develop that we believe should be regulated as a 361 HCT/P.

Some of the future new products and enhancements of existing products that we expect to develop and market may not be 361 HCT/Ps, and may require premarket approval or clearance from the FDA. As a result, those product candidates would be subject to additional regulatory requirements, including premarket approval or clearance. There can be no assurance, however, that approval or clearance will be granted with respect to any such products or enhancements of existing products. Such products or enhancements may encounter significant delays during FDA's premarket review process that would adversely affect our ability to market such products or enhancements.

Even if premarket approval or clearance are obtained from the FDA, the approvals or clearances may contain substantial limitations on the indicated uses of such products and other uses may be prohibited. Product approvals by the FDA can also be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval. Furthermore, the FDA could limit or prevent the distribution of products, and the FDA has the power to require the recall of such products. FDA regulations depend heavily on administrative interpretation, and there can be no assurance that future interpretations made by the FDA or other regulatory bodies will not adversely affect our operations. 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 initiate or take enforcement action, including, without limitation, any of the following actions or 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;
- Orders to recall or destroy products.
- 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.

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 compliance, with respect to our 361 HCT/P products. To the extent that future products we develop or enhancements of existing products we develop are not regulated as 361 HCT/Ps, we will be subject to regulation under cGMP with respect to any such product candidates that are not 361 HCT/Ps. Complying with cGTP or cGMP 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 premarket approval or clearance, we must also pass a pre-approval inspection prior to FDA approval or clearance. Failure to pass a pre-approval inspection may significantly delay FDA approval or clearance of our product candidates. If we fail to comply with these requirements, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our product candidates. As a result, our business, financial condition, and results of operations may be materially harmed.

The manufacture of cell and tissue-based therapy products, 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, either ourselves or through third-party contractors with whom we may enter strategic relationships. 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 necessary 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.

Even if the FDA regulates SkinTE as 361 HCT/P, 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 we may not need to submit SkinTE 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 clinical use, case studies, 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 products, including SkinTE, the FTC or one or more states conclude that we lack adequate substantiation for our claims, we may be subject to significant penalties, or may be forced to alter our marketing approach in one or more jurisdictions. Any of this could materially harm our business.

Even if SkinTE meets the criteria for a 361 HCT/P, it will be subject to ongoing regulation. We could be subject to significant penalties if we fail to comply with these requirements, which would adversely affect our results of operations.

Even if SkinTE meets the criteria for a 361 HCT/P, we are still subject to numerous post-market requirements, including those related to registration and listing, record keeping, labeling, cGTP, donor eligibility, deviation and adverse event reporting, and other activities. HCT/Ps that do not meet the definition of a 361 HCT/P 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 delays in distribution and sales of our product, 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.

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 there are 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 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 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, as well as potential exclusion from federal healthcare programs (including Medicare and Medicaid). 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, in order to settle allegations of FCA violations, 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.

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 the U.S. Department of Health and Human Services 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 that 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.

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 12-month period ended February 29, 2020, with closing stock prices ranging from a high of $16.43 per share to a low of $1.35 per share. The stock market in general, and the market for biotech companies in particular, have experienced extreme volatility that, at times, has 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:

- our ability to develop and commercialize our lead product candidate, SkinTE;
- results and timing of our clinical trials;
- failure or discontinuation of any of our development programs;
- issues in manufacturing our product candidates or future approved products;
- issues in designing or constructing our commercial manufacturing facilities;
- regulatory developments or enforcement in the United States and foreign countries with respect to our product candidates or our competitors' products;
- competition from existing products or new products that may emerge;
- developments or disputes concerning patents, patent applications, or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- public concern over our product candidates or any future approved products;
- threatened or actual litigation;
- future or anticipated sales of our common stock;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key personnel;
- changes in the structure of health care payment systems in the United States or overseas;
- failure of any of our products or product candidates to perform safely or effectively or achieve commercial success;
- economic and other external factors or other disasters or crises;
- period-to-period fluctuations in our financial condition and results of operations;
- general market conditions and market conditions for biopharmaceutical stocks; and
- overall fluctuations in U.S. equity markets.

In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. Defending such litigation could result in substantial defense costs and divert the time and attention of our management, which could seriously harm our business. As discussed above under "Item 3. Legal Proceedings," we are currently in the early stages of a stockholder class action lawsuit and, to the extent we incur substantial costs to defend or resolve that lawsuit, our ability to fund our business will be diminished, which would adversely affect our operations and financial condition.

We are the subject of an SEC investigation, which could result in litigation, government investigations and enforcement actions that could have a material adverse impact on our operations and financial condition.

On September 7, 2018, the SEC filed a complaint in the U.S. District Court for the Southern District of New York (SEC v. Honig et al., No. 1:18-cv-01875 (S.D.N.Y. 2018)) alleging that certain persons, including John Stetson, our former Chief Financial Officer and Chief Investment Officer, Barry Honig, who is also a current 5% shareholder of the Company, and Michael Brauser, who is also a current 5% shareholder of the Company, manipulated the price of securities of three public companies (none of which is PolarityTE). This complaint, which was amended on March 8, 2019 (as amended, the "Complaint"), alleges that the defendants violated the anti-fraud and other provisions of the Securities Act, the Exchange Act and SEC rules promulgated thereunder by writing, or causing to be written, false or misleading promotional articles, engaging in a variety of other manipulative trading practices as well as filing false reports of their beneficial ownership or failure to file reports of their beneficial ownership when required to do so.

In October 2018, we received a document request and inquiries from the SEC relating to subjects addressed in the short seller reports and cooperated fully by providing the SEC with all information relevant to their requests. On March 1, 2019, we received a subpoena from the SEC requesting additional documents related to, among other things, (i) communications and agreements between us and, among others, John Stetson, Barry Honig and Michael Brauser, (ii) the transaction pursuant to which Majesco Entertainment Company acquired PolarityTE NV and our current regenerative medicine business, (iii) the performance of and communications with regulators regarding SkinTE, our lead product, and (iv) any promotion of the Company or its securities. On March 4, 2019, we obtained from the SEC a copy of the formal order of investigation of the Company and its affiliates with respect to possible violations of the federal securities laws, including, among other things, the anti-fraud provisions of the Securities Act and the Exchange Act with respect to the Company's public disclosures, the beneficial ownership reporting provisions of the Exchange Act and the anti-price manipulation provisions of the Exchange Act. We intend to fully cooperate with the SEC regarding their March 2019 subpoena and this ongoing investigation. Since March 2019, we have received four additional subpoenas seeking documents on these and other topics. The documents and information requested in the subpoenas include materials concerning (i) the circumstances under which the Company placed Denver Lough, former Chief Executive Officer, and Naveen Krishnan, former Vice President of Analytics, on paid administrative leave, (ii) termination and separation agreements with former employees, and (iii) certain commercialization metrics included in Company disclosures. We have already provided a substantial amount of documents and information to the SEC in response to these requests and expect to make additional productions in response to the subpoenas. We met with the SEC on February 11, 2020, to review the status of the investigation and completion of the document production.

As a result of the SEC investigation, we could be subject to additional stockholder litigation, government inquiries or enforcement actions that could name us, our affiliates, or others. While we will not tolerate stock manipulation and will continue to report suspected wrongdoing to authorities, we cannot predict whether any of these will arise or, if they do, the possible outcomes. Stockholder litigation, government inquiries or enforcement actions could adversely affect our reputation, result in significant expenditures, including legal expenses, and potentially result in significant fines, penalties or other remedies against us, which could have a material adverse effect on our results of operations and financial condition. Although we maintain insurance that may provide coverage for some of these expenses and costs, and we have given notice to our insurers of the claims, there is risk that the insurers will rescind or otherwise not renew the policies, that some or all of the claims will not be covered by such policies, or that, even if covered, our ultimate liability will exceed the available insurance.

Our stock price may also be negatively affected by the SEC investigation, any negative press or other coverage we receive as a result thereof and the uncertainty surrounding the result of any of these developments, which could adversely affect our ability to raise capital to fund future operations, result in the loss of potential business opportunities, be exploited by our competitors, undermine the confidence that hospitals and doctors, key potential adopters of our products, have in us and our technology, cause concern to our current or potential customers, and make it more difficult to attract and retain qualified personnel and business partners, any of which would materially harm our financial condition, results of operations and prospects. We expect management will continue to devote significant time, attention and resources to these matters and any additional matters that may arise, which could have a material adverse impact on our commercial development, results of operations and financial condition.

Future sales of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. In addition, certain future sales of our equity securities may trigger a downward adjustment in the exercise price of 10,638,298 common stock purchase warrants we issued in February 2020 with an original exercise price of $2.80 per share, which could apply additional pressure to depress the market price of our common stock because of the lower warrant exercise price. As of March 6, 2020, we had 38,358,450 shares of common stock outstanding, all of which, other than shares held by our directors and certain officers and affiliates, were eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including the volume limitations and manner of sale requirements. As of December 31, 2019, we also had a significant number of securities convertible into, or allowing the purchase of, our common stock, including 4,529,988 options and rights to acquire shares of our common stock that are outstanding under our equity incentive plans, and 5,353,257 shares of common stock reserved for future issuance under our equity incentive plans, including our 2020 Stock Option and Incentive Plan. Pursuant to a Purchase Agreement that we have entered with Keystone Capital Partners, LLC (“Keystone”), Keystone has agreed to purchase up to $25.0 million of shares of our common stock, subject to certain limitations, at our direction from time to time during the 36-month term of the Purchase Agreement. As of February 29, 2020, we have sold 270,502 shares of our common stock under the Purchase Agreement generating total gross proceeds of $725,000 and have up to $24,275,000 available for future sale under the Purchase Agreement.

Our Restated Certificate of Incorporation, our Restated Bylaws, our Rights Agreement 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.

We also entered into a rights agreement (the "Rights Agreement"), dated as of November 7, 2019, with Equity Stock Transfer, LLC, as rights agent. Generally, the Rights Agreement works by imposing a significant penalty upon any person or group (including a group of persons that are acting in concert with each other) that acquires 10% or more (or 20% or more in the case of a "Passive Institutional Investor," as defined in the Rights Agreement) of our common stock without the approval of the Board. As a result, the overall effect of the Rights Agreement may be to render more difficult or discourage a tender or exchange offer or other acquisition of our common stock that is not approved by the Board. The Rights Agreement could reduce the price that stockholders might be willing to pay for shares of our common stock in the future. Furthermore, the anti-takeover provisions of the Rights Agreement may make it more difficult to replace management even if the stockholders consider it beneficial to do so. The Rights Agreement does not prevent the Board from considering any offer that it considers to be in the best interest of its stockholders.

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.

Because we do not expect to declare cash dividends on our common stock in the foreseeable future, stockholders must rely on appreciation of the value of our common stock for any return on their investment.

While we have in the past declared and paid cash dividends on our capital stock, we currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not expect to declare or pay any additional cash dividends in the foreseeable future. As a result, only appreciation of the price of our common stock, if any, will provide a return to investors in this offering.

A material weakness in our 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," below, we have identified a material weakness in our internal control over financial reporting through our evaluation of our controls at December 31, 2019. In 2019 we failed to execute controls relating to reconciliation procedures. In addition, we did not have a sufficient level of precision in our review procedures to detect potentially material errors in accrual and related accounts.

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.

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.

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.

Item 3. Legal Proceedings.

Shareholder Litigation

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. On January 16, 2019, the Court granted the motion of Yedid Lawi for appointment as lead plaintiff, and on February 1, 2019, the Court granted the lead plaintiff's motion for approval of lead counsel and liaison counsel. The Court also ordered that the lead plaintiff file and serve a consolidated complaint no later than 60 days after February 1, 2019. The Lead Plaintiff filed a consolidated complaint on Aril 2, 2019, and asserted essentially the same violations of Federal securities laws recited in the original complaints. The Company filed a motion to dismiss the consolidated complaint on June 3, 2019. Plaintiffs' opposition to the Company's motion to dismiss was filed on August 2, 2019, and the Company filed a reply to the opposition on September 13, 2019. A hearing on the Company's motion to dismiss was held on November 19, 2019; no order has been issued to date. 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.

Other Matters

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, employment, regulatory compliance, and other matters. Except as noted above, at December 31, 2019, 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."

At February 29, 2020, there were approximately 111 holders of record of our common stock.

Information regarding our equity compensation plans as of December 31, 2019, is disclosed in Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" of this Annual Report on Form 10-K.

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

On January 11, 2019, the Board of Directors (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. We made this change to align our fiscal year end with other companies within our industry. Information contained in this section covers the reporting periods for the year ended December 31, 2019, the two-month period ended December 31, 2018, and the fiscal year ended October 31, 2018.

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 advanced the commercialization of SkinTE, our first commercial product, by expanding the sales team, pursuing clinical studies of SkinTE, and working on the development of Skin TE Cryo, SkinTE POC, and PTE 11000. The commercial launch of SkinTE in 2018 included the build out of commercial, manufacturing, and corporate structure to support SkinTE manufacturing and distribution. This includes equipment, personnel, systems, and leased properties.

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 $1.2 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. We offer research services to unrelated third parties on a contract basis through our subsidiary, Arches Research. We also use these facilities to advance our own research and development projects. Contract research services help us defray the costs of maintaining a research facility.

Revenue Recognition

In the regenerative medicine products segment, we record product revenues primarily from the sale of its regenerative tissue products. We sell our products to healthcare providers, primarily through direct sales representatives. Product revenues consist of a single performance obligation that we satisfy at a point in time. In general, we recognize product revenue upon delivery to the customer. In the contract services segment, we earn service revenues from the provision of contract research services, which includes delivery of preclinical studies and other research services to unrelated third parties. Service revenues generally consist of a single performance obligation that we satisfy over time using an input method based on costs incurred to date relative to the total costs expected to be required to satisfy the performance obligation.

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, clinical trial costs, 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.

Sales and Marketing Expenses

Sales and marketing expenses primarily represent employee related costs, including stock compensation for sales and marketing executives and staff, marketing and advertising expenses, trade shows and other promotional costs, and other related charges.

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.

Leases

On January 1, 2019 the Company adopted ASU 2016-02, *Leases (ASC 842)* and related amendments, which require lease assets and liabilities to be recorded on the balance sheet for leases with terms greater than twelve months. 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. The standard was adopted using the modified retrospective transition approach by applying the new standard to all leases existing at the date of the initial application and not restating comparative periods. The most significant impact was the recognition of ROU assets and lease liabilities for operating leases, while our accounting for finance leases remained substantially unchanged. See Note 2 – Summary of Significant Accounting Policies and Note 8 – Leases in the notes to the consolidated financial statements included in this Annual Report for additional information regarding the adoption.

Results of Operations
Comparison of the year ended December 31, 2019 compared to the year ended December 31, 2018.

We changed our fiscal year end from October 31 to December 31 effective December 31, 2018. Accordingly, the following presentation and discussion of the results of operations for the year ended December 31, 2019, which has been audited, will be compared to the unaudited results of operations for the year end December 31, 2018 to allow comparable year-over-year analysis and discussion of results of operation.

	For the Year Ended		Increase (Decrease)	
(in thousands)	December 31, 2019	December 31, 2018 (Unaudited)	Amount	%
Net revenues				
Products	$ 2,353	$ 886	$ 1,467	166%
Services	3,299	1,337	1,962	147%
Total net revenues	5,652	2,223	3,429	154%
Cost of sales				
Products	1,365	693	672	97%
Services	1,114	689	425	62%
Total cost of sales	2,479	1,382	1,097	79%
Gross profit	3,173	841	2,332	277%
Operating costs and expenses				
Research and development	16,397	17,904	(1,507)	(8)%
General and administrative	63,189	52,912	10,277	19%
Sales and marketing	16,980	5,090	11,890	234%
Total operating costs and expenses	96,566	75,906	20,660	27%
Operating loss	(93,393)	(75,065)	(18,328)	24%
Other income (expense)				
Interest income, net	151	457	(306)	*
Other income, net	749	32	717	*
Change in fair value of derivative	-	1,850	(1,850)	*
Loss on extinguishment of warrant liability	-	(520)	520	*
Net loss before income taxes	(92,493)	(73,246)	(19,247)	26%
Benefit for income taxes	-	302	(302)	*
Net loss	$ (92,493)	$ (72,944)	$ (19,549)	27%

***Not meaningful**

Net Revenues

During the year ended December 31, 2019, we recorded net revenues of $5.65 million, which represents an increase of $3.43 million from the $2.22 million of net revenues recorded during the year ended December 31, 2018. The $3.43 million year-over-year increase in net revenues was due primarily to increased revenues in both our regenerative medicine products and contract services operating segments.

Net revenues from regenerative medicine products increased by 166% from $0.89 million in 2018 to $2.35 million for the year ended December 31, 2019. The increase is attributable primarily to the fact we started our effort to gain meaningful market penetration for SkinTE in the fourth calendar quarter of 2018, and we were pursuing and expanding the marketing effort throughout 2019.

Net revenues from contract services increased by 147% from $1.34 million in 2018 to $3.30 million for the year ended December 31, 2019. The increase is attributable primarily to organic growth arising from what we believe is a growing recognition of the research capabilities of our contract services group within the biotechnology industry.

Gross Profit

Gross profit increased by a higher percentage than net revenues period over period from $0.84 million in 2018 to $3.17 million for 2019, or an increase in gross profit of 277%. We believe this is a result of built-in production capacity for both our goods and services that allows us to sell more of each at a lower incremental cost. While net revenues from regenerative medicine products increased by 166% year over year, cost of sales increased only 97%. Similarly, net contract services increased by 147% year over year and cost of sales increased only 62%.

Research and Development

During the year ended December 31, 2019, we recorded research and development expenses totaling approximately $16.40 million, which represents a decrease of $1.51 million, or 8%, from $17.90 million of research and development expenses in 2018. There was a reduction in staff in research and development that reduced compensation and benefits costs by $2.51 million, and this reduction was partially offset by an increase in clinical trial costs of $0.96 million.

General and Administrative Expenses

For the year ended December 31, 2019, general and administrative expenses totaled $63.19 million, which represents an increase of $10.28 million as compared to $52.91 million of general and administrative expenses incurred during the year ended December 31, 2018. Compensation and benefit costs increased $4.05 million, which was primarily due to an increase in employees added to support our SkinTE commercialization effort and a one-time severance expense of $3.76 million recognized under the separation agreement with our former chief executive officer. Asset disposals increased by $0.93 million. Legal fees increased by $2.48 million due to the costs of responding to SEC subpoenas and resolving the employment situation with our former chief executive officer, so we expect that much of this added legal expense in 2019 will not recur in 2020. Depreciation expense increased by $1.18 million as a result of significant equipment purchases in 2018.

Sales and Marketing

For the year ended December 31, 2019, sales and marketing expenses totaled $16.98 million, which represents an increase of $11.89 million as compared to $5.09 million of sales and marketing expenses incurred during the year ended December 31, 2018. The increase is attributable primarily to the fact that we started our effort to gain meaningful market penetration for SkinTE in the fourth calendar quarter of 2018, and we were pursuing and expanding the marketing effort throughout 2019. As a result, we added approximately $6.09 million of compensation and benefit cost to our selling and marketing expense in 2019 for our sales team. Costs related to our marketing efforts for travel, recruiting, and training increased by $1.43 million for 2019 compared to 2018. Also, in 2019 external marketing costs, including trade shows, consulting fees, and promotional costs increased $4.27 million in 2019 compared to 2018. We plan to continue expanding our sales effort, so we expect selling and marketing expense will increase in future periods.

Comparison of the two- month period ended December 31, 2018 compared to the two-month period ended December 31, 2017 (unaudited).

Net Revenues

For the two-month period ended December 31, 2018, total net revenues were $0.7 million including net revenues from products sales of $0.2 million from the sale of the Company's core product SkinTE in the regenerative medicine business segment. Regenerative medicine revenues for the two-month period ended December 31, 2017 were immaterial. Net revenues from services were $0.5 million from the contract research segment operations driven primarily by the IBEX preclinical research business, which was acquired in the 2018 fiscal year.

Cost of Sales

For the two-month period ended December 31, 2018, cost of sales was approximately $0.4 million and approximately 57% of net revenues. Products cost of sales were $0.2 million or 92% of products sales due to fixed overhead costs. Services cost of sales were $0.2 million or 40% of service sales. Regenerative medicine cost of sales for the two-month period ended December 31, 2017 were immaterial.

Research and Development Expenses

Research and development expenses decreased $1.5 million, or 30%, in the two-month period ended December 31, 2018, compared to the two-month period ended December 31, 2017. The decrease is primarily driven by a shift in mix between commercial and operational infrastructure build out in the current period, as well as research and development costs in the prior period.

General and Administrative Expenses

General and administrative expenses increased $4.7 million, or 58%, in the two-month period ended December 31, 2018 compared to the two-month period ended December 31, 2017. The Company expanded its infrastructure to support the commercial launch of SkinTE. 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 two-month period ended December 31, 2018, sales and marketing expenses were $2.7 million. This represents sales personnel and marketing costs primarily driven by the initial regional release of SkinTE. There were no sales personnel and marketing costs during the two-month period ended December 31, 2017.

Other (Expenses) Income

For the two-month period ended December 31, 2018, other (expenses) income decreased $1.9 million or 95% compared to the two-month period ended December 31, 2017. This resulting decrease was primarily driven by a change in the fair value of derivatives of $2.0 million recorded in the two months ended December 31, 2017. There were no warrants outstanding for the two-month period ended December 31, 2018.

Net Loss

Net loss for the two-month period ended December 31, 2018 was approximately $18.4 million compared to a net loss of approximately $11.0 million for the two-month period ended December 31, 2017, primarily reflecting the increase in sales and operating expenses driven by expanding operations discussed above.

Liquidity and Capital Resources

As of December 31, 2019, our cash and cash equivalents and short-term investments totaled $29.24 million and our working capital was approximately $22.43 million, compared to cash and cash equivalents and short-term investments of $61.84 million and working capital of $56.79 million at December 31, 2018. Our accumulated deficit at December 31, 2019, was approximately $435.36 million.

On February 14, 2020, we completed an underwritten offering of 10,638,298 shares of our common stock and warrants to purchase 10,638,298 shares of common stock. Each common share and warrant were sold together for a combined purchase price of $2.35. The exercise price of each warrant is $2.80 per share, were exercisable immediately, and will expire February 12, 2027. The net proceeds to the Company from the offering are estimated to be approximately $22.7 million, after estimated offering expenses payable by us.

We are party to an Equity Purchase Agreement dated as of December 5, 2019 (the "Purchase Agreement"), with Keystone Capital Partners, LLC ("Keystone"), pursuant to which Keystone has agreed to purchase from us up to $25.0 million of shares of our common stock, subject to certain limitations including a minimum purchase price of $2.00 per share, at our direction from time to time during the 36-month term of the Purchase Agreement. Concurrently, we entered into a Registration Rights Agreement with Keystone, pursuant to which we agreed to register the sales of our common stock pursuant to the Purchase Agreement under our existing shelf registration statement on Form S-3 or a new registration statement. During the period from the date of Purchase Agreement to the date of this filing, we have sold 270,502 shares of our common stock under the Purchase Agreement generating total gross proceeds of $725,000 and have up to $24,275,000 available for future sale under the Purchase Agreement. In connection with the underwritten offering described in the preceding paragraph, we agreed not to sell any additional shares under the Purchase Agreement for a period of 90 days after the closing date of the offering.

Based upon the current status of our product development and commercialization plans, we believe that our existing cash and cash equivalents, with planned operating cost reductions, will be adequate to satisfy our capital and operating needs for at least the next 12 months from the date of filing. This conclusion is based on our current capital resources, plans for commercialization of SkinTE, and plans for implementing operating cost reductions. We believe we may need additional financing to continue clinical deployment and commercialization of SkinTE and development of our other product candidates. 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, or effectuate substantial cost reductions in our commercial operations, or be unable to continue operations over a longer term. We plan to meet our future capital requirements primarily through issuances of equity securities, debt financing, revenue from product sales, or strategic partnership arrangements. 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 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.

The following table sets forth the primary sources and uses of cash for each period indicated:

(in thousands)	Year ended December 31, 2019	Two months ended December 31, 2018	Year ended October 31, 2018
Net cash provided by (used in)			
Operating activities	$ (56,648)	$ (7,999)	$ (28,546)
Investing activities	(15,617)	(7,021)	(11,419)
Financing activities	26,810	(268)	93,259
Net (decrease)/increase in cash and cash equivalents	$ (45,455)	$ (15,288)	$ 53,294

Cash used in operating activities

During the year ended December 31, 2019, net cash used in operating activities was $56.65 million, which was due to a net loss of $92.49 million mostly offset by the non-cash expenses of $31.40 million for stock compensation expense and $2.99 million for depreciation and amortization.

During the two-month period ended December 31, 2018, net cash used in operating activities was $8.00 million, which was due to a net loss of $18.42 million mostly offset by the non-cash expenses of $8.95 million for stock compensation expense and net cash changes in operating assets and liabilities of $1.0 million.

During the year ended October 31, 2018, net cash used in operating activities was $28.55 million, which was due to a net loss of $65.44 million mostly offset by the non-cash expenses of $38.82 million for stock compensation expense and $1.39 million for depreciation and amortization, and increased by a change in fair value of derivatives in the amount of $3.81 million.

Cash used in investing activities

During the year ended December 31, 2019, net cash used in investing activities was $15.62 million, which was due primarily to investments in available for sale securities offset by proceeds from the maturities and sales of such securities.

During the two-month period ended December 31, 2018, net cash used in investing activities was $7.02 million, which was due primarily to investments in available for sale securities offset by proceeds from the maturities of such securities.

During the year ended October 31, 2018, net cash used in investing activities was $11.42 million, which was due to the acquisition of IBEX and the purchase of other property and equipment.

Cash (used in) provided by financing activities

During the year ended December 31, 2019, net cash provided by financing activities was $26.81 million primarily from net proceeds received from sale of common stock.

During the two-month period ended December 31, 2018, net cash used in financing activities was $0.27 million, which was due to principal payments on term note payable and financing arrangements. There were no equity financing transactions during the period.

During the year ended October 31, 2018, net cash provided by financing activities was $93.26 million primarily from net proceeds received from sale of common stock.

Critical Accounting Policies and Estimates

For a description of our significant accounting policies, see note 2 to our consolidated financial statements.

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 is the extent of progress toward completion of contracts, 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.

Revenue Recognition

Revenue was recognized under ASC 605 for the year ended October 31, 2018. Under ASC 605, regenerative medicine revenue is recognized 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. In the contract services segment, revenue is recognized on the proportional performance method over the term of the service contract, which requires the Company 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 contract. As a result, unbilled receivables and deferred revenue are recognized based on payment timing and work completed.

Revenue was recognized under ASC 606 for the year ended December 31, 2019 and the two months ended December 31, 2018. Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

In the regenerative medicine products segment, the Company records product revenues primarily from the sale of its regenerative tissue products. The Company sells its products to healthcare providers, primarily through direct sales representatives. Product revenues consist of a single performance obligation that the Company satisfies at a point in time. In general, the Company recognizes product revenue upon delivery to the customer.

In the contract services segment, the Company records service revenues from the sale of its contract research services, which includes delivery of preclinical studies and other research services to unrelated third parties. Service revenues generally consist of a single performance obligation that the Company satisfies over time using an input method based on costs incurred to date relative to the total costs expected to be required to satisfy the performance obligation. The Company believes that this method provides a faithful depiction of the transfer of services over the term of the performance obligation based on the remaining services needed to satisfy the obligation. This requires the Company to make reasonable estimates of the extent of progress toward completion of the contract. As a result, unbilled receivables and deferred revenue are recognized based on payment timing and work completed. Generally, a portion of the payment is due upfront and the remainder upon completion of the contract, with most contracts completing in less than a year. As of December 31, 2019 and 2018, the Company had unbilled receivables of $0.1 million and $0.2 million, respectively, and deferred revenue of $0.1 million and $0.2 million, respectively. The unbilled receivables balance is included in consolidated accounts receivable. Revenue of $0.2 million was recognized during the year ended December 31, 2019 that was included in the deferred revenue balance as of December 31, 2018.

Costs to obtain the contract are incurred for product revenue as they are shipped and are expensed as incurred.

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 using a fair value method and records such expense in research and development, general and administrative, and sales and marketing expenses. Compensation Expense for stock options with graded vesting is recognized 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 fair 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.

Leases

The Company determines if an arrangement is a lease at inception. Right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Finance leases are reported in the consolidated balance sheet in property and equipment and other current and long-term liabilities. The short-term portion of operating lease obligations are included in other current liabilities. The classification of the Company's leases as operating or finance leases along with the initial measurement and recognition of the associated ROU assets and lease liabilities is performed at the lease commencement date. The measurement of lease liabilities is based on the present value of future lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future lease payments. The ROU asset is based on the measurement of the lease liability and also includes any lease payments made prior to or on lease commencement and excludes lease incentives and initial direct costs incurred, as applicable. The lease terms may include options to extend or terminate the lease when it is reasonably certain the Company will exercise any such options. Rent expense for the Company's operating leases is recognized on a straight-line basis over the lease term. Amortization expense for the ROU asset associated with its finance leases is recognized on a straight-line basis over the term of the lease and interest expense associated with its finance leases is recognized on the balance of the lease liability using the effective interest method based on the estimated incremental borrowing rate.

The Company has lease agreements with lease and non-lease components. As allowed under ASC 842, the Company has elected not to separate lease and non-lease components for any leases involving real estate and office equipment classes of assets and, as a result, accounts for the lease and nonlease components as a single lease component. The Company has also elected not to apply the recognition requirement of ASC 842 to leases with a term of 12 months or less for all classes of assets.

Accruals for Research and Development Expenses and Clinical Trials

As part of the process of preparing its financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment terms that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the timing of various aspects of the expenses. The Company determines accrual estimates by taking into account discussion with applicable personnel and outside service providers as to the progress of clinical trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period.

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. There were no impairments of long-lived assets for any of the periods presented.

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 President, Chief Operating 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 December 31, 2019, our President, Chief Operating Officer, and Chief Financial Officer concluded that, as of such date, were not effective due to the material weakness identified below. To address the material weakness, 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 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.

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 December 31, 2019. 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 December 31, 2019.

A material weakness is a deficiency, or a combination of deficiencies, within the meaning of Public Company Accounting Oversight Board ("PCAOB") Audit Standard No. 5, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Management has identified the following material weakness, which has caused management to conclude that as of December 31, 2019 our internal control over financial reporting was not effective at the reasonable assurance level:

In 2019 we failed to execute controls relating to reconciliation procedures. In addition, we did not have a sufficient level of precision in our review procedures to detect potentially material errors in accrual and related accounts.

EisnerAmper, LLP has provided an attestation report on the Company's internal control over financial reporting as of December 31, 2019.

Changes in Internal Control over Financial Reporting

With respect to failure in execution of controls relating to reconciliation procedures identified as a material weakness, above, the material weakness was identified in the course of management's assessment of internal controls as of December 31, 2019, so no remedial action was taken in the fourth quarter of 2019. Management plans on evaluating its reconciliation procedures with the expectation it will implement a control to address the matter for the first quarter of 2020.

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 December 31, 2019, based on criteria established in the *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 weakness 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 December 31, 2019, based on criteria established in the *Internal Control - Integrated Framework* (*2013*) issued by COSO.

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 weakness has been identified and included in management's assessment.

> In 2019 the Company failed to execute controls relating to reconciliation procedures. In addition, the Company did not have a sufficient level of precision in its review procedures to detect potentially material errors in accrual and related accounts.

This material weakness was considered in determining the nature, timing, and extent of the audit tests applied in our audit of the December 31, 2019 financial statements, and this report does not affect our report dated March 12, 2020, 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 December 31, 2019 and 2018, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 2019, the transition period from November 1, 2018 through December 31, 2018, and the year ended October 31, 2018, and the related notes, and our report dated March 12, 2020 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
March 12, 2020

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Board of Directors

Our Board currently consists of six members and is divided into three classes. The term of office for the directors in each class is three years, and the term expirations of the three classes are staggered so that only one of the three classes of directors is up for election in each year. The following table sets forth the names, ages and class designation of all our directors.

Peter A. Cohen	73	Class III Director, Chairman
Jeff Dyer	61	Class I Director
Jon Mogford	51	Class I Director
Minnie Baylor-Henry	72	Class I Director
Willie C. Bogan	70	Class II Director
Rainer Erdtmann	56	Class III Director

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

Peter A. Cohen joined the Board in June 2018 and became Chairman of the Board in August 2019. Mr. Cohen has served as Vice Chairman of the Board and Lead Independent Director 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, and served as Chairman and Chief Executive Officer from 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, as a result of a business combination, is now known as Tempus Applied Solutions Holdings, Inc.) from 2013 to 2015. 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.

Jeff Dyer was appointed to our Board 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 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.

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.

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 (which relocated its headquarters to Las Colinas, TX in 2019) currently ranked 7th 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.

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.

Executive Officers

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

David Seaburg	President (1)
Richard Hague	Chief Operating Officer (1)
Paul E. Mann	Chief Financial Officer (1)
Cameron Hoyler	General Counsel, Secretary, EVP Corporate Development & Strategy

(1) Effective May 31, 2019, the Board established the Office of the Chief Executive, consisting of the President, Chief Operating Officer, and Chief Financial Officer to function as a team to advance our business objectives.

The following is a summary of the background of each of our executive officers.

David Seaburg, age 50, has served as President of the Company since August 2019. Prior to becoming President, he served as President of Corporate Development for the Company beginning in March 2019. From August 2018 to March 2019, he provided consulting services to the Company. He served as a director on our Board from August 2018 to August 2019. During the four-year period prior to March 11, 2019, he served as the 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 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 was a CNBC Fast Money Contributor and provided regular on-air commentary for the network. Mr. Seaburg holds a Bachelor of Arts degree in Business Finance and Economics from Northeastern University.

Richard Hague, age 59, served as the Chief Commercial Officer of Anika Therapeutics, Inc., from October 2015 to April 2019, when he joined PolarityTE as Chief Operating Officer. From November 2014 to October 2015, Mr. Hague was the Vice President Sales and Marketing at TEI Medical where he was responsible for driving the revenue growth of that corporation's dermal scaffold product, as well as for the build out of its sales and marketing teams. From 2011 through 2014, Mr. Hague was Vice President Sales, Marketing, and Commercial Operations for Sanofi Biosurgery's Cell Therapy and Regenerative Medicine group. In this role, Mr. Hague was responsible for the global commercial operations of the group's products in the orthopedic sports medicine and burn markets. Prior to this, Mr. Hague was the Senior Director and Head of Sales for Genzyme Biosurgery where he headed the U.S. sales team in the orthopedics and sports medicine market. Mr. Hague holds a B.S. in marketing from the University of Connecticut.

Paul E. Mann, age 44, served as the Healthcare Portfolio Manager for Highbridge Capital Management from August 2016 until he joined the PolarityTE 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, age 36, 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.

Delinquent Section 16(a) Reports

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: Cameron Hoyler filed one report on Form 4 one day late, and Peter Cohen, Jeffrey Dyer, and Willie Bogan each failed to file a Form 4 reporting the vesting of restricted stock units, which was subsequently reported by each of them in a Form 5 filing.

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 "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 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 has a standing Audit Committee. The Board 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 are Rainer Erdtmann, Peter A. Cohen, and Jeff Dyer. The Board has determined that Rainer Erdtmann 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 fiscal year ended December 31, 2019, the two-month period ended December 31, 2018, and the 12-month period ended October 31, 2018. 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	Period (1)	Salary ($)	Bonus ($)	Stock Awards ($)(2)	Option Awards ($)(2)	All Other Compensation ($)	Total ($)
David Seaburg	2019	265,000(3)	-0-	1,864,248(3)	2,860,000	15,163(4)	5,004,411
President	2018	6,667(5)	-0-	-0-	-0-	-0-	6,667
	2018	9,238(5)	-0-	1,347,600(6)	-0-	-0-	1,356,838
Richard Hague	2019	273,231(7)	30,000(8)	1,745,047(7)	501,123	74,306(9)	2,623,707
Chief Operating Officer							
Paul E. Mann	2019	401,538(10)	-0-	1,412,428(10)	-0-	4,938	1,818,904
Chief Financial Officer	2018	66,667	-0-	-0-	-0-		66,667
	2018	133,846	75,666	3,971,124	9,682,330		13,862,967
Denver Lough	2019	346,538	-0-	766,000(11)	-0-	3,008,443(11)	4,120,981
Former Chief Executive	2018	88,333	-0-	-0-	-0-		88,333
Officer	2018	448,462	1,010,000	2,395,050	9,860,825		13,714,337

(1) For each person listed the top row is the compensation for the 12-month period ended December 31, 2019, the middle row is the compensation for the two-month period ended December 31, 2018, and the bottom row is the compensation for the 12-month period ended October 31, 2018. Richard Hague joined us in April 2019, so there is no compensation to report for prior periods.

(2) The figures in these columns represent the aggregate grant date fair value for restricted stock and option awards, respectively, granted during the reported periods computed in accordance with FASB ASC Topic 718. See Note 13 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.

(3) Effective July 1, 2019, Mr. Seaburg agreed to reduce his salary from an annual base salary of $325,000 to an annual base salary of $162,500 for a two-year period ending June 30, 2021. (See the discussion under the "Narrative Disclosure to Compensation Table," below.) In exchange for the reduction in salary Mr. Seaburg was granted 114,305 shares of common stock restricted from transfer by reference to continued employment by the Company, and the restriction on transfer lapses with respect to 38,012 shares in March 2020 and the remainder in quarterly installments through June 2021. The salary figure includes $82,500 for the salary that Mr. Seaburg agreed to forego for 2019 in exchange for restricted shares of common stock. Mr. Seaburg will forego an additional $162,500 in 2020 and $80,000 in 2021. The grant date fair value of the restricted stock granted to Mr. Seaburg was $638,596, so the difference between that value and the total amount of salary he agreed to forego over two years is $313,596. The figure in the Stock Awards column of the table includes the total grant date fair value of the restricted shares granted for salary less the $82,500 of salary that Mr. Seaburg agreed to forego in 2019. The salary amount also includes $9,713 of consulting fees paid to Mr. Seaburg prior to his employment on a full-time basis in March 2019.

(4) This figure includes $15,163 of rental fees we pay for an apartment Mr. Seaburg uses in Salt Lake City.

(5) These amounts are consulting fees we paid to Mr. Seaburg under a consulting agreement we agreed to in August 2018.

(6) This is figure is the grant date fair value of 60,000 restricted shares granted to Mr. Seaburg in August 2018 under our consulting agreement with him. When Mr. Seaburg joined us as a full-time employee, the forfeiture restrictions on 15,000 shares with a value of $336,900 had lapsed and were retained by Mr. Seaburg, and the remaining 45,000 restricted shares were forfeited.

(7) Effective July 1, 2019, Mr. Hague agreed to reduce his salary from an annual base salary of $370,000 to an annual base salary of $185,000 for a two-year period ending June 30, 2021. (See the discussion under the "Narrative Disclosure to Compensation Table," below.) In exchange for the reduction in salary Mr. Hague was granted 129,825 shares of common stock restricted from transfer by reference to continued employment by the Company, and the restriction on transfer lapsed with respect to 21,638 shares in 2019 and will lapse on the remaining shares in quarterly installments from March 2020 through June 2021. The salary figure includes $93,923 for the salary that Mr. Hague agreed to forego for 2019 in exchange for restricted shares of common stock. Mr. Hague will forego an additional $185,000 in 2020 and $91,077 in 2021. The grant date fair value of the restricted stock granted to Mr. Hague was $727,020, so the difference between that value and the total amount of salary he agreed to forego over two years is $357,020. The figure in the Stock Awards column of the table includes the total grant date fair value of the restricted shares granted for salary less the $93,923 of salary Mr. Hague agreed to forego in 2019.
(8) We agreed to pay Mr. Hague a signing bonus of $30,000.
(9) This figure includes $74,268 of relocation expenses we agreed to pay for Mr. Hague.
(10) Effective July 1, 2019, Mr. Mann agreed to reduce his salary from an annual base salary of $400,000 to an annual base salary of $200,000 for a two-year period ending June 30, 2021. (See the discussion under the "Narrative Disclosure to Compensation Table," below.) In exchange for the reduction in salary Mr. Mann was granted 140,351 shares of common stock restricted from transfer by reference to continued employment by the Company, and the restriction on transfer lapses with respect to 52,631 shares in March 2020 and the remainder in quarterly installments through June 2021. The salary figure includes $101,538 for the salary that Mr. Mann agreed to forego for 2019 in exchange for restricted shares of common stock. Mr. Mann will forego an additional $200,000 in 2020 and $98,462 in 2021. The grant date fair value of the restricted stock granted to Mr. Mann was $785,966, so the difference between that value and the total amount of salary he agreed to forego over two years is $385,966. The figure in the Stock Awards column of the table includes the total grant date fair value of the restricted shares granted for salary less the $101,538 of salary that Mr. Mann agreed to forego in 2019.
(11) On August 21, 2019, we reached a settlement with Dr. Denver Lough in connection with the end of his employment with us. The figure under the Stock Awards column of the table is the grant date fair value of 200,000 shares granted as stock awards in the settlement, which are issuable in 18 monthly installments beginning October 1, 2019. The figure under the All Other Compensation column in the table includes $3,000,000 in cash we agreed to pay in the settlement, of which $1,500,000 was paid on October 1, 2019, and the remainder payable in 18 monthly installments beginning November 1, 2019.

Narrative Disclosure to Summary Compensation Table

David Seaburg's Employment Agreement

In August 2018 David Seaburg was elected by the Board to serve as a director of the Company. Subsequently the Company entered into a written consulting agreement with Mr. Seaburg pursuant to which he agreed to 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. The agreement terminated effective March 11, 2019, when he joined the Company as President of Corporate Development. In August 2019 he was elected President.

The new employment agreement with Mr. Seaburg was effective in March 2019, and was subsequently amended on June 28, 2019. The agreement has an initial term that expires on June 30, 2021, 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 30 days prior to the expiration of the current term. Mr. Seaburg's employment agreement provides for an annual base salary of $325,000 from inception to June 30, 2019, $162,500 from July 1, 2019, through June 30, 2021, and $325,000 for any renewal term after June 30, 2021. Mr. Seaburg is eligible for an annual bonus of up to 40% of his base salary as determined at the discretion of the Board. Mr. Seaburg was also granted under the Company's 2019 Equity Incentive Plan an option to purchase 250,000 shares of Company common stock at a price of $16.50 per share, which vests subject to continued employment in 24 equal monthly installments beginning April 1, 2019, and a restricted stock award representing the right to receive a total of 40,000 shares of common stock that vests, subject to continued employment, in four installments every six months beginning on September 1, 2019. At the time his agreement was amended in June 2019, Mr. Seaburg was granted 114,305 shares of common stock restricted from transfer by reference to continued employment by the Company, and the restriction on transfer lapses with respect to 38,012 shares in March 2020 and the remainder in quarterly installments through June 2021. Mr. Seaburg is entitled to participate in the Company's insurance and benefit plans on the same basis as other employees of the Company.

Richard Hague's Employment Agreement

Richard Hague joined us as Chief Operating Officer in April 2019. The employment agreement with Mr. Hague was effective in April 2019 and subsequently amended on June 28, 2019. The agreement has an initial term that expires on June 30, 2021, 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 30 days prior to the expiration of the current term. Mr. Hague's employment agreement provides for an annual base salary of $370,000 from inception to June 30, 2019, $185,000 from July 1, 2019, through June 30, 2021, and $370,000 for any renewal term after June 30, 2021. Mr. Hague is eligible for an annual bonus as determined at the discretion of the Board, with a target of 50% of the base salary. The Company agreed to pay Mr. Hague a signing bonus of $30,000 in two equal installments on the effective date of the engagement and September 1, 2019. On the effective date of his engagement, Mr. Hague was granted under the Company's 2019 Equity Incentive Plan (a) an option to purchase 65,000 shares of Company common stock at an exercise price of $10.82 per share that vests subject to continued employment in 24 equal monthly installments beginning May 8, 2019, and (b) a restricted stock award representing the right to receive a total of 35,000 shares of common stock that vests, subject to continued employment, in four installments every six months beginning on October 8, 2019. At the time his agreement was amended in June 2019, Mr. Hague was granted 129,825 shares of common stock restricted from transfer by reference to continued employment by the Company, of which the restriction on transfer lapsed with respect to 21,638 shares in 2019 and will lapse on the remaining shares in quarterly installments from March 2020 through June 2021. Mr. Hague is entitled to participate in the Company's insurance and benefit plans on the same basis as other employees of the Company.

Paul E. Mann's Employment Agreement

We have a written employment agreement with Mr. Mann dated May 12, 2018, which was effective on June 20, 2018, and subsequently amended on June 28, 2019. The agreement has an initial term that expires on June 30, 2012, 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. Mr. Mann's employment agreement provides for an annual base salary of $400,000 from inception to June 30, 2019, $200,000 from July 1, 2019, through June 30, 2021, and $400,000 for any renewal term after June 30, 2021. He is eligible to receive a discretionary annual bonus up to 100% of his base salary as determined at the discretion of the Board. On the effective date of his engagement, Mr. Mann was granted under the Company's 2017 Equity Incentive Plan (a) an option to purchase 350,000 shares of Company common stock at an exercise price of $31.88 that vests subject to continued employment in 24 equal monthly installments beginning July 20, 2018, and (b) a restricted stock award representing the right to receive a total of 100,000 shares of common stock that vests, subject to continued employment, in four installments every six months beginning December 20, 2018. At the time his agreement was amended in June 2019, Mr. Mann was granted 140,351 shares of common stock restricted from transfer by reference to continued employment by the Company, and the restriction on transfer lapses with respect to 52,631 shares in March 2020 and the remainder in quarterly installments through June 2021.

Denver Lough's Employment Agreement

We had a written Employment Agreement with Denver Lough dated November 10, 2017 (the "Lough Agreement"), which was terminated on August 21, 2019. We paid Dr. Lough a bonus of $150,000 when we signed the Employment Agreement. Dr. Lough's base salary was $530,000 per year, and he was eligible to receive a bonus in the amount of 100% of annual salary, as may have been determined from time to time by the Board in its discretion, and was eligible to participate in any equity-based incentive compensation plan or program we adopted.

On August 12, 2019, we received from Dr. Lough a written demand claiming that actions taken by the Board to place him on administrative leave, and deprive him of the authority to grant salary raises to employees, approve capital expenditures, engage outside consultants or advisors, and supervise the legal department constituted the assignment of duties that were substantially different from, or that resulted in a substantial diminution of the duties originally assigned to him as Chief Executive Officer, giving him grounds to terminate for "good reason" the Lough Agreement and demanding the foregoing actions be rescinded within 30 days. On August 21, 2019, we reached a settlement resolving Dr. Lough's demand and his status, which included termination of the Employment Agreement on August 21, 2019, except for specific sections that survive termination, including sections pertaining to (i) non-disclosure of confidential information, (ii) non-competition and non-solicitation, and (iii) indemnification related to service to the Company. The following are the principal terms of the settlement agreement relating to his compensation:

- Dr. Lough will be paid $1,500,000 in cash on October 1, 2019 and paid an additional $1,500,000 payable in equal monthly installments beginning November 1, 2019 and ending April 1, 2021,
- All salary under the Employment Agreement ended as of the effective date of his resignation as an officer and director on August 26, 2019,
- We will award to Dr. Lough 200,000 restricted stock units that vest in 18 equal monthly installments beginning October 1, 2019,
- All restricted stock units and options to purchase common stock previously granted to Dr. Lough that were unvested on August 26, 2019, ceased to vest on that date, and
- Dr. Lough is entitled to receive a 5% participation payment on profits generated from commercial transactions (sales or licenses to third parties) associated with U.S. Patent Application No. 14/954,335 and PCT International Patent Application No. PCT/US2015/063114 on and following the final issuance by the USPTO of a United States Patent under U.S. Patent Application No. 14/954,335, all as determined pursuant to the terms and conditions in Section 6(B) of the EEA.

Dr. Lough has advised us that he believes the settlement between the parties includes an agreement to modify his equity awards previously granted under the Company's 2017 Equity Incentive Plan to accelerate vesting of all awards and extend the exercise period for the stock options to ten years from the original grant date. We advised Dr. Lough we do not agree that modification to his equity awards was included in the settlement or agreed to by the parties.

Potential Payments Upon Termination or Change-In-Control

Termination Payments

Under our employment agreements with Messrs. Seaburg and Hague we agreed to pay each of them their monthly base salary for a period of nine months following termination by us without "cause." Our obligation to make any such payments is subject to receiving from the executive a written release, in form and substance reasonably satisfactory to us, whereby the executive waives any and all claims the executive may have against PolarityTE and its affiliates.

Under the agreements, "cause" means any of the following, as determined by the Board in its reasonable judgment: (i) the commission by the executive of any felony (or any crime involving fraud or moral turpitude or otherwise having a material adverse effect on the Company or any of its affiliates); (ii) theft, conversion, embezzlement or misappropriation by the executive of funds or other assets of the Company or any of its affiliates or any other act involving fraud or dishonesty with respect to the Company (including acceptance of any bribes or kickbacks or other acts of self-dealing); (iii) intentional, grossly negligent or unlawful misconduct by the executive which causes harm to the Company or its affiliates or exposes the Company or its affiliates to a substantial risk of harm; (iv) the violation by the executive of any law regarding employment discrimination or sexual harassment as reasonably determined by the Board after a reasonable investigation into any allegation, charge or lawsuit (and not merely based solely on the existence of such allegation, charge or lawsuit); (v) the failure by Executive to comply with any material policy generally applicable to Company employees; (vi) Executive's repeated failure to follow the reasonable directives of the chief executive officer; (vii) the failure to devote full business time to the Company's affairs; (viii) any other material breach by the executive of the employment agreement or any other agreement or policy relating to employment with the Company or applicable to the executive (including the failure by the executive to devote adequate on-site time at the Company's principal offices); or (ix) the Company's discovery that, prior to the executive's employment, he engaged in any conduct prohibited by clauses (i) through (iv) immediately above.

Change in Control Plan

On August 6, 2019, the Board adopted a change in control compensation plan for our named executive officers and other senior executives. The plan provides that our executive officers that have been employed the Company for at least 90 days shall receive severance benefits upon the involuntary termination of their employment within six months after a change of control. A change in control occurs if, after the adoption of the plan: (i) any person (other than Denver Lough) acquires beneficial ownership of 30% or more of either the then-outstanding shares of our common stock, or the combined voting power of our then-outstanding voting securities entitled to vote generally in the election of directors; (ii) persons who currently constitute the Board cease for any reason to constitute at least a majority of the Board; or (iii) consummation of a reorganization, merger or consolidation, or sale or other disposition of all or substantially all of our assets, or our acquisition of assets or stock of another entity, in each case, unless, (a) all or substantially all of the individuals and entities who were the beneficial owners of either the outstanding shares of our common stock, or the combined voting power of our outstanding voting securities entitled to vote generally in the election of directors immediately prior to the transaction beneficially own, directly or indirectly, more than 80% of, respectively, our then-outstanding shares of common stock and the combined voting power of our then-outstanding voting securities entitled to vote generally in the election of directors, as the case may be, of the corporation resulting from the transaction, (b) no person beneficially owns, directly or indirectly, 50% or more of, respectively, the then-outstanding shares of common stock of the corporation resulting from the transaction, or the combined voting power of the then-outstanding voting securities of such corporation except to the extent that such ownership existed prior to the transaction, and (c) at least a majority of the members of the board of directors of the corporation resulting from the transaction were members of the Board at the time of the execution of the initial agreement, or of the action of the Board, providing for the transaction.

For any participant in the plan who is designated as the Chief Operating Officer (currently Richard Hague), President (currently David Seaburg), or Chief Financial Officer (currently Paul Mann), the plan provides for a payment equal to the sum of 1.5 multiplied by the greater of $400,000 or base annual salary, and 1.5 multiplied by the greater of $400,000 or the target bonus established in an annual executive target bonus plan in effect on the Termination Date. For any other participant, the plan provides for a payment equal to the sum of 1.0 multiplied by the greater of $350,000 or base annual salary, and 1.0 multiplied by the greater of $350,000 or the target bonus established in an annual executive target bonus plan in effect on the Termination Date.

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 December 31, 2019, to each of the executive officers named in the Summary Compensation Table.

	Option Awards					Stock Awards	
Name	Option Grant Date	Number of Securities Underlying Unexercised Options Exercisable (#) (1)	Number of Securities Underlying Unexercised Options Unexercisable (#)(1)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)(2)
David Seaburg	3-11-2019	93,750	156,250	16.5	3-11-2029	30,000	78,000
	7-1-2019					114,035	296,491
	8-6-2019					175,000	455,000
Richard Hague	4-8-2019	21,666	43,334	10.82	4-8-2029	26,250	68,250
	7-1-2019					108,187	281,286
	8-6-2019					175,000	455,000
Paul E. Mann	6-20-2018	262,500	87,500	$ 31.88	6-20-2028	25,000	$ 65,000
	9-20-2018	13,541	8,125	$ 20.12	9-20-2028	5,833	$ 15,166
	7-1-2019					140,351	364,913
	8-6-2019					175,000	455,000
Denver Lough	8-26-2019					166,667	$ 433,334
						-	-
						-	-

(1) All stock options listed vest in 24 monthly installments beginning one month following the grant date.
(2) Market value is based on closing stock price of $2.60 on December 31, 2019

Board Compensation

The following table shows the total compensation paid or accrued during the fiscal year ended December 31, 2019, to each of our current and former directors, except for David Seaburg whose compensation information is presented in the executive summary compensation table, below.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)(1)(4)	Option Awards ($)(1)(4)	All Other Compensation ($)	Total ($)
Peter A. Cohen	55,000	17,355	-0-	-0-	59,310
Jeff Dyer	61,000	64,834(2)	-0-	53,363(2)	179,197
Jon Mogford	57,000	72,222(2)	-0-	63,492(2)	197,714
Minnie Baylor-Henry	37,500	12,574	-0-	-0-	50,074
Willie C. Bogan	55,000	-0-	-0-	-0-	55,000
Rainer Erdtmann	32,500	-0-	27,422	-0-	59,922
Steve Gorlin(3)	39,194	123,628(2)	-0-	101,755(2)	264,576

(1) The figures in these columns represent the aggregate grant date fair value for restricted stock and option awards, respectively, granted during fiscal years 2019 computed in accordance with FASB ASC Topic 718. See Note 13 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) In 2017 and 2018 we did not provide Jeff Dyer, Jon Mogford, and Steve Gorlin with correct information on tax reporting for equity awards and the corresponding tax liability, which resulted in substantial tax liability and diminution in the value of the compensation paid. As reparations for the lost value we agreed to grant to Jeff Dyer 15,585 restricted stock units, Jon Morford 18,563 restricted stock units, and Steve Gorlin 29,718 restricted stock units, and pay cash compensation to each of them in the amounts listed in the "All Other Compensation" column.
(3) The service of Mr. Gorlin as a director of the Company ended August 26, 2019.
(4) The following table shows the aggregate number of stock option awards and unvested restricted stock awards outstanding on the last day of the fiscal year ended December 31, 2019, for each of the directors named in the director compensation table.

Name	Stock Option Awards	Stock Awards
Peter Cohen	8,624	9,280
Jon Mogford	68,268	--
Jeff Dyer	139,624	--
Willie Bogan	8,624	7,500
Minnie Baylor- Henry	19,329	7,273
Rainer Erdtmann	69,171	--

2019 Director Compensation

For the calendar year ended December 31, 2019, non-employee directors were compensated as follows:

- Each non-employee director received an annual cash retainer of $45,000;
- The non-executive Chairman of the Board received an annual fee of $22,500;
- Our Audit Committee Chairman received an annual fee of $20,000, our Compensation Committee Chairman received an annual fee of $15,000, and our Nominating and Governance Committee Chairman received an annual fee of $10,000;

- Non-chair members of our Audit Committee received an annual fee of $9,000, our Compensation Committee members received an annual fee of $7,000, and of our Nominating and Governance Committee members received an annual fee of $5,000; and
- Each non-employee director was granted 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.

All cash fees were payable in quarterly installments. Beginning with the fourth calendar quarter of 2019, each non-employee director may, at his or her option, elect by written notice given to the Company prior to the end of each calendar quarter to take in lieu of cash for all or a portion of the non-employee director's cash compensation payable for the next calendar quarter the equivalent value in stock options that vest monthly in three installments beginning one month following the grant date exercisable for a term of 10 years, restricted shares that vest monthly in three installments beginning one month following the grant date; or a combination of the foregoing.

2020 Director Compensation

For the calendar year ending December 31, 2020, non-employee directors will be compensated as follows:

- Each non-employee director will receive an annual cash retainer of $45,000;
- The Chairman of the Board will receive an annual fee of $80,000 paid quarterly in equity awards;
- 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, our Compensation Committee members will receive an annual fee of $7,000, and of our Nominating and Governance Committee members received an annual fee of $5,000; and
- Each non-employee director will be granted an annual equity award with a value of $80,000 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 awards that vest, subject to continuing service, in 12 monthly installments beginning one month after the grant date, or 100% in restricted stock awards that vest, subject to continuing service, in 12 monthly installments beginning one month after the grant date.

All cash fees are payable in quarterly installments. Not less than three business days prior to the last business day of each calendar quarter a non-employee director may elect by written notice to the Company to take in lieu of cash for all or a portion of the non-employee director's cash compensation payable for the next calendar quarter the equivalent value determined using the Black-Scholes formula (as applicable) in the form of stock options that vest monthly in three installments beginning one month following the grant date exercisable for a term of 10 years, restricted stock awards that vest monthly in three installments beginning one month following the grant date, or a combination of the foregoing.

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 the common stock of the Company as of February 29, 2020 by (i) each person known to the Company to be the beneficial owner of more than 5% of the Company's common stock, (ii) each of the Company's current directors and nominees for director, (iii) each individual who meets the definition of "named executive officer" under SEC regulations, and (iv) all directors and executive officers of the Company as a group. The number of shares of common stock beneficially owned by each person is determined under rules promulgated by the SEC. Under such rules, beneficial ownership includes any shares as to which the person has sole or shared voting power or investment power, and also includes 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 38,320,161 voting shares issued and outstanding as of February 29, 2020, 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.

	Number of Shares of Common Stock Beneficially Owned	Percentage of Common Stock
Executive Officers and Directors (1):		
Peter A. Cohen	127,502	0.3
Jeff Dyer	192,640	0.5
Jon Mogford	149,523	0.4
Minnie Baylor-Henry	22,864	0.1
Willie C. Bogan	44,711	0.1
Rainer Erdtmann	121,312	0.3
David Seaburg	487,569	1.3
Paul Mann	750,461	1.9
Richard Hague	331,478	0.9
Executive Officers and Directors as a Group (9 persons)	2,228,060	5.7
Greater that 5% Holders:		
Denver Lough (2)(4) 1287 E. 530 North, Orem, UT 84097	7,127,112	18.6
Barry Honig (3)(4) 555 S. Federal Hwy, #450, Boca Raton, FL 33432	2,278,114	5.9

(1) Includes the following number of shares of options that were exercisable or restricted share awards expected to vest within 60 days of February 29, 2020: Peter A. Cohen, 23,303; Jeff Dyer, 148,226; Jon Mogford, 73,396; Minnie Baylor-Henry, 12,814; Willie C. Bogan, 15,002; Rainer Erdtmann, 71,312; David Seaburg, 144,868; Paul Mann, 340,901; and Richard Hague, 35,833.

(2) The stock information for Dr. Lough is based on the most recent Form 4 filed by Dr. Lough with the SEC, which shows direct common stock ownership of 7,104,890 shares. The figure for Dr. Lough includes an additional 22,222 common shares issuable to Dr. Lough within 60 days under the terms of the stock award granted under the settlement with Dr. Lough in August 2019.

(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 December 13, 2019. As stated in that filing, the shares listed for Mr. Honig include (i) 1,296,800 shares of common stock held by Twipee Incorporated ("Twipee"), (ii) 483,054 shares of common stock held by GRQ Consultants, Inc. Roth 401K FBO Barry Honig ("Roth 401K"), (iii) 434,952 shares of common stock held by GRQ Consultants, Inc. 401K ("401K"), (iv) 49,308 shares of common stock held by GRQ Consultants, Inc. Roth 401K FBO Renee Honig ("Renee 401K") and (v) 14,000 shares of common stock held by GRQ Consultants, Inc. ("GRQ Inc."). Barry Honig's father, Alan S. Honig ("Alan Honig"), and Barry Honig's wife, Renee Honig ("Renee Honig"), are co-trustees of each of 401K, Roth 401K and Renee 401K. Alan Honig, is the President of each of GRQ Inc. and Twipee. Renee Honig is the sole shareholder and Secretary of Twipee. Both Alan Honig and Renee Honig are directors of Twipee. By virtue of his current relationship with his father with regard to the shares of common stock held by 401K, Roth 401K, Renee 410K, GRQ Inc. and Twipee, and the spousal relationship with his wife with regard to the shares of common stock held by 401K, Roth 401K, Renee 401K and Twipee, Barry Honig may have influence on all of the shares of common stock held by each of 401K, Roth 401K, Renee 401K, GRQ Inc. and Twipee, and may be deemed, directly or indirectly, to have beneficial ownership of all such shares of common stock.

The following table provides information on our compensation plans at December 31, 2019 under which equity securities are authorized for issuance.

Plan category	(a) Number of securities to be issued upon exercise of outstanding options, warrants, and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuances under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	4,374,988	$ 15.45	5,353,257
Equity compensation plans not approved by security holders (1)	155,000	$ 10.13	-0-
Total	4,529,988	$	5,353,257

(1) These plans are individual grants of stock options to one consultant and four employees in connection with their engagement or employment by us. Each stock option vests in 24 monthly installments subject to continued engagement or employment. The grant date, number of shares, and exercise price for each stock option granted are as follows:

Grant Date	No. of Shares	Exercise Price
02/28/2017	50,000	$ 4.72
03/10/2017	10,000	$ 6.57
04/05/2017	75,000	$13.12
04/10/2017	10,000	$14.25
04/10/2017	10,000	$14.25

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

Director Independence

Our Board is currently comprised of six 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 Peter A. Cohen, Jeff Dyer, Dr. Jon Mogford, Willie C. Bogan, 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 with Lefrak SBN Limited Partnership 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 workstations 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 the year ended December 31, 2019, the two-month period ended December 31, 2018, and the fiscal year ended October 31, 2018, for the categories of services indicated.

	Year Ended December 31, 2019 ($)	Two Months Ended 12/31/18 ($)	Year Ended October 31, 2018 ($)
Audit Fees	604,467	285,200	485,210
Audit Related Fees	—	—	—
Tax Fees	—	—	—
Other Fees	—	—	—
Total Fees	604,467	285,200	485,210

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 2019, the Audit Committee took the following actions:

- reviewed and discussed the audited financial statements for the year ended December 31, 2019, 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 index lists the exhibits that are filed with this report or incorporated by reference, as noted:

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 SEC 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 SEC 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 SEC on April 7, 2017)
3.10	Articles of Merger (incorporated by reference to Exhibit 3.2 to our Form 8-K filed with the SEC 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 SEC 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 SEC on September 20, 2017)
3.13	Certificate of Designation of Series A Junior Participating Preferred Stock (incorporated by reference to Exhibit 3.1 to our Form 8-K filed with the SEC on November 7, 2019)

3.14	Amendment No. 1 to Restated Bylaws dated January 11, 2019, Changing Fiscal Year (incorporated by reference to Exhibit 3.13 to our Form 10-K filed with the SEC on January 14, 2019)
4.1	Form of Warrant (incorporated by reference to Exhibit 4.1 to our Form 8-K filed with the SEC on September 20, 2017)
4.2	Rights Agreement dated November 7, 2019 (incorporated by reference to Exhibit 4.1 to our Form 8-K filed with the SEC on November 7, 2019)
4.3	Form of Rights Certificate Agreement dated November 7, 2019, between the Company and Equity Stock Transfer, LLC as rights agent (incorporated by reference to Exhibit 4.2 to our Form 8-K filed with the SEC on November 7, 2019)
4.4	Registration Rights Agreement dated December 5, 2019, between the Company and Keystone Capital Partners, LLC (incorporated by reference to Exhibit 4.1 to our Form 8-K filed with the SEC on December 5, 2019)
4.5	Form of Common Stock Warrant Certificate (incorporated by reference to Exhibit 4.1 to our Form 8-K filed with the SEC on February 14, 2020)
4.6	Form of Warrant Agency Agreement (incorporated by reference to Exhibit 4.2 to our Form 8-K filed with the SEC on February 14, 2020)
*4.7	Description of Securities
#10.1	Employment Agreement with David Seaburg (incorporated by reference to Exhibit 10.30 to our Form 10-KT filed with the SEC on March 18, 2019)
#10.2	Employment Agreement with Richard Hague (incorporated by reference to Exhibit 10.1 to our Form 10-Q filed with the SEC on May 10, 2019)
#10.3	Employment Agreement with Paul Mann (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on September 14, 2018)
#10.4	Amendment No. 1 to Employment Agreement with David Seaburg (incorporated by reference to Exhibit 10.2 to our Form 10-Q filed with the SEC on August 8, 2019)
#10.5	Amendment No. 1 to Employment Agreement with Richard Hague (incorporated by reference to Exhibit 10.1 to our Form 10-Q filed with the SEC on August 8, 2019)
#10.6	Amendment No. 1 to Employment Agreement with Paul Mann (incorporated by reference to Exhibit 10.3 to our Form 10-Q filed with the SEC on August 8, 2019)
#10.7	Form of Notice of Restricted Stock Grant and Restricted Stock Award Agreement under the 2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to our Form 10-Q filed with the SEC on August 8, 2019)
#10.8	Change in Control Compensation Plan (incorporated by reference to Exhibit 10.2 to our Form 10-Q filed with the SEC on November 12, 2019)
#10.9	Form of Restricted Stock Unit Agreement – 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.20 to our Form 10-K filed with the SEC on January 14, 2019)
#10.10	Form of Stock Option Agreement – 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.21 to our Form 10-K filed with the SEC on January 14, 2019)
#10.11	Form of Restricted Stock Unit Agreement – 2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.22 to our Form 10-K filed with the SEC on January 14, 2019)
#10.12	Form of Stock Option Agreement – 2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.23 to our Form 10-K filed with the SEC on January 14, 2019)
#10.13	PolarityTE (formerly Majesco Entertainment Company) 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to our Form 8-K filed with the SEC on December 7, 2016)
#10.14	PolarityTE 2019 Equity Incentive Plan (incorporated by reference to Exhibit 99.1 to our Form S-8 registration Statement filed with the SEC on October 5, 2018)
#10.15	PolarityTE 2019 Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.2 to our Form S-8 registration Statement filed with the SEC on October 5, 2018)

#10.16	PolarityTE 2020 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on December 20, 2019)
*#10.17	Form of Incentive Stock Option Agreement – 2020 Stock Option and Incentive Plan
*#10.18	Form of Non-qualified Stock Option Agreement – Non-employee Directors – 2020 Stock Option and Incentive Plan
*#10.19	Form of Non-qualified Stock Option Agreement – Employees – 2020 Stock Option and Incentive Plan
*#10.20	Form of Non-qualified Stock Option Agreement – Consultants – 2020 Stock Option and Incentive Plan
*#10.21	Form of Restricted Stock Award – 2020 Stock Option and Incentive Plan
*#10.22	Form of Restricted Stock Unit Award – Non-employee Directors - 2020 Stock Option and Incentive Plan
*#10.23	Form of Restricted Stock Unit Award – Employees - 2020 Stock Option and Incentive Plan
#10.24	Employment Agreement with Denver Lough (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on November 16, 2017)
#10.25	Settlement Terms Agreement dated August 21, 2019, between Denver Lough and the Company (incorporated by reference to Exhibit 10.1 to our Form 10-Q filed with the SEC on November 12, 2019)
10.26	Agreement of Lease between the Company and Lefrak SBN Limited Partnership dated October 19, 2018 (incorporated by reference to Exhibit 10.26 to our Form 10-K filed with the SEC on January 14, 2019)
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 (incorporated by reference to Exhibit 10.27 to our Form 10-K filed with the SEC on January 14, 2019)
*10.28	Sublease Agreement with Joseph M. Still Burn Centers, Inc., dated April 22, 2019
10.29	Purchase Agreement dated December 5, 2019 between the Company and Keystone Capital Partners, LLC (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on December 5, 2019)
*21.1	Subsidiaries
*23.1	Consent of EisnerAmper LLP
*31.1	Certification Pursuant to Rule 13a-14(a)
*31.2	Certification Pursuant to Rule 13a-14(a)
*31.3	Certification Pursuant to Rule 13a-14(a)
*32.1	Certification Pursuant to Rule 13a-14(b) and Section 1350, Chapter 63 of Title 18, United States Code

*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
*104	Cover Page Interactive Data File

#	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.

By: */s/ David Seaburg*
President (Principal Executive Officer)

Date: March 12, 2020

By: */s/ Richard Hague*
Chief Operating Officer (Principal Executive Officer)

Date: March 12, 2020

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

Date: March 12, 2020

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/ Peter A. Cohen Peter A. Cohen	Chairman of the Board of Directors	March 12, 2020
/s/ Jeffrey Dyer Jeffrey Dyer	Director	March 12, 2020
/s/ Jon Mogford Jon Mogford	Director	March 12, 2020
/s/ Minnie Baylor-Henry Minnie Baylor-Henry	Director	March 12, 2020
/s/ Willie C. Bogan Willie C. Bogan	Director	March 12, 2020
/s/ Rainer Erdtmann Rainer Erdtmann	Director	March 12, 2020

POLARITYTE, INC. AND SUBSIDIARIES

Consolidated Financial Statements

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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 December 31, 2019 and 2018 and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for the year ended December 31, 2019, the transition period from November 1, 2018 through December 31, 2018, and the year ended October 31, 2018, 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 December 31, 2019 and 2018, and the consolidated results of their operations and their cash flows for the year ended December 31, 2018, the transition period from November 1, 2018 through December 31, 2018, and the year ended October 31, 2018, 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 December 31, 2018, based on criteria established in the *Internal Control - Integrated Framework* (*2013*) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated March 12, 2020 expressed an adverse opinion.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company has changed its method of accounting for leases in 2019 due to the adoption of ASU 2016-02 - Leases.

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
March 12, 2020

POLARITYTE, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31, 2019	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 10,218	$ 55,673
Short-term investments	19,022	6,162
Accounts receivable, net	1,731	712
Inventory	252	336
Prepaid expenses and other current assets	1,264	1,432
Total current assets	32,487	64,315
Property and equipment, net	14,911	13,736
Operating lease right-of-use assets	4,590	–
Intangible assets, net	731	924
Goodwill	278	278
Other assets	602	913
TOTAL ASSETS	$ 53,599	$ 80,166
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 7,095	$ 6,508
Other current liabilities	2,338	316
Current portion of long-term note payable	528	529
Deferred revenue	98	170
Total current liabilities	10,059	7,523
Long-term note payable, net	–	479
Operating lease liabilities	2,994	–
Other long-term liabilities	1,630	131
Total liabilities	14,683	8,133
Commitments and Contingencies (Note 17)		
STOCKHOLDERS' EQUITY		
Preferred stock – 25,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2019 and 2018	–	–
Common stock - $.001 par value; 250,000,000 shares authorized; 27,374,653 and 21,447,088 shares issued and outstanding at December 31, 2019 and 2018	27	21
Additional paid-in capital	474,174	414,840
	72	36
Accumulated other comprehensive income		
Accumulated deficit	(435,357)	(342,864)
Total stockholders' equity	38,916	72,033
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 53,599	$ 80,166

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 Year Ended December 31, 2019	For the Two Months Ended December 31, 2018	For the Year Ended October 31, 2018
Net revenues			
Products	$ 2,353	$ 210	$ 689
Services	3,299	463	874
Total net revenues	5,652	673	1,563
Cost of sales			
Products	1,365	194	500
Services	1,114	187	502
Total costs of sales	2,479	381	1,002
Gross profit	3,173	292	561
Operating costs and expenses			
Research and development	16,397	3,458	19,376
General and administrative	63,189	12,639	48,252
Sales and marketing	16,980	2,725	2,365
Total operating costs and expenses	96,566	18,822	69,993
Operating loss	(93,393)	(18,530)	(69,432)
Other income (expense)			
Interest income, net	151	80	395
Other income, net	749	32	–
Change in fair value of derivatives	–	–	3,814
Loss on extinguishment of warrant liability	–	–	(520)
Loss before income taxes	(92,493)	(18,418)	(65,743)
Benefit for income taxes	–	–	302
Net loss	(92,493)	(18,418)	(65,441)
Deemed dividend – accretion of discount on Series F preferred stock	–	–	(1,290)
Deemed dividend – exchange of Series F preferred stock	–	–	(7,057)
Cumulative dividends on Series F preferred stock	–	–	(373)
Net loss attributable to common stockholders	$ (92,493)	$ (18,418)	$ (74,161)
Net loss per share, basic and diluted:			
Net loss	(3.70)	(0.86)	(4.29)
Deemed dividend – accretion of discount on Series F preferred stock	–	–	(0.09)
Deemed dividend – exchange of Series F preferred stock	–	–	(0.46)
Cumulative dividends on Series F preferred stock	–	–	(0.02)
Net loss per share attributable to common stockholders	$ (3.70)	$ (0.86)	$ (4.86)
Weighted average shares outstanding, basic and diluted	24,966,355	21,343,446	15,259,731

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

POLARITYTE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	For the Year Ended December 31, 2019	For the Two Months Ended December 31, 2018	For the Year Ended October 31, 2018
Net loss	$ (92,493)	$ (18,418)	$ (65,441)
Other comprehensive income:			
Unrealized gain on available-for-sale securities	493	36	–
Reclassification of realized gain included in net loss	(457)	–	–
Comprehensive loss	$ (92,457)	$ (18,382)	$ (65,441)

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 Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Number	Amount	Number	Amount				
Balance - October 31, 2017	3,230,655	$ 109,995	6,515,524	$ 7	$ 149,173	$ –	$ (259,005)	$ 170
Issuance of common stock in connection with:								
Conversion of Series A preferred stock to common stock	(3,146,671)	(769)	713,036	1	768	–	–	–
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 exercise	–	–	161,433	–	687	–	–	687
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 - October 31, 2018	–	$ –	21,423,999	$ 21	$ 406,087	$ –	$ (324,446)	$ 81,662
Stock-based compensation expense	–	–	–	–	8,908	–	–	8,908
Vesting of restricted stock units, net	–	–	23,089	–	–	–	–	–
Shares withheld for tax withholding on vesting of restricted stock	–	–	–	–	(155)	–	–	(155)
Other comprehensive income	–	–	–	–	–	36	–	36
Net loss	–	–	–	–	–	–	(18,418)	(18,418)
Balance - December 31, 2018	–	$ –	21,447,088	$ 21	$ 414,840	$ 36	$ (342,864)	$ 72,033
Issuance of common stock, net of issuance costs of $1,147	–	–	3,473,008	3	28,070	–	–	28,073
Issuance of restricted stock awards, net	–	–	1,579,919	2	(2)	–	–	–
Stock option exercise	–	–	292,417	–	529	–	–	529
Stock-based compensation expense	–	–	–	–	31,440	–	–	31,440
Purchase of ESPP shares	–	–	36,177	–	99	–	–	99
Vesting of restricted stock units, net	–	–	645,473	1	(1)	–	–	–
Shares withheld for tax withholding on vesting of restricted stock	–	–	(99,429)	–	(801)	–	–	(801)
Other comprehensive income	–	–	–	–	–	36	–	36
Net loss	–	–	–	–	–	–	(92,493)	(92,493)
Balance - December 31, 2019	–	$ –	27,374,653	$ 27	$ 474,174	$ 72	$ (435,357)	$ 38,916

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 Year Ended December 31, 2019	For the Two Months Ended December 31, 2018	For the Year Ended October 31, 2018
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (92,493)	$ (18,418)	$ (65,441)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock based compensation expense	31,402	8,946	38,821
Change in fair value of derivatives	–	–	(3,814)
Depreciation and amortization	2,992	330	1,394
Loss on extinguishment of warrant liability	–	–	520
Amortization of intangible assets	193	33	100
Amortization of debt discount	49	10	35
Change in fair value of contingent consideration	(36)	57	20
Loss on disposal of property and equipment	914	–	–
Other non-cash adjustments	20	86	–
Changes in operating assets and liabilities:			
Accounts receivable	(1,019)	228	(940)
Inventory	84	(98)	(238)
Prepaid expenses and other current assets	193	(279)	(911)
Operating lease right-of-use assets	1,651	–	–
Other assets	(249)	(535)	(378)
Accounts payable and accrued expenses	1,269	1,621	2,136
Other current liabilities	32	–	–
Deferred revenue	(72)	20	150
Operating lease liabilities	(1,578)	–	–
Net cash used in operating activities	(56,648)	(7,999)	(28,546)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of property and equipment	(2,773)	(834)	(9,221)
Purchase of available-for-sale securities	(40,072)	(10,200)	–
Proceeds from maturities of available-for-sale securities	23,327	4,003	–
Proceeds from sale of available-for-sale securities	3,901	–	–
Acquisition of IBEX	–	–	(2,258)
Net cash used in continuing investing activities	(15,617)	(7,031)	(11,479)
Net cash provided by discontinued investing activities	–	10	60
Net cash used in investing activities	(15,617)	(7,021)	(11,419)
CASH FLOWS FROM FINANCING ACTIVITIES			
Net proceeds from the sale of common stock	28,073	–	92,676
Proceeds from stock options exercised	529	–	687
Proceeds from ESPP purchase	99	–	–
Cash paid for tax withholdings related to net share settlement	(679)	–	–
Payment of contingent consideration liability	(225)	–	(30)
Principal payments on financing leases	(453)	(11)	(74)
Principal payments on term note payable and financing arrangements	(534)	(257)	–
Net cash provided by/(used in) financing activities	26,810	(268)	93,259
Net (decrease)/increase in cash and cash equivalents	(45,455)	(15,288)	53,294
Cash and cash equivalents - beginning of period	55,673	70,961	17,667
Cash and cash equivalents - end of period	$ 10,218	$ 55,673	$ 70,961
Supplemental schedule of non-cash investing and financing activities:			
Property and equipment additions acquired through finance leases	$ 2,578	$ 20	$ 251
Property and equipment acquired through financing arrangements	$ 58	$ –	$ –
Unpaid liability for acquisition of property and equipment	$ 273	$ 600	$ 300
Reclassification of stock-based compensation expense that was previously classified as a liability to paid-in capital	$ 38	$ –	$ –
Conversion of Series A, B, C, D, E preferred stock to common stock	$ –	$ –	$ 109,995
Unpaid tax liability related to net share settlement of restricted stock units	$ –	$ 155	$ –
Contingent consideration earned and recorded in accounts payable	$ –	$ 31	$ 33
Exchange of Series F preferred stock for common stock	$ –	$ –	$ 13,061
Extinguishment of warrant liability	$ –	$ –	$ 2,525
Deemed dividend – accretion of discount on Series F preferred stock	$ –	$ –	$ 1,290
Cumulative dividends on Series F preferred stock	$ –	$ –	$ 373
Series F preferred stock dividends paid in common stock	$ –	$ –	$ 306
Contingent consideration for IBEX acquisition	$ –	$ –	$ 278
Note payable issued as partial consideration for IBEX acquisition	$ –	$ –	$ 1,220

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

1. PRINCIPAL BUSINESS ACTIVITY

PolarityTE, Inc. and subsidiaries (the "Company") is a biotechnology company developing and commercializing regenerative tissue products and biomaterials.

Change in Fiscal Year end. 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 Company made this change to align its fiscal year end with other companies within its industry. The change in the Company's fiscal year end resulted in a two-month transition period that began on November 1, 2018 and ended on December 31, 2018

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation. The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP").

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.

Use of estimates. The preparation of financial statements in conformity with U.S. GAAP 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 is the extent of progress toward completion of contracts, 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.

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 the Office of the Chief Executive consisting of the President, Chief Operating Officer, and Chief Financial Officer. The CODM allocates resources to and assesses the performance of each operating segment using information about its revenue and operating income (loss). 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"). Prior to the acquisition of IBEX, the Company operated in one segment.

Cash and cash equivalents. Cash equivalents consist of highly liquid investments with original maturities of three months or less from the date of purchase.

Investments. Investments in debt securities have been classified as available-for-sale and are carried at fair value, with unrealized gains and losses reported as a component of accumulated other comprehensive income. Realized gains and losses are included in other income, net. The cost of securities sold is based on the specific-identification method. Interest on marketable securities is included in interest income, net. Investments with original maturities of greater than three months but less than one year from the date of purchase are classified as current. Investments with original maturities of greater than one year from the date of purchase are classified as non-current.

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 December 31, 2019, the Company recorded an allowance of $26,000. As of December 31, 2018 and October 31, 2018, an allowance for doubtful accounts was not considered necessary.

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 are stated at cost less accumulated depreciation and amortization. Depreciation is computed on the straight-line basis over the estimated useful lives of the related assets, generally ranging from three to eight years. Leasehold improvements are amortized using the straight-line method over the shorter of the assets' estimated useful lives or the remaining term of the lease. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations.

Leases. The Company determines if an arrangement is a lease at inception. Right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Finance leases are reported in the consolidated balance sheet in property and equipment and other current and long-term liabilities. The short-term portion of operating lease obligations are included in other current liabilities. The classification of the Company's leases as operating or finance leases along with the initial measurement and recognition of the associated ROU assets and lease liabilities is performed at the lease commencement date. The measurement of lease liabilities is based on the present value of future lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future lease payments. The ROU asset is based on the measurement of the lease liability and also includes any lease payments made prior to or on lease commencement and excludes lease incentives and initial direct costs incurred, as applicable. The lease terms may include options to extend or terminate the lease when it is reasonably certain the Company will exercise any such options. Rent expense for the Company's operating leases is recognized on a straight-line basis over the lease term. Amortization expense for the ROU asset associated with its finance leases is recognized on a straight-line basis over the term of the lease and interest expense associated with its finance leases is recognized on the balance of the lease liability using the effective interest method based on the estimated incremental borrowing rate.

The Company has lease agreements with lease and non-lease components. As allowed under ASC 842, the Company has elected not to separate lease and non-lease components for any leases involving real estate and office equipment classes of assets and, as a result, accounts for the lease and non-lease components as a single lease component. The Company has also elected not to apply the recognition requirement of ASC 842 to leases with a term of 12 months or less for all classes of assets.

Goodwill and Intangible Assets. Goodwill represents the excess purchase price over the fair value of net tangible and intangible assets acquired. Goodwill is not amortized, rather the carrying amount of goodwill is assessed for impairment at least annually, or more frequently if impairment indicators exist.

Goodwill is tested for impairment at a reporting unit level by performing either a qualitative or quantitative analysis. The qualitative analysis is an assessment of factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If 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 no further testing is necessary.

If the Company concludes otherwise, a quantitative analysis is performed by comparing the fair value of a reporting unit to its carrying amount. If the fair value exceeds the carrying value, there is no impairment. If the fair value is less than the carrying value, an impairment charge is recorded for the difference between the fair value and the carrying value. During the year, the Company 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 analysis was not required.

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 and an impairment charge would be recorded for the excess of the carrying value over its fair 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. There were no impairments of long-lived assets for any of the periods presented.

Capitalized Software. The Company capitalizes 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.

Revenue Recognition. Revenue was recognized under ASC 605 for the year ended October 31, 2018. Under ASC 605, regenerative medicine revenue is recognized 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. In the contract services segment, revenue is recognized on the proportional performance method over the term of the service contract, which requires the Company 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 contract. As a result, unbilled receivables and deferred revenue are recognized based on payment timing and work completed.

The Company adopted ASC 606 for the year ended December 31, 2019 and the two months ended December 31, 2018. Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

In the regenerative medicine products segment, the Company records product revenues primarily from the sale of its regenerative tissue products. The Company sells its products to healthcare providers, primarily through direct sales representatives. Product revenues consists of a single performance obligation that the Company satisfies at a point in time. In general, the Company recognizes product revenue upon delivery to the customer.

In the contract services segment, the Company records service revenues from the sale of its contract research services, which includes delivery of preclinical studies and other research services to unrelated third parties. Service revenues generally consist of a single performance obligation that the Company satisfies over time using an input method based on costs incurred to date relative to the total costs expected to be required to satisfy the performance obligation. The Company believes that this method provides a faithful depiction of the transfer of services over the term of the performance obligation based on the remaining services needed to satisfy the obligation. This requires the Company to make reasonable estimates of the extent of progress toward completion of the contract. As a result, unbilled receivables and deferred revenue are recognized based on payment timing and work completed. Generally, a portion of the payment is due upfront and the remainder upon completion of the contract, with most contracts completing in less than a year. As of December 31, 2019 and 2018, the Company had unbilled receivables of $0.1 million and $0.2 million, respectively, and deferred revenue of $0.1 million and $0.2 million, respectively. The unbilled receivables balance is included in consolidated accounts receivable. Revenue of $0.2 million was recognized during the year ended December 31, 2019 that was included in the deferred revenue balance as of December 31, 2018. The impact of the new revenue standard did not have a material impact to the financial statements.

Costs to obtain the contract are incurred for product revenue as they are shipped and are expensed as incurred.

The Company considers a significant customer to be one that comprises more than 10% of net revenues or accounts receivable. Concentration of revenues was as follows:

		For the Year Ended December 31, 2019	For the Two Months Ended December 31, 2018	For the Year Ended October 31, 2018
	Segment	% of Revenue	% of Revenue	% of Revenue
Customer A	Contract Services	23%	32%	19%
Customer B	Regenerative Medicine	*	17%	*
Customer C	Contract Services	*	11%	*

Concentration of accounts receivable was as follows:

		December 31, 2019	December 31, 2018
	Segment	% of Accounts Receivable	% of Accounts Receivable
Customer A	Contract services	*	23%
Customer B	Regenerative medicine	*	20%
Customer D	Regenerative medicine	*	14%
Customer E	Regenerative medicine	11%	*
Customer F	Contract services	15%	*
Customer G	Regenerative medicine	14%	*

*The amount did not exceed 10%

Research and Development Expenses. Costs incurred for research and development are expensed as incurred. Nonrefundable advance payments for goods or services that have the characteristics that will be used or rendered for future research and development activities pursuant to executory contractual arrangements with third party research organizations are deferred and recognized as an expense as the related goods are delivered or the related services are performed.

Accruals for Research and Development Expenses and Clinical Trials. As part of the process of preparing its financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment terms that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the timing of various aspects of the expenses. The Company determines accrual estimates by taking into account discussion with applicable personnel and outside service providers as to the progress of clinical trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period.

Stock-Based Compensation. The Company measures all stock-based compensation to employees and non-employees using a fair value method and records such expense in general and administrative, research and development, and sales and marketing expenses. 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 based on the fair value on the date of grant.

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 fair 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.

Stock-based compensation expense for nonemployee services had historically been subject to remeasurement at each reporting date as the underlying equity instruments vest and was recognized as an expense over the period during which services are received. Upon the adoption of ASU 2018-07, Compensation – Stock Compensation on January 1, 2019, the valuation was fixed at the implementation date and will be recognized as an expense on a straight-line basis over the remaining service period.

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 balance sheet date and records a valuation allowance for assets for which realization is not more likely than not. The Company recognizes interest and penalties as a component of income tax expense.

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.

Recent Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820), Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*. The ASU modifies the disclosure requirements for fair value measurements by removing, modifying or adding certain disclosures. The standard is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years with early adoption permitted. The Company does not expect the adoption of this ASU to have a material impact on its financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses (Topic 326)*, which requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost. This standard is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years with early adoption permitted. In November 2019, the FASB issued ASU No. 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates* , which defers the effective date of Topic 326. As a smaller reporting company, Topic 326 will now be effective for the Company beginning January 1, 2023. As such, the Company plans to adopt this ASU beginning January 1, 2023. The Company is currently evaluating the impact that the standard will have on its consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncements

On January 1, 2019 the Company adopted ASU 2016-02, *Leases (ASC 842)* and related amendments, which require lease assets and liabilities to be recorded on the balance sheet for leases with terms greater than twelve months. 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. The standard was adopted using the modified retrospective transition approach by applying the new standard to all leases existing at the date of the initial application and not restating comparative periods.

The Company elected the package of practical expedients permitted under the transition guidance, which allowed it to carryforward its historical lease classification, its assessment on whether a contract was or contains a lease, and its initial direct costs for any leases that existed prior to January 1, 2019. The impact of the adoption of ASC 842 on the accompanying consolidated balance sheet as of January 1, 2019 was as follows (in thousands):

	December 31, 2018	Adjustments Due to the Adoption of ASC 842	January 1, 2019
Operating lease right-of-use assets	$ –	$ 5,305	$ 5,305
Liabilities:			
Accounts payable and accrued expenses	$ 6,508	$ (75)	$ 6,433
Other current liabilities	316	1,432	1,748
Operating lease liabilities	–	3,948	3,948

The adjustments due to the adoption of ASC 842 related to the recognition of operating lease right-of-use assets and operating lease liabilities for the existing operating leases. A cumulative-effect adjustment to beginning accumulated deficit was not required.

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 adopted this ASU on January 1, 2019. The adoption of this ASU did not 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. The Company early adopted this standard on November 1, 2018. The adoption of this ASU had no impact on the Company's consolidated financial statements and related disclosures.

3. LIQUIDITY

The Company has experienced recurring losses and cash outflows from operating activities. As of December 31, 2019, the Company has an accumulated deficit of $435.4 million. As of December 31, 2019, the Company had cash and cash equivalents and short-term investments of $29.2 million.

On April 10, 2019, the Company completed an underwritten offering providing for the issuance and sale of 3,418,918 shares of the Company's common stock, par value $0.001 per share, at an offering price of $8.51 per share, for net proceeds of approximately $27.9 million, after deducting offering expenses payable by the Company.

On December 5, 2019, the Company entered into an Equity Purchase Agreement (the "Purchase Agreement"), with Keystone Capital Partners, LLC ("Keystone"), pursuant to which Keystone has agreed to purchase from the Company up to $25.0 million of shares of its common stock, subject to certain limitations including a minimum stock price of $2.00, at the direction of the Company from time to time during the 36-month term of the Purchase Agreement. Concurrently, the Company entered into a Registration Rights Agreement with Keystone, pursuant to which it agreed to register the sales of its common stock pursuant to the Purchase Agreement under the Company's existing shelf registration statement on Form S-3 or a new registration statement. On December 19, 2019, the Company sold 54,090 shares under the Purchase Agreement at a purchase price of $2.31 per share, for total proceeds of $0.1 million.

On February 14, 2020, the Company completed an underwritten offering of 10,638,298 shares of its common stock and warrants to purchase 10,638,298 shares of common stock. Each common share and warrant were sold together for a combined purchase price of $2.35. The exercise price of each warrant is $2.80 per share, the warrants were exercisable immediately, and they will expire February 12, 2027. The net proceeds to the Company from the offering are estimated to be approximately $22.7 million, after estimated offering expenses payable by the Company.

Following the end of 2019, the Company effectuated four additional sales of common stock to Keystone under the Purchase Agreement for a total of 216,412 shares generating total gross proceeds of $0.6 million. In connection with the underwritten offering described in the preceding paragraph, the Company agreed not to sell any additional shares under the Purchase Agreement for a period of 90 days after the closing date of the offering.

Based upon the current status of product development and commercialization plans, the Company believes that its existing cash and cash equivalents, with planned operating cost reductions, will be adequate to satisfy its capital and operating needs for at least the next 12 months from the date of filing. The Company believes it may need additional financing to continue clinical deployment and commercialization of SkinTE and development of its other product candidates. The Company will continue to pursue fundraising opportunities when available, but such financing may not be available in the future on favorable terms, if at all. If adequate financing is not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its product development programs, or be unable to continue operations over a longer term. The Company plans to meet its capital requirements primarily through issuances of equity securities, debt financing, revenue from product sales or strategic partnership arrangements. Failure to generate revenue or raise additional capital would adversely affect the Company's ability to achieve its 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, entered into agreements with 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 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 11) 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 $0.9 million to net revenues and approximately $0.3 million to gross profit, respectively.

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 consolidated balance sheet. 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. During the year ended December 31, 2019, the Company recognized a decrease in the fair value of contingent consideration of $36,000. During the two months ended December 31, 2018 and the year ended October 31, 2018, the Company recognized an increase in fair value of the contingent consideration of $20,000 and $57,000, respectively. The change in fair value was recognized in general and administrative expense in the Company's consolidated statement of operations. 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 as of the acquisition date (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. This methodology applies to the Company's Level 1 investments, which are composed of money market funds.
- Level 2: Quoted prices for similar instruments that are directly or indirectly observable in the market. This methodology applies to the Company's Level 2 investments, which are composed of corporate debt securities, commercial paper, and U.S. government debt securities.
- 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. This methodology applies to the Company's Level 3 financial instruments, which are composed of contingent consideration.

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. There were no transfers within the hierarchy for any of the periods presented.

In connection with the offering of Units in September 2017 (see Note 12), 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 expired in two years from the date of issuance. 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 discussed in Note 12, 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 at March 5, 2018 as calculated using the Monte Carlo simulation with the following assumptions:

	Series F Conversion Feature
	March 5, 2018
Stock price	$ 20.05
Exercise price	$ 27.50
Risk-free rate	2.2%
Volatility	88.2%
Term	1.5

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

	Warrant Liability
	March 5, 2018
Stock price	$ 20.05
Exercise price	$ 30.00
Risk-free rate	2.2%
Volatility	88.2%
Term	1.5

The following table sets forth the fair value of the Company's financial assets and liabilities measured on a recurring basis by level within the fair value hierarchy as of December 31, 2019 and 2018 (in thousands):

	Fair Value Measurement as of December 31, 2019			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets				
Money market funds	$ 2,019	$ –	$ –	$ 2,019
Commercial paper	–	11,064	–	11,064
Corporate debt securities	–	8,982	–	8,982
U.S. government debt securities	–	3,770	–	3,770
Total	$ 2,019	$ 23,816	$ –	$ 25,835
Liabilities				
Contingent consideration	$ –	$ –	$ 31	$ 31
Total	$ –	$ –	$ 31	$ 31

	Fair Value Measurement as of December 31, 2018			
	Level 1	Level 2	Level 3	Total
Assets				
Money market funds	$ 7	$ –	$ –	$ 7
Commercial paper	–	21,392	–	21,392
Corporate debt securities	–	5,448	–	5,448
U.S. government debt securities	–	3,226	–	3,226
Total	$ 7	$ 30,066	$ –	$ 30,073
Liabilities				
Contingent consideration	$ –	$ –	$ 261	$ 261
Total	$ –	$ –	$ 261	$ 261

The following table sets forth the changes in the estimated fair value of the contingent consideration liability (in thousands) which is included in other current liabilities:

	Contingent Consideration
Fair value - October 31, 2018	$ 235
Change in fair value	57
Earned and moved to accounts payable	(31)
Fair value – December 31, 2018	261
Change in fair value	(36)
Earned and paid	(194)
Fair value – December 31, 2019	$ 31

6. Cash Equivalents and Short-Term Investments

Cash equivalents and short-term investments consisted of the following as of December 31, 2019 and 2018 (in thousands):

	December 31, 2019			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Market Value
Cash equivalents				
Money market funds	$ 2,019	$ –	$ –	$ 2,019
Commercial paper	1,020	4	–	1,024
U.S. government debt securities	3,761	9	–	3,770
Total cash equivalents (1)	6,800	13	–	6,813
Short-term investments				
Commercial paper	9,986	54	–	10,040
Corporate debt securities	8,977	5	–	8,982
Total short-term investments	18,963	59	–	19,022
Total	$ 25,763	$ 72	$ –	$ 25,835

(1) Included in cash and cash equivalents in the Company's consolidated balance sheet as of December 31, 2019 in addition to $3.4 million of cash.

	December 31, 2018			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Market Value
Cash equivalents				
Money market funds	$ 7	$ –	$ –	$ 7
Commercial paper	20,648	30	–	20,678
U.S. government debt securities	3,224	2	–	3,226
Total cash equivalents (1)	23,879	32	–	23,911
Short-term investments				
Commercial paper	714	–	–	714
Corporate debt securities	5,444	5	(1)	5,448
Total short-term investments	6,158	5	(1)	6,162
Total	$ 30,037	$ 37	$ (1)	$ 30,073

(1) Included in cash and cash equivalents in the Company's consolidated balance sheet as of December 31, 2018 in addition to $31.8 million of cash.

All investments of debt securities held as of December 31, 2019 and 2018 had maturities of less than one year. During the year ended December 31, 2019, the Company recognized $0.5 million net realized gains on available-for-sale securities. For the two months ended December 31, 2018, realized gains or losses on available-for-sale securities were immaterial.

The interest earned from available-for-sale securities was $0.4 million for the year ended December 31, 2019 and is included in interest income, net in the consolidated statements of operations. For the two months ended December 31, 2018, interest earned from available-for-sale securities was immaterial.

7. PROPERTY AND EQUIPMENT, NET

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

	December 31, 2019	December 31, 2018
Machinery and equipment	$ 12,083	$ 8,276
Land and buildings	2,000	2,000
Computers and software	1,189	1,372
Leasehold improvements	2,282	1,230
Construction in progress	1,606	2,402
Furniture and equipment	470	614
Total property and equipment, gross	19,630	15,894
Accumulated depreciation	(4,719)	(2,158)
Total property and equipment, net	$ 14,911	$ 13,736

Depreciation and amortization expense for property and equipment, including assets acquired under financing leases was as follows (in thousands):

	For the Year Ended December 31, 2019	For the Two Months ended December 31, 2018	For the Year Ended October 31, 2018
General and administrative expense	$ 1,562	$ 155	$ 223
Research and development expense	1,430	175	$ 1,171
Total depreciation and amortization expense	$ 2,992	$ 330	$ 1,394

For the year ended December 31, 2019, the Company recognized a loss on disposal of property and equipment of $0.9 million.

8. LEASES

The Company leases facilities and certain equipment under noncancelable leases that expire at various dates through November 2024. These leases require monthly lease payments that may be subject to annual increases throughout the lease term. Certain of these leases may include options to extend or terminate the lease at the election of the Company. These optional periods have not been considered in the determination of the right-of-use-assets or lease liabilities associated with these leases as the Company did not consider it reasonably certain it would exercise the options.

In April 2019, the Company entered into an operating lease to obtain 6,307 square feet of manufacturing, laboratory, and office space. The lease expires April 2024 and requires monthly lease payments subject to annual increases. During the year ended December 31, 2019, the Company also increased office space under an existing lease, which requires additional monthly lease payments.

As of December 31 2019, the maturities of operating and finance lease liabilities were as follows (in thousands):

	Operating leases	Finance leases
2020	$ 2,114	$ 659
2021	1,730	656
2022	1,345	405
2023	132	336
2024	87	42
Thereafter	–	1
Total lease payments	5,408	2,099
Less:		
Imputed interest	(668)	(324)
Total	$ 4,740	$ 1,775

Supplemental balance sheet information related to leases was as follows (in thousands):

Finance leases

	December 31, 2019
Finance lease right-of-use assets included within property and equipment, net	$ 2,177
Current finance lease liabilities included within other current liabilities	$ 508
Non-current finance lease liabilities included within other long-term liabilities	1,267
Total	$ 1,775

Operating leases

	December 31 2019
Current operating lease liabilities included within other current liabilities	$ 1,746
Operating lease liabilities – non current	2,994
Total	$ 4,740

The components of lease expense was as follows (in thousands):

	For the Year Ended December 31, 2019
Operating lease costs included within operating costs and expenses	$ 2,173
Finance lease costs:	
Amortization of right of use assets	$ 654
Interest on lease liabilities	152
Total	$ 806

Supplemental cash flow information related to leases was as follows (in thousands):

	For the Year Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash out flows from operating leases	$ 2,100
Operating cash out flows from finance leases	152
Financing cash out flows from finance leases	453
Lease liabilities arising from obtaining right-of-use assets:	
Finance leases	$ 2,043
Lease payments made in prior period reclassified to property and equipment	535
Operating leases	936

As of December 31, 2019, the weighted average remaining operating lease term is 2.8 years and the weighted average discount rate used to determine the operating lease liability was 9.83%. The weighted average remaining finance lease term is 3.5 years and the weighted average discount rate used to determine the finance lease liability was 9.77%.

The following disclosures as of December 31, 2018 continue to be in accordance with ASC 840. Future minimum lease payments for operating and capital leases at December 31, 2018 was as follows (*in thousands*):

	Operating leases	Capital leases
2019	$ 1,895	$ 66
2020	1,819	58
2021	1,455	55
2022	1,216	28
	$ 6,385	$ 207

Rent expense under ASC 840 for the two months ended December 31, 2018 and the year ended October 31, 2018 was $0.4 million and $1.4 million, respectively.

9. INTANGIBLE ASSETS AND GOODWILL

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

	December 31, 2019	December 31, 2018
Non-compete agreement	$ 410	$ 410
Customer contracts and relationships	534	534
Trade names and trademarks	101	101
Backlog	12	12
Total intangible assets, gross	1,057	1,057
Accumulated amortization	(326)	(133)
Total intangible assets, net	$ 731	$ 924

Amortization expense for the year ended December 31, 2019, the two months ended December 31, 2018 and the year ended October 31, 2018 was approximately $0.2 million, $33,000 and $0.1 million, respectively.

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

2020	$ 189
2021	189
2022	121
2023	87
2024	87
Thereafter	58
	$ 731

As a result of the IBEX acquisition in May 2018, the Company recognized $0.3 million of goodwill in the contract services segment. There were no changes in the carrying amount of goodwill for any of the periods presented.

10. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

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

	December 31, 2019	December 31, 2018
Accounts payable	$ 1,689	$ 2,918
Salaries and other compensation	1,462	1,041
Legal and accounting	1,404	640
Accrued severance	1,053	–
Benefit plan accrual	557	239
Other	930	1,670
Total accounts payable and accrued expenses	$ 7,095	$ 6,508

Salaries and other compensation include accrued payroll expense, accrued bonus, and estimated employer 401(k) plan contributions.

Accrued severance includes $0.9 million of accrued compensation owed to Dr. Denver Lough, a former officer and director, under a settlement terms agreement dated August 21, 2019 (Note 18). The remaining amount due of $0.3 million is included in other long-term liabilities.

11. 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 $1.2 million. The promissory note has a principal balance of $1.3 million and bears interest at a rate of 3.5% interest per annum. Principal and interest are payable in five equal installments that began 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. As of December 31, 2019 the note payable balance was $0.5 million.

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 $0.1 million, which is being amortized to interest expense over the term of the promissory note using the effective interest method. The unamortized debt discount was $19,000 and $68,000 at December 31, 2019 and 2018, respectively. Amortization of debt discount of $49,000, $10,000 and $35,000 was included in interest expense for the year ended December 31, 2019, the two months ended December 31, 2018 and the year ended October 31, 2018, respectively.

12. PREFERRED SHARES AND COMMON SHARES

Common Stock Issuance

On April 10, 2019, the Company completed an underwritten offering providing for the issuance and sale of 3,418,918 shares of the Company's common stock, par value $0.001 per share, at an offering price of $8.51 per share, for net proceeds of approximately $27.9 million, after deducting offering expenses payable by the Company.

On December 5, 2019, the Company entered into the Purchase Agreement with Keystone pursuant to which Keystone has agreed to purchase from the Company up to $25.0 million of shares of its common stock, subject to certain limitations including a minimum stock price of $2.00, at the direction of the Company from time to time during the 36-month term of the Purchase Agreement. Concurrently, the Company entered into a Registration Rights Agreement with Keystone, pursuant to which it agreed to register the sales of its common stock pursuant to the Purchase Agreement under the Company's existing shelf registration statement on Form S-3 or a new registration statement. On December 19, 2019, the Company sold 54,090 shares under the Purchase Agreement at a purchase price of $2.31 per share, for total proceeds of $0.1 million.

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.

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 former 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. On March 14, 2019, the Company's registration obligation was waived, and the Lough Registration Rights Agreement amended to provide that Dr. Lough may demand registration by written request to the Company. Dr. Lough demanded registration of his 7,050,000 common shares in August 2019, and pursuant to that demand a registration statement on Form S-3 was filed with the Securities and Exchange Commission in October 2019 and declared effective November 1, 2019. The Company is obligated to keep the registration statement effective until the earlier of the date all the registered shares have been sold pursuant to the registration statement or the date one year from the date the registration statement is first effective.

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 December 31, 2019 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	**Preferred Stock Conversions and Series F Exchange – During the Year Ended October 31, 2018**	**Common Stock Shares Issued – During the Year Ended October 31, 2018**
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 December 31, 2019 and December 31, 2018.

13. STOCK-BASED COMPENSATION

2020, 2019 and 2017 Equity Incentive Plans

2020 Plan

On October 25, 2019, the Company's Board of Directors (the "Board") approved the Company's 2020 Stock Option and Incentive Plan (the "2020 Plan"). The 2020 Plan became effective on December 19, 2019, the date approved by the stockholders. The 2020 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights, unrestricted stock awards, dividend equivalent rights, and cash-based awards to the Company's employees, officers, directors and consultants. The Compensation Committee of the Board will administer the 2020 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 3,000,000 shares of common stock are issuable pursuant to awards under the 2020 Plan. No grants of awards may be made under the 2020 Plan after the later of December 19, 2029, or the tenth anniversary of the latest material amendment of the 2020 Plan and no grants of incentive stock options may be made after October 25, 2029. As of December 31, 2019, the Company had 3,000,000 shares available for future issuances under the 2020 Plan.

2019 Plan

On October 5, 2018, the Company's Board approved the Company's 2019 Equity Incentive Plan (the "2019 Plan"). The 2019 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 2019 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 3,000,000 shares of common stock are issuable pursuant to awards under the 2019 Plan. Unless earlier terminated by the Board, the 2019 Plan shall terminate at the close of business on October 5, 2028. As of December 31, 2019, the Company had approximately 273,649 shares available for future issuances under the 2019 Plan.

2017 Plan

On December 1, 2016, the Company's 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 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 December 31, 2019, the Company had approximately 2,079,608 shares available for future issuances under the 2017 Plan.

A summary of the Company's employee and non-employee stock option activity is presented below:

	Number of shares	Weighted-Average Exercise Price
Outstanding - December 31, 2018	6,499,885	$ 14.02
Granted	904,403	$ 12.75
Exercised (1)	(292,417)	$ 4.31
Forfeited	(2,581,883)	$ 8.19
Outstanding – December 31, 2019	4,529,988	$ 15.26
Options exercisable, December 31, 2019	3,198,887	$ 14.94

(1) The number of exercised options includes shares withheld on behalf of employees to satisfy minimum statutory tax withholding requirements.

During the year ended December 31, 2019, the two months ended December 31, 2018 and the year ended October 31, 2018, the estimated weighted-average grant-date fair value of options granted was $9.14, $9.95, and $17.56 per share, respectively. The intrinsic value of options exercised for the year ended December 31, 2019, the two months ended December 31, 2018 and the year ended October 31, 2018 was $3.5 million, $1.6 million, and $2.1 million, respectively. During the year ended December 31, 2019, the two months ended December 31, 2018 and the year ended October 31, 2018, the estimated total grant-date fair value of options vested was $32.0 million, $5.2 million, and $20.0 million, respectively.

The aggregate intrinsic value of options outstanding and exercisable at December 31, 2019 was $0. The weighted average remaining contractual term of options outstanding and exercisable at December 31, 2019 was 8.1 years and 7.7 years, respectively.

Employee Stock Purchase Plan (ESPP)

In May 2018, the Company adopted the Employee Stock Purchase Plan ("ESPP"). The Company has initially reserved 500,000 shares of common stock for purchase under the ESPP. The initial offering period began January 1, 2019 and ended on June 30, 2019 with the first purchase date. Subsequent offering periods will automatically commence on each January 1 and July 1 and will have a duration of six months ending with a purchase date June 30 and December 31 of each year. On each purchase date, ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of (1) the fair market value per share of the common stock on the offering date or (2) the fair market value of the common stock on the purchase date.

Stock Options and ESPP Valuation

The fair value of each option grant and ESPP purchase right is estimated on the date of grant using the Black-Scholes option-pricing model with the following range of assumptions:

	For the Year Ended December 31, 2019	For the Two Months Ended December 31, 2018	For the Year Ended October 31, 2018
Option grants			
Risk free annual interest rate	1.4% - 2.7%	2.6% - 3.2%	2.0% - 3.2%
Expected volatility	80.8% - 97.5%	80.6% - 94.4%	80.9% - 96.5%
Expected term of options (years)	5.0 - 7.0	5.0 - 6.5	5.0-6.0
Assumed dividends	–	–	–
ESPP			
Risk free annual interest rate	2.1% - 2.5%	–	–
Expected volatility	76.6% - 88.9%	–	–
Expected term of options (years)	0.5	–	–
Assumed dividends	–	–	–

Stock-Based Compensation Expense

Total stock-based compensation expense related to stock options, restricted stock awards, and ESPP was as follows (in thousands):

	For the Year Ended December 31, 2019	For the Two Months Ended December 31, 2018	For the Year Ended October 31, 2018
General and administrative expense	$ 27,692	$ 7,505	$ 31,982
Research and development expense	2,643	919	6,322
Sales and marketing expense	1,067	522	517
Total stock-based compensation expense	$ 31,402	$ 8,946	$ 38,821
Stock-based compensation expense classified as a liability	$ –	$ 38	$ –
Stock-based compensation expense classified to equity (1)	$ 31,440	$ 8,908	$ 38,821

(1) The year ended December 31, 2019 includes $38,000 reclassified from liability to equity.

As of December 31, 2019, there was approximately $3.5 million of unrecognized compensation cost related to stock option awards, which is expected to be recognized over a remaining weighted-average vesting period of 0.5 years.

Stock-based compensation related to the ESPP for the year ended December 31, 2019 was $49,000. A total of 36,177 shares of common stock were purchased at a weighted-average purchase price of $2.74 for total proceeds of $0.1 million pursuant to the ESPP during the year ended December 31, 2019.

Restricted Stock

A summary of the Company's employee and non-employee restricted-stock activity is presented below:

	Number of shares
Unvested - December 31, 2018	651,110
Granted	2,202,672
Vested (1)	(830,667)
Forfeited	(180,114)
Unvested – December 31, 2019	1,843,001

(1) The number of vested restricted stock units includes shares that were withheld on behalf of employees to satisfy the minimum statutory tax withholding requirements.

The weighted-average grant-date fair value of restricted stock granted during the year ended December 31, 2019, two months ended December 31, 2018 and year ended October 31, 2018 was $4.74, $14.17, and $25.27 per share, respectively. The total fair value of restricted stock vested during the year ended December 31, 2019, two months ended December 31, 2018 and year ended October 31, 2018 was approximately $12.4 million, $2.1 million and $2.9 million, respectively.

As of December 31, 2019, there was approximately $5.7 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 1.1 years.

14. EMPLOYEE BENEFIT PLAN

The Company's 401(k) Plan is a deferred salary arrangement under Section 401(k) of the Internal Revenue Code. Under the 401(k) Plan, participating employees (full-time employees with the Company for one year) may defer a portion of their pre-tax earnings, up to the IRS annual contribution limit ($19,000 for calendar year 2019). The Company contributes 3% of employee's eligible earnings. The Company recorded contribution expense related to its 401(k) Plan of $0.3 million for the year ended December 31, 2019, $35,000 for the two months ended December 31, 2018, and $0.1 million for the year ended October 31, 2018.

15. INCOME TAXES

The Company calculates its provision for federal and state income taxes based on current tax law. The provision (benefit) for income taxes consisted of the following (in thousands):

	For the Year Ended December 31, 2019	For the Two Months Ended December 31, 2018	For the Year Ended October 31, 2018
Current:			
Federal	$ –	$ –	$ (302)
State	–	–	–
Deferred:			
Federal	(19,057)	(3,734)	(11,561)
State	(8,595)	(257)	(475)
Change in: valuation allowance	27,652	3,991	12,036
Total provision (benefit) for income taxes	$ –	$ –	$ (302)

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

	For the Year Ended December 31, 2019		For the Two Months Ended December 31, 2018		For the Year Ended October 31 2018	
	Amount	Percent of Pretax Income	Amount	Percent of Pretax Income	Amount	Percent of Pretax Income
Tax (benefit) at federal statutory rate	$ (19,423)	21%	$ (3,867)	21%	$ (22,325)	34%
State income taxes, net of federal income taxes	(8,595)	9%	(254)	1%	(475)	(1)%
Effect of warrant liability	–	–%	–	–%	(1,120)	2%
Effect of other permanent items	418	–%	5	–%	30	–%
Effect of stock compensation	129	–%	27	–%	–	–%
Change in valuation allowance	27,652	(30)%	3,991	(22)%	12,036	(18)%
Effect of State NOL tracking	–	–%	–	–%	–	–%
Reduction of NOL's due to Section 382 limitations	–	–%	101	–%	11,552	(17)%
Other	(181)	–%	98	– %	–	–%
	$ –	–%	$ –	–%	$ (302)	–%

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

	As of December 31, 2019	As of December 31, 2018
Leases	$ 38	$ –
Depreciation and amortization	(956)	(533)
Compensation expense not deductible until options are exercised	18,295	12,543
All other temporary differences	934	236
Net operating loss carry forward	32,113	10,526
Less valuation allowance	(50,424)	(22,772)
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. The federal net operating loss carryforwards available for income tax purposes at December 31, 2019 amounts to approximately $120.3 million. Of this amount, $38.5 million will expire between 2037 and 2038 and $81.8 million will have an indefinite life. The federal net operating losses with an indefinite life can only offset 80% of taxable income in any one tax year. Approximately $145.1 million for state income taxes will primarily expire between 2032 and 2033.

The Company files income tax returns in the U.S. and various states. As of December 31, 2019, the Company had no unrecognized tax benefits, which would impact its tax rate if recognized. As of December 31, 2019, the Company had no accrual for the potential payment of penalties or interest. As of December 31, 2019, the Company was not subject to any U.S. federal, and state tax examinations. The Company does not anticipate any significant changes in its unrecognized tax benefits over the next 12 months.

16. 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:

	December 31, 2019	December 31, 2018	October 31 2018
Stock options	4,529,988	6,499,885	6,080,505
Unvested restricted stock grants	1,843,001	651,110	673,960

17. 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 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. On January 16, 2019, the Court granted the motion of Yedid Lawi for appointment as lead plaintiff, and on February 1, 2019, the Court granted the lead plaintiff's motion for approval of lead counsel and liaison counsel. The Court also ordered that the lead plaintiff file and serve a consolidated complaint no later than 60 days after February 1, 2019. The Lead Plaintiff filed a consolidated complaint on Aril 2, 2019, and asserted essentially the same violations of Federal securities laws recited in the original complaints. The Company filed a motion to dismiss the consolidated complaint on June 3, 2019. Plaintiffs' opposition to the Company's motion to dismiss was filed on August 2, 2019, and the Company filed a reply to the opposition on September 13, 2019. A hearing on the Company's motion to dismiss was held on November 19, 2019; no order has been issued to date. 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.

Other Matters

In the ordinary course of business, the Company may become involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements, employment, regulatory compliance, and other matters. Except as noted above, at December 31, 2019, the Company was not party to any legal or arbitration proceedings that may have significant effects on its financial position or results of operations. No governmental proceedings are pending or, to the Company's knowledge, contemplated against the Company. The Company is not a party to any material proceedings in which any director, member of senior management or affiliate of the Company's is either a party adverse to the Company or its subsidiaries or has a material interest adverse to the Company or its subsidiaries.

Commitments

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

18. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

On August 21, 2019, the Company and Dr. Denver Lough, a principal shareholder and former officer and director, signed a settlement terms agreement that provides, in part, that the Company pay to Dr. Lough $1,500,000 in cash on October 1, 2019 and an additional $1,500,000 in cash in equal monthly installments beginning November 1, 2019 and ending April 1, 2021. In addition, the Company agreed to award to Dr. Lough 200,000 restricted stock units that vest in 18 equal monthly installments beginning October 1, 2019. For the year ended December 31, 2019 the Company recognized $2.9 million of severance expense related to the cash portion of the agreement. As of December 31, 2019, the Company has recorded a liability of $1.3 million related to future cash payments under the agreement. The fair value of the restricted stock units was $0.8 million and was fully expensed upon Dr. Lough's termination.

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. 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.

During 2019, the Company increased the space leased from 3,275 square feet to 6,232 square feet. The Company is using 1,648 square feet, and Cohen LLC is using approximately 4,584 square feet as of December 31, 2019. The monthly lease payment for 6,232 square feet is $31,160. Of this amount $22,920 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. Once the space is fully occupied, the Company will reduce the overall annual lease rate for the Cohen LLC space to $58.60 per square foot. The Company recognized $0.3 million and $21,000 of sublease income related to this agreement for the year ended December 31, 2019 and two months ended December 31, 2018, respectively. The sublease income is included in other income, net in the statement of operations. As of December 31, 2019 and December 31, 2018, there were no amounts due from the related party under this agreement.

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, which terminated effective March 11, 2019 when he joined the Company as President of Corporate Development. Mr. Seaburg has since resigned from his Director position and is now serving as President of the Company.

19. 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.

During the year ended December 31, 2019, the Company's CODM changed the reporting of segment net income and loss to allocate additional noncash expenses from the regenerative medicine segment to the contract services segment. For the two months ended December 31, 2018 and the year ended October 31, 2018, this resulted in reallocation of noncash expense of $0.1 million and $0.3 million, respectively. The change is reflected in the two months ended December 31, 2018 and the year ended October 31, 2018 net loss amounts presented below.

Certain information concerning the Company's segments is presented in the following tables (in thousands):

	For the Year Ended December 31, 2019	For the Two Months Ended December 31, 2018	For the Year Ended October 31, 2018
Net revenues:			
Reportable segments:			
Regenerative medicine	$ 2,353	$ 210	$ 689
Contract services	3,299	463	874
Total net revenues	$ 5,652	$ 673	$ 1,563
Net loss:			
Reportable segments:			
Regenerative medicine	$ (91,259)	$ (18,242)	$ (64,887)
Contract services	(1,234)	(176)	(554)
Total net loss	$ (92,493)	$ (18,418)	$ (65,441)

	December 31, 2019	December 31, 2018
Identifiable assets employed:		
Reportable segments:		
Regenerative medicine	$ 48,615	$ 74,795
Contract services	4,984	5,371
Total assets	$ 53,599	$ 80,166

20. TRANSITION PERIOD COMPARATIVE FINANCIALS (UNAUDITED)

The Company changed its fiscal year end from October 31 to December 31 effective December 31, 2018. The unaudited consolidated results of operations for the year ended December 31, 2018 and the two month ended December 31, 2017 were as follows (in thousands):

	For the Year Ended December 31, 2018	For the Two Months Ended December 31, 2017
	(Unaudited)	
Net revenues		
Products	$ 886	$ 13
Services	1,337	–
Total net revenues	2,223	13
Cost of sales		
Products	693	1
Services	689	–
Total costs of sales	1,382	1
Gross profit	841	12
Operating costs and expenses		
Research and development	17,904	4,930
General and administrative	52,912	7,979
Sales and marketing	5,090	–
Total operating costs and expenses	75,906	12,909
Operating loss	(75,065)	(12,897)
Other income (expense)		
Interest income, net	457	18
Other income, net	32	–
Change in fair value of derivatives	1,850	1,964
Loss on extinguishment of warrant liability	(520)	–
Loss before income taxes	(73,246)	(10,915)
Benefit for income taxes	302	–
Net loss	(72,944)	(10,915)
Deemed dividend – accretion of discount on Series F preferred stock	(697)	(593)
Deemed dividend – exchange of Series F preferred stock	(7,057)	–
Cumulative dividends on Series F preferred stock	(191)	(182)
Net loss attributable to common stockholders	$ (80,889)	$ (11,690)
Net loss per share, basic and diluted:		
Net loss	(4.36)	(1.68)
Deemed dividend – accretion of discount on Series F preferred stock	(0.04)	(0.09)
Deemed dividend – exchange of Series F preferred stock	(0.42)	–
Cumulative dividends on Series F preferred stock	(0.01)	(0.03)
Net loss per share attributable to common stockholders	$ (4.83)	$ (1.80)
Weighted average shares outstanding, basic and diluted	16,734,610	6,496,841

Exhibit 4.7

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2019, PolarityTE, Inc. ("we", "us", "our", or the "Company") had two classes of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock and preferred stock. The following description summarizes the material terms and provisions of our common stock and preferred stock. The following description of our capital stock does not purport to be complete and is subject to, and qualified in its entirety by, our certificate of incorporation and bylaws, which are exhibits to the Annual Report on Form 10-K to which this document is attached as an exhibit, and by applicable law. You should read those documents for provisions that may be important to you. The terms of our common stock and preferred stock may also be affected by Delaware law.

Authorized Capital Stock

Our authorized capital stock consists of 250,000,000 shares of common stock, par value $0.001 per share, and 25,000,000 shares of preferred stock, par value $0.001 per share, all of which are undesignated preferred stock except for 100,000 shares designated as Series A Junior Participating Preferred Stock.

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. All outstanding shares are fully paid and non-assessable.

Preferred Stock

Our board of directors is authorized to issue up to 25,000,000 shares of undesignated preferred stock in one or more series without stockholder approval. Our board of directors may determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock in one or more series and determine the number of shares in the series and its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. Examples of rights and preferences that the board of directors may fix are:

- dividend rights;
- conversion rights;
- voting rights;
- preemptive rights;

- terms of redemption;
- liquidation preferences;
- sinking fund terms; and
- the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock.

The existence of authorized but unissued shares of undesignated preferred stock may enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of us or our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer, stockholder or stockholder group. The rights of holders of our common stock described above, will be subject to, and may be adversely affected by, the rights of any preferred stock that we may designate and issue in the future. The issuance of shares of undesignated preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

In connection with the adoption of the Rights Agreement described below, we filed a Certificate of Designation of Series A Junior Participating Preferred Stock of PolarityTE, Inc. (the "Certificate of Designation") with the Secretary of State of the State of Delaware, which designated 100,000 shares of Preferred Stock as Series A Junior Participating Preferred Stock. The Rights Agreement is described in more detail below.

Rights Agreement

On November 7, 2019, the Board authorized and declared a dividend to stockholders of record at the close of business on November 18, 2019 (the "Record Date") of one preferred share purchase right (a "Right") for each outstanding share of our common stock. Each Right entitles the holder to purchase from us one one-thousandth (subject to adjustment) of one share of our Series A Junior Participating Preferred Stock, $0.001 par value per share ("Preferred Stock") at an exercise price of $12.00 per one one-thousandth of a share of Preferred Stock (the "Purchase Price"). The complete terms of the Rights are set forth in the Rights Agreement (the "Rights Agreement"), dated as of November 7, 2019, between us and Equity Stock Transfer, LLC, as rights agent.

Generally, the Rights Agreement works by imposing a significant penalty upon any person or group (including a group of persons that are acting in concert with each other) that acquires 10% or more (or 20% or more in the case of a "Passive Institutional Investor," as defined in the Rights Agreement) of our common stock without the approval of the Board. As a result, the overall effect of the Rights Agreement and the issuance of the Rights may be to render more difficult or discourage a tender or exchange offer or other acquisition of our common stock that is not approved by the Board. The Rights Agreement does not prevent the Board from considering any offer that it considers to be in the best interest of its stockholders.

The following is a summary of the terms of the Rights Agreement. The summary is qualified in its entirety by reference to the complete text of the Rights Agreement, a copy of which is filed as Exhibit 4.1 to the Form 8-K that we filed with the SEC on November 7, 2019 and which is incorporated by reference herein.

Distribution and Transfer of Rights; Rights Certificates

The Board has declared a dividend of one Right for each outstanding share of our common stock. Prior to the Distribution Date referred to below:

- the Rights will be evidenced by and trade with the certificates for the shares of our common stock (or, with respect to any uncertificated common stock registered in book-entry form, by notation in book-entry), and no separate rights certificates will be distributed;
- new certificates for shares of our common stock issued after the Record Date will contain a legend incorporating the Rights Agreement by reference (for uncertificated shares of Common Stock registered in book-entry form, this legend will be contained in a notation in book-entry);
- the surrender for transfer of any certificates for shares of our common stock (or the surrender for transfer of any uncertificated shares of our common stock registered in book-entry form) will also constitute the transfer of the Rights associated with such shares of our common stock; and
- the Rights will accompany any new shares of our common stock that are issued after the Record Date.

Distribution Date

Subject to certain exceptions specified in the Rights Agreement, the Rights will separate from the shares of our common stock and become exercisable following the earlier of (i) the tenth (10^{th}) business day after a public announcement that either discloses that a person or a group of related persons has acquired beneficial ownership of 10% or more (or 20% or more in the case of a Passive Institutional Investor) of the shares of our common stock other than as a result of repurchases of shares of our common stock by us or certain inadvertent acquisitions (an "Acquiring Person") or information which reveals the existence of an Acquiring Person, or (ii) the tenth (10^{th}) business day (or, if such tenth (10^{th}) business day occurs before the Record Date, the close of business on the Record Date), or such later date as may be determined by the Board, after a person or a group of related persons announce or commence a tender or exchange offer that would result in a person or a group of related persons becoming an Acquiring Person. For purposes of the Rights Agreement, beneficial ownership is defined to include the ownership of derivative securities.

The date on which the Rights separate from the shares of our common stock and become exercisable is referred to as the "Distribution Date."

After the Distribution Date, we will mail Rights certificates to the Company's stockholders as of the close of business on the Distribution Date and the Rights will become transferable apart from the shares of our common stock. Thereafter, such Rights certificates alone will represent the Rights.

Exempt Persons

The Rights Agreement provides that an Acquiring Person does not include the Company, any subsidiary of the Company, any employee benefit plan of the Company or any subsidiary of the Company, or any person holding shares of our common stock for or pursuant to the terms of any such employee benefit plan of the Company. In addition, certain inadvertent acquisitions will not trigger the occurrence of the Distribution Date. The Rights Agreement also provides that any person that would otherwise be deemed an Acquiring Person as of the date of the adoption of the Rights Agreement will be exempted but only for so long as neither it nor any of its Related Persons (as defined in the Rights Agreement) acquire or are deemed to acquire, without the prior approval of the Board, beneficial ownership of any additional shares of our common stock following the adoption of the Rights Agreement.

Grandfathered Persons

The Rights Agreement provides that a "Grandfathered Person" means any Person which, together with all of its Affiliates and Associates, is, as of the date of the Agreement, the Beneficial Owner of 20% or more of the shares of our common stock then outstanding; *provided, however*, that such Person shall cease to be a Grandfathered Person and shall become an Acquiring Person if such Person exceeds its Grandfathered Percentage (as defined in the Rights Agreement) by 0.01% or more of the shares of our common stock, subject to certain exemptions for (i) any unilateral grant of any security by the Company, (ii) the exercise of any options, warrants, rights or similar interests, (iii) the grant of stock options pursuant to any written agreement with us and (iv) any increase in the percentage of stock ownership as a result of any Company stock repurchases.

Preferred Stock Purchasable Upon Exercise of Rights

After the Distribution Date, each Right will entitle the holder to purchase, for the Purchase Price, one one-thousandth of a share of Preferred Stock having economic and other terms similar to that of one share of our common stock. This portion of a share of Preferred Stock is intended to give a stockholder approximately the same dividend, voting and liquidation rights as would one share of our common stock.

Flip-In Trigger

If a person or group of related persons becomes an Acquiring Person, then each Right will entitle the holder thereof to purchase, upon payment of the Purchase Price, in accordance with the terms of the Rights Agreement, in lieu of a number of one one-thousandths of a share of Preferred Stock, a number of shares of our common stock (or, in certain circumstances, cash, property or other securities of the Company) having a then-current market value of twice the Purchase Price. However, the Rights are not exercisable following the occurrence of the foregoing event until such time as the Rights are no longer redeemable by us, as further described below.

Following the occurrence of an event set forth in the preceding paragraph, all Rights that are or, under certain circumstances specified in the Rights Agreement, were beneficially owned by an Acquiring Person or certain of its transferees will be null and void.

Flip-Over Trigger

If, after an Acquiring Person obtains 10% or more (or 20% or more in the case of a Passive Institutional Investor) of the shares of our common stock, (i) we merge into another entity, (ii) an acquiring entity merges into us, and, in connection with such transaction, all or part of the outstanding shares of our common stock are converted into stock or other securities of another entity, cash, or other property or (iii) we sell or transfer 50% or more of the Company's assets or earning power, then each Right (except for Rights that have previously been voided as set forth above) will entitle the holder thereof to purchase, upon payment of the Purchase Price, in accordance with the terms of the Rights Agreement, a number of shares of common stock of the person engaging in the transaction having a then-current market value of twice the Purchase Price.

Redemption of the Rights

The Rights will be redeemable at the Board's sole discretion for $0.001 per Right (payable in cash, shares of our common stock or other consideration deemed appropriate by the Board) at any time ending on the earlier of (i) the tenth (10^{th}) business day (or such later date as may be determined by the Board) after the public announcement that a person has acquired beneficial ownership of 10% or more (or 20% or more in the case of a Passive Institutional Investor) of the shares of our common stock and (ii) the final expiration date of the Rights Agreement. Until such time as the Rights are no longer redeemable by us, the Rights are not exercisable. Immediately upon the action of the Board ordering redemption, the Rights will terminate and the only right of the holders of the Rights will be to receive the $0.001 redemption price. The redemption price will be adjusted if we undertake a stock dividend, a stock split or similar transaction.

Exchange Provision

At any time after the date on which a person beneficially owns 10% or more (or 20% or more in the case of a Passive Institutional Investor) of the shares of our common stock and prior to the acquisition by the person of 50% or more of the shares of our common stock, the Board may exchange the Rights (other than Rights owned by the Acquiring Person or any Related Person, which would have become void), in whole or in part, for shares of our common stock at an exchange ratio (subject to adjustment) of one share of our common stock per Right (or, if insufficient shares are available, we may issue preferred stock, cash, debt or equity securities, property or a combination thereof in exchange for the Rights).

Expiration of the Rights

The Rights expire at or prior to the earlier of (i) November 7, 2020 or (ii) the redemption or exchange of the Rights as described above.

Amendment of Terms of Rights Agreement and Rights

The terms of the Rights and the Rights Agreement may be amended by action of the Board in any respect without the consent of the holders of the Rights on or prior to the time a person becomes an Acquiring Person. Thereafter, the terms of the Rights and the Rights Agreement may not be supplemented or amended in any manner that would adversely affect the interests of the holders of the Rights.

Rights of Holders

Until a Right is exercised, the holder thereof, as such, will have no rights as a stockholder of the Company, including, without limitation, the right to vote or to receive dividends.

Anti-Dilution Provisions

The Board may adjust the Purchase Price, the number of shares of Preferred Stock issuable and the number of outstanding Rights to prevent dilution that may occur from a stock dividend, a stock split or a reclassification of the Preferred Stock or common stock.

With certain exceptions, no adjustments to the Purchase Price will be made until the cumulative adjustments amount to at least 1% of the Purchase Price.

Taxes

The distribution of Rights should not be taxable for federal income tax purposes. However, following an event that renders the Rights exercisable or upon redemption of the Rights, stockholders may recognize taxable income.

Certain Anti-Takeover Effects

The Rights are not intended to prevent a takeover of the Company and should not interfere with any merger or other business combination approved by the Board. However, the Rights may cause substantial dilution to a person or group that acquires beneficial ownership of 10% or more (or 20% or more in the case of a Passive Institutional Investor) of the outstanding shares of our common stock (which includes for this purpose stock referenced in derivative transactions and securities).

Antitakeover Effects of Delaware Law and Provisions of our Restated Certificate of Incorporation and Amended and Restated Bylaws

Certain provisions of the Delaware General Corporation Law and of our restated certificate of incorporation and amended and restated bylaws could have the effect of delaying, deferring or discouraging another party from acquiring control of us unless such takeover or change of control is approved by the board of directors. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, therefore, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of us to first negotiate with our board of directors. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, we believe that the advantages gained by protecting our ability to negotiate with any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our common stock, because, among other reasons, the negotiation of such proposals could improve their terms.

Delaware Takeover Statute. We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

- Section 203 defines a business combination to include:
- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge, exchange, mortgage or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Provisions of our Restated Certificate of Incorporation and Amended and Restated Bylaws. Our restated certificate of incorporation and amended and restated bylaws include several provisions that may have the effect of delaying, deferring or discouraging another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board composition and filling vacancies. In accordance with our restated certificate of incorporation, our board is divided into three classes serving staggered three-year terms, with one class being elected each year. Our restated certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum.

No written consent of stockholders. Our restated certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholder without holding a meeting of stockholders.

Meetings of stockholders. Our bylaws provide that only a majority of the members of our board of directors then in office or stockholders holding at least one-quarter of the voting power of all the then outstanding shares of our capital stock entitled to vote generally in the election of directors may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance notice requirements. Our bylaws establish advance notice procedures regarding stockholder proposals pertaining to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 45 days or more than 75 days prior to the first anniversary date of the annual meeting for the preceding year. The notice must contain certain information specified in our bylaws.

Amendment to certificate of incorporation and bylaws. As required by the Delaware General Corporation Law, any amendment of our restated certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our restated certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment, and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, directors, amending our bylaws, limitation of liability and the amendment of our restated certificate of incorporation must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and a majority of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority vote of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of at least two-thirds of the voting power of all the then outstanding shares of our capital stock entitled to vote generally in the election of directors, voting together as a single class.

Exhibit 10.17

INCENTIVE STOCK OPTION AGREEMENT
UNDER THE POLARITYTE, INC.
2020 STOCK OPTION AND INCENTIVE PLAN

Name of Optionee:

No. of Option Shares:

Option Exercise Price per Share: $
[FMV on Grant Date]

Grant Date:

Expiration Date:
[No more than 10 years]

Pursuant to the PolarityTE, Inc. 2020 Stock Option and Incentive Plan as amended through the date hereof (the "Plan"), PolarityTE, Inc. (the "Company") hereby grants to the Optionee named above an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value $0.001 per share (the "Stock"), of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein and in the Plan.

SECTION 1 .Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as set forth below, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall be exercisable with respect to the following number of Option Shares on the dates indicated so long as the Optionee remains an employee of the Company or a Subsidiary on such dates:

Incremental Number of Option Shares Exercisable	Exercisability Date
_____ (___%)	
_____ (___%)	
_____ (___%)	
_____ (___%)	
_____ (___%)	

* Max. of $100,000 per yr.

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

SECTION 2 .Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written notice to the Administrator of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Administrator; (ii) through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that are beneficially owned by the Optionee and are not then subject to any restrictions under any Company plan and that otherwise satisfy any holding periods as may be required by the Administrator; or (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; or (iv) a combination of (i), (ii) and (iii) above. Payment instruments will be received subject to collection.

The transfer to the Optionee on the records of the Company or of the transfer agent of the Option Shares will be contingent upon (i) the Company's receipt from the Optionee of the full purchase price for the Option Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in the Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the Shares attested to.

(b) The shares of Stock purchased upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Administrator with all requirements under applicable laws or regulations in connection with such transfer and with the requirements hereof and of the Plan. The determination of the Administrator as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company or the transfer agent shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.

(c) The minimum number of shares with respect to which this Stock Option may be exercised at any one time shall be 100 shares, unless the number of shares with respect to which this Stock Option is being exercised is the total number of shares subject to exercise under this Stock Option at the time.

(d) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.

SECTION 3. Termination of Service Relationship. If the Optionee's Service Relationship by the Company or a Subsidiary (as defined in the Plan) is terminated, the period within which to exercise the Stock Option may be subject to earlier termination as set forth below.

(a) Termination Due to Death. If the Optionee's Service Relationship terminates by reason of the Optionee's death, any portion of this Stock Option outstanding on such date, to the extent exercisable on the date of death, may thereafter be exercised by the Optionee's legal representative or legatee for a period of 12 months from the date of death or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of death shall terminate immediately and be of no further force or effect.

(b) Termination Due to Disability. If the Optionee's Service Relationship terminates by reason of the Optionee's disability (as determined by the Administrator), any portion of this Stock Option outstanding on such date, to the extent exercisable on the date of such termination of Service Relationship, may thereafter be exercised by the Optionee for a period of 12 months from the date of disability or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of disability shall terminate immediately and be of no further force or effect.

(c) Termination for Cause. If the Optionee's Service Relationship terminates for Cause, any portion of this Stock Option outstanding on such date shall terminate immediately and be of no further force and effect. For purposes hereof, "Cause" shall mean, unless otherwise provided in an employment agreement (or similar services agreements) between the Company and the Optionee, a determination by the Administrator that the Optionee shall be dismissed as a result of (i) any material breach by the Optionee of any agreement between the Optionee and the Company; (ii) the conviction of, indictment for or plea of nolo contendere by the Optionee to a felony or a crime involving moral turpitude; or (iii) any material misconduct or willful and deliberate non-performance (other than by reason of disability) by the Optionee of the Optionee's duties to the Company.

(d) Other Termination. If the Optionee's Service Relationship terminates for any reason other than the Optionee's death, the Optionee's disability, or Cause, and unless otherwise determined by the Administrator, any portion of this Stock Option outstanding on such date may be exercised, to the extent exercisable on the date of termination, for a period of three months from the date of termination or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of termination shall terminate immediately and be of no further force or effect.

The Administrator's determination of the reason for termination of the Optionee's Service Relationship shall be conclusive and binding on the Optionee and his or her representatives or legatees.

SECTION 4. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

SECTION 5. Transferability. This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee.

SECTION 6. Status of the Stock Option. This Stock Option is intended to qualify as an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"), but the Company does not represent or warrant that this Stock Option qualifies as such. The Optionee should consult with his or her own tax advisors regarding the tax effects of this Stock Option and the requirements necessary to obtain favorable income tax treatment under Section 422 of the Code, including, but not limited to, holding period requirements. To the extent any portion of this Stock Option does not so qualify as an "incentive stock option," such portion shall be deemed to be a non-qualified stock option. If the Optionee intends to dispose or does dispose (whether by sale, gift, transfer or otherwise) of any Option Shares within the one-year period beginning on the date after the transfer of such shares to him or her, or within the two-year period beginning on the day after the grant of this Stock Option, he or she will so notify the Company within 30 days after such disposition.

SECTION 7. Tax Withholding. The Optionee shall, not later than the date as of which the exercise of this Stock Option becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Administrator for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Company shall have the authority to cause the required tax withholding obligation to be satisfied, in whole or in part, by withholding from shares of Stock to be issued to the Optionee a number of shares of Stock with an aggregate Fair Market Value that would satisfy the withholding amount due; provided, however, that the amount withheld does not exceed the maximum statutory tax rate or such lesser amount as is necessary to avoid adverse accounting treatment or as determined by the Administrator.

SECTION 8. No Obligation to Continue Service Relationship. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Optionee's Service Relationship and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the Service Relationship of the Optionee at any time.

SECTION 9. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.

SECTION 10. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan or this Agreement (the "Relevant Information"). By entering into this Agreement, the Optionee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Optionee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Optionee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

SECTION 11. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

POLARITYTE, INC.

By: _____

Name: _____

Title: _____

The foregoing Agreement is hereby accepted, and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

Dated: _____

_____

Grantee's Signature

Grantee's Name and address:

_____

_____

_____

_____

Exhibit 10.18

NON-QUALIFIED STOCK OPTION AGREEMENT
FOR NON-EMPLOYEE DIRECTORS
UNDER THE POLARITYTE, INC.
2020 STOCK OPTION AND INCENTIVE PLAN

Name of Optionee:

No. of Option Shares:

Option Exercise Price per Share: $
[FMV on Grant Date]

Grant Date:

Expiration Date:
[No more than 10 years]

Pursuant to the PolarityTE, Inc. 2020 Stock Option and Incentive Plan as amended through the date hereof (the "Plan"), PolarityTE, Inc. (the "Company") hereby grants to the Optionee named above, who is a Director of the Company but is not an employee of the Company, an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value $0.001 per share (the "Stock"), of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein and in the Plan. This Stock Option is not intended to be an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended.

SECTION 1. Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as set forth below, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall be exercisable with respect to the following number of Option Shares on the dates indicated so long as the Optionee remains in service as a member of the Board on such dates:

Incremental Number of Option Shares Exercisable	Exercisability Date
_____ (___%)	
_____ (___%)	
_____ (___%)	
_____ (___%)	
_____ (___%)	

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

SECTION 2. Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written notice to the Administrator of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Administrator; (ii) through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that are beneficially owned by the Optionee and are not then subject to any restrictions under any Company plan and that otherwise satisfy any holding periods as may be required by the Administrator; (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; (iv) by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; or (v) a combination of (i), (ii), (iii) and (iv) above. Payment instruments will be received subject to collection.

The transfer to the Optionee on the records of the Company or of the transfer agent of the Option Shares will be contingent upon (i) the Company's receipt from the Optionee of the full purchase price for the Option Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in the Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the Shares attested to.

(b) The shares of Stock purchased upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Administrator with all requirements under applicable laws or regulations in connection with such transfer and with the requirements hereof and of the Plan. The determination of the Administrator as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company or the transfer agent shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.

(c) The minimum number of shares with respect to which this Stock Option may be exercised at any one time shall be 100 shares, unless the number of shares with respect to which this Stock Option is being exercised is the total number of shares subject to exercise under this Stock Option at the time.

(d) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.

SECTION 3. Termination as Director. If the Optionee ceases to be a Director of the Company, the period within which to exercise the Stock Option may be subject to earlier termination as set forth below.

(a) Termination Due to Death. If the Optionee's service as a Director terminates by reason of the Optionee's death, any portion of this Stock Option outstanding on such date, to the extent exercisable on the date of death, may thereafter be exercised by the Optionee's legal representative or legatee for a period of 12 months from the date of death or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of death shall terminate immediately and be of no further force or effect.

(b) Other Termination. If the Optionee ceases to be a Director for any reason other than the Optionee's death, any portion of this Stock Option outstanding on such date may be exercised, to the extent exercisable on the date the Optionee ceased to be a Director, for a period of six months from the date the Optionee ceased to be a Director or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date the Optionee ceases to be a Director shall terminate immediately and be of no further force or effect.

SECTION 4. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

SECTION 5. Transferability. This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee.

SECTION 6. No Obligation to Continue as a Director. Neither the Plan nor this Stock Option confers upon the Optionee any rights with respect to continuance as a Director.

SECTION 7. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.

SECTION 8. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan or this Agreement (the "Relevant Information"). By entering into this Agreement, the Optionee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Optionee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Optionee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

SECTION 9. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

POLARITYTE, INC.

By: _____

Name: _____

Title: _____

The foregoing Agreement is hereby accepted, and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

Dated: _____

_____

Grantee's Signature

Grantee's Name and address:

_____

_____

_____

_____

NON-QUALIFIED STOCK OPTION AGREEMENT
FOR COMPANY EMPLOYEES
UNDER THE POLARITYTE, INC.
2020 STOCK OPTION AND INCENTIVE PLAN

Name of Optionee:

No. of Option Shares:

Option Exercise Price per Share: $
[FMV on Grant Date]

Grant Date:

Expiration Date:
[No more than 10 years]

Pursuant to the PolarityTE, Inc. 2020 Stock Option and Incentive Plan as amended through the date hereof (the "Plan"), PolarityTE, Inc. (the "Company") hereby grants to the Optionee named above an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value $0.001 per share (the "Stock") of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein and in the Plan. This Stock Option is not intended to be an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended.

SECTION 1. Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as set forth below, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall be exercisable with respect to the following number of Option Shares on the dates indicated so long as Optionee continues to have a Service Relationship with the Company or a Subsidiary on such dates:

Incremental Number of Option Shares Exercisable	Exercisability Date
_____ (___%)	
_____ (___%)	
_____ (___%)	
_____ (___%)	
_____ (___%)	

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

SECTION 2. Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written notice to the Administrator of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Administrator; (ii) through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that are beneficially owned by the Optionee and are not then subject to any restrictions under any Company plan and that otherwise satisfy any holding periods as may be required by the Administrator; (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; (iv) by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; or (v) a combination of (i), (ii), (iii) and (iv) above. Payment instruments will be received subject to collection.

The transfer to the Optionee on the records of the Company or of the transfer agent of the Option Shares will be contingent upon (i) the Company's receipt from the Optionee of the full purchase price for the Option Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in the Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the Shares attested to.

(b) The shares of Stock purchased upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Administrator with all requirements under applicable laws or regulations in connection with such transfer and with the requirements hereof and of the Plan. The determination of the Administrator as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company or the transfer agent shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.

(c) The minimum number of shares with respect to which this Stock Option may be exercised at any one time shall be 100 shares, unless the number of shares with respect to which this Stock Option is being exercised is the total number of shares subject to exercise under this Stock Option at the time.

(d) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.

SECTION 3. Termination of Service Relationship. If the Optionee's Service Relationship by the Company or a Subsidiary (as defined in the Plan) is terminated, the period within which to exercise the Stock Option may be subject to earlier termination as set forth below.

(a) Termination Due to Death. If the Optionee's Service Relationship terminates by reason of the Optionee's death, any portion of this Stock Option outstanding on such date, to the extent exercisable on the date of death, may thereafter be exercised by the Optionee's legal representative or legatee for a period of 12 months from the date of death or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of death shall terminate immediately and be of no further force or effect.

(b) Termination Due to Disability. If the Optionee's Service Relationship terminates by reason of the Optionee's disability (as determined by the Administrator), any portion of this Stock Option outstanding on such date, to the extent exercisable on the date of such termination of Service Relationship, may thereafter be exercised by the Optionee for a period of 12 months from the date of disability or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of disability shall terminate immediately and be of no further force or effect.

(c) Termination for Cause. If the Optionee's Service Relationship terminates for Cause, any portion of this Stock Option outstanding on such date shall terminate immediately and be of no further force and effect. For purposes hereof, "Cause" shall mean, unless otherwise provided in an employment agreement (or similar services agreements) between the Company and the Optionee, a determination by the Administrator that the Optionee shall be dismissed as a result of (i) any material breach by the Optionee of any agreement between the Optionee and the Company; (ii) the conviction of, indictment for or plea of nolo contendere by the Optionee to a felony or a crime involving moral turpitude; or (iii) any material misconduct or willful and deliberate non-performance (other than by reason of disability) by the Optionee of the Optionee's duties to the Company.

(d) Other Termination. If the Optionee's Service Relationship terminates for any reason other than the Optionee's death, the Optionee's disability or Cause, and unless otherwise determined by the Administrator, any portion of this Stock Option outstanding on such date may be exercised, to the extent exercisable on the date of termination, for a period of three months from the date of termination or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date of termination shall terminate immediately and be of no further force or effect.

The Administrator's determination of the reason for termination of the Optionee's Service Relationship shall be conclusive and binding on the Optionee and his or her representatives or legatees.

SECTION 4. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

SECTION 5. Transferability. This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee.

SECTION 6. Tax Withholding. The Optionee shall, not later than the date as of which the exercise of this Stock Option becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Administrator for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Company shall have the authority to cause the required tax withholding obligation to be satisfied, in whole or in part, by withholding from shares of Stock to be issued to the Optionee a number of shares of Stock with an aggregate Fair Market Value that would satisfy the withholding amount due; provided, however, that the amount withheld does not exceed the maximum statutory tax rate or such lesser amount as is necessary to avoid adverse accounting treatment or as determined by the Administrator.

SECTION 7. No Obligation to Continue Service Relationship. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Optionee's Service Relationship and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the Service Relationship of the Optionee at any time.

SECTION 8. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.

SECTION 9. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan or this Agreement (the "Relevant Information"). By entering into this Agreement, the Optionee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Optionee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Optionee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

SECTION 10. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

POLARITYTE, INC.

By: _____
Name: _____
Title: _____

The foregoing Agreement is hereby accepted, and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

Dated: _____

_____

Grantee's Signature

Grantee's Name and address:

_____

_____

_____

_____

Exhibit 10.20

NON-QUALIFIED STOCK OPTION AGREEMENT
FOR NON-EMPLOYEE CONSULTANTS
UNDER THE POLARITYTE, INC.
2020 STOCK OPTION AND INCENTIVE PLAN

Name of Optionee:

No. of Option Shares:

Option Exercise Price per Share: $
[FMV on Grant Date]

Grant Date:

Expiration Date:
[No more than 10 years]

Pursuant to the PolarityTE, Inc. 2020 Stock Option and Incentive Plan as amended through the date hereof (the "Plan"), PolarityTE, Inc. (the "Company") hereby grants to the Optionee named above, who is a Consultant of the Company, an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value $0.001 per share (the "Stock"), of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein and in the Plan. This Stock Option is not intended to be an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended.

SECTION 1. Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as set forth below, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall be exercisable with respect to the following number of Option Shares on the dates indicated so long as the Optionee remains in service to the Company or a Subsidiary as a Consultant on such dates:

Incremental Number of Option Shares Exercisable	Exercisability Date
_____ (___%)	
_____ (___%)	
_____ (___%)	
_____ (___%)	
_____ (___%)	

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

SECTION 2. Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written notice to the Administrator of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Administrator; (ii) through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that are beneficially owned by the Optionee and are not then subject to any restrictions under any Company plan and that otherwise satisfy any holding periods as may be required by the Administrator; (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; (iv) by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; or (v) a combination of (i), (ii), (iii) and (iv) above. Payment instruments will be received subject to collection.

The transfer to the Optionee on the records of the Company or of the transfer agent of the Option Shares will be contingent upon (i) the Company's receipt from the Optionee of the full purchase price for the Option Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in the Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the Shares attested to.

(b) The shares of Stock purchased upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Administrator with all requirements under applicable laws or regulations in connection with such transfer and with the requirements hereof and of the Plan. The determination of the Administrator as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company or the transfer agent shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.

(c) The minimum number of shares with respect to which this Stock Option may be exercised at any one time shall be 100 shares, unless the number of shares with respect to which this Stock Option is being exercised is the total number of shares subject to exercise under this Stock Option at the time.

(d) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.

SECTION 3. Termination of Service Relationship. If the Optionee ceases to have a Service Relationship with the Company or a Subsidiary for any reason, any portion of this Stock Option outstanding on such date may be exercised, to the extent exercisable on the date the Optionee ceased to provide services, for a period of three months from the date the Optionee ceased to provide services or until the Expiration Date, if earlier. Any portion of this Stock Option that is not exercisable on the date the Optionee ceases to have a Service Relationship with the Company or a Subsidiary shall terminate immediately and be of no further force or effect.

SECTION 4. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

SECTION 5. Transferability. This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee.

SECTION 6. No Obligation to Continue Service Relationship. Neither the Plan nor this Stock Option confers upon the Optionee any rights with respect to the continuance of Optionee's Service Relationship with the Company or a Subsidiary.

SECTION 7. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Stock Option and supersedes all prior agreements and discussions between the parties concerning such subject matter.

SECTION 8. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan or this Agreement (the "Relevant Information"). By entering into this Agreement, the Optionee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Optionee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Optionee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

SECTION 9. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

POLARITYTE, INC.

By: _____

Name: _____

Title: _____

The foregoing Agreement is hereby accepted, and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

Dated: _____

_____

Grantee's Signature

Grantee's Name and address:

_____

_____

_____

_____

Exhibit 10.21

RESTRICTED STOCK AWARD AGREEMENT
UNDER THE POLARITYTE, INC.
2020 STOCK OPTION AND INCENTIVE PLAN

Name of Optionee:

No. of Restricted Stock Shares:

Grant Date:

Pursuant to the PolarityTE, Inc. 2020 Stock Option and Incentive Plan as amended through the date hereof (the "Plan"), PolarityTE, Inc. (the "Company") hereby grants a Restricted Stock Award (an "Award") to the Grantee named above. Upon acceptance of this Award, the Grantee shall receive the number of shares of Common Stock, par value $0.001 per share (the "Stock") of the Company specified above, subject to the restrictions and conditions set forth herein and in the Plan. The Company acknowledges the receipt from the Grantee of consideration with respect to the par value of the Stock in the form of cash, past or future services rendered to the Company by the Grantee or such other form of consideration as is acceptable to the Administrator.

SECTION 1. Award. The shares of Restricted Stock awarded hereunder shall be issued and held by the Company's transfer agent in book entry form, and the Grantee's name shall be entered as the stockholder of record on the books of the Company. Thereupon, the Grantee shall have all the rights of a stockholder with respect to such shares, including voting and dividend rights, subject, however, to the restrictions and conditions specified in Paragraph 2 below. The Grantee shall (i) sign and deliver to the Company a copy of this Award Agreement and (ii) deliver to the Company a stock power endorsed in blank.

SECTION 2. Restrictions and Conditions.

(a) Any book entries for the shares of Restricted Stock granted herein shall bear an appropriate legend, as determined by the Administrator in its sole discretion, to the effect that such shares are subject to restrictions as set forth herein and in the Plan.

(b) Shares of Restricted Stock granted herein may not be sold, assigned, transferred, pledged or otherwise encumbered or disposed of by the Grantee prior to vesting.

(c) If the Grantee's Service Relationship with the Company and its Subsidiaries is voluntarily or involuntarily terminated for any reason (including death) prior to vesting of shares of Restricted Stock granted herein, all shares of Restricted Stock shall immediately and automatically be forfeited and returned to the Company.

SECTION 3. Vesting of Restricted Stock. The restrictions and conditions in Paragraph 2 of this Agreement shall lapse on the Vesting Date or Dates specified in the following schedule so long as the Grantee continues to have a Service Relationship with the Company or a Subsidiary on such Dates. If a series of Vesting Dates is specified, then the restrictions and conditions in Paragraph 2 shall lapse only with respect to the number of shares of Restricted Stock specified as vested on such date.

Incremental Number of Shares Vested	Vesting Date
_____ (___%)	
_____ (___%)	
_____ (___%)	
_____ (___%)	
_____ (___%)	

Subsequent to such Vesting Date or Dates, the shares of Stock on which all restrictions and conditions have lapsed shall no longer be deemed Restricted Stock. The Administrator may at any time accelerate the vesting schedule specified in this Paragraph 3.

SECTION 4. Dividends. Dividends on shares of Restricted Stock shall be paid currently to the Grantee.

SECTION 5. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Award shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

SECTION 6. Transferability. This Agreement is personal to the Grantee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution.

SECTION 7. Tax Withholding . The Grantee shall, not later than the date as of which the receipt of this Award becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Administrator for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. Except in the case where an election is made pursuant to Paragraph 8 below, the Company shall have the authority to cause the required tax withholding obligation to be satisfied, in whole or in part, by withholding from shares of Stock to be issued or released by the transfer agent a number of shares of Stock with an aggregate Fair Market Value that would satisfy the withholding amount due; provided, however, that the amount withheld does not exceed the maximum statutory tax rate or such lesser amount as is necessary to avoid adverse accounting treatment or as determined by the Administrator.

SECTION 8. Election Under Section 83(b). The Grantee and the Company hereby agree that the Grantee may, within 30 days following the Grant Date of this Award, file with the Internal Revenue Service and the Company an election under Section 83(b) of the Internal Revenue Code. In the event the Grantee makes such an election, he or she agrees to provide a copy of the election to the Company. The Grantee acknowledges that he or she is responsible for obtaining the advice of his or her tax advisors with regard to the Section 83(b) election and that he or she is relying solely on such advisors and not on any statements or representations of the Company or any of its agents with regard to such election.

SECTION 9. No Obligation to Continue Service Relationship. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Grantee in the Service Relationship and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the Service Relationship of the Grantee at any time.

SECTION 10. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Award and supersedes all prior agreements and discussions between the parties concerning such subject matter.

SECTION 11. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of

the Plan or this Agreement (the "Relevant Information"). By entering into this Agreement, the Grantee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Grantee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Grantee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

SECTION 12. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Grantee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

POLARITYTE, INC.

By: _____
Name: _____
Title: _____

The foregoing Agreement is hereby accepted, and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

Dated: _____

_____
Grantee's Signature

Grantee's Name and address:

_____
_____
_____
_____

Exhibit 10.22

RESTRICTED STOCK UNIT AWARD AGREEMENT
FOR NON-EMPLOYEE DIRECTORS
UNDER THE POLARITYTE, INC.
2020 STOCK OPTION AND INCENTIVE PLAN

Name of Optionee:

No. of Restricted Stock Units:

Grant Date:

Pursuant to the PolarityTE, Inc. 2020 Stock Option and Incentive Plan as amended through the date hereof (the "Plan"), PolarityTE, Inc. (the "Company") hereby grants an award of the number of Restricted Stock Units listed above (an "Award") to the Grantee named above. Each Restricted Stock Unit shall relate to one share of Common Stock, par value $0.001 per share (the "Stock") of the Company.

SECTION 1. Restrictions on Transfer of Award. This Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of by the Grantee, and any shares of Stock issuable with respect to the Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until (i) the Restricted Stock Units have vested as provided in Paragraph 2 of this Agreement and (ii) shares of Stock have been issued to the Grantee in accordance with the terms of the Plan and this Agreement.

SECTION 2. Vesting of Restricted Stock Units. The restrictions and conditions of Paragraph 1 of this Agreement shall lapse on the Vesting Date or Dates specified in the following schedule so long as the Grantee remains in service as a member of the Board on such Dates. If a series of Vesting Dates is specified, then the restrictions and conditions in Paragraph 1 shall lapse only with respect to the number of Restricted Stock Units specified as vested on such date.

Incremental Number of Restricted Stock Units Vested	Vesting Date
_____ (___%)	
_____ (___%)	
_____ (___%)	
_____ (___%)	

The Administrator may at any time accelerate the vesting schedule specified in this Paragraph 2.

SECTION 3. Termination of Service. If the Grantee's service with the Company and its Subsidiaries terminates for any reason (including death or disability) prior to the satisfaction of the vesting conditions set forth in Paragraph 2 above, any Restricted Stock Units that have not vested as of such date shall automatically and without notice terminate and be forfeited, and neither the Grantee nor any of his or her successors, heirs, assigns, or personal representatives will thereafter have any further rights or interests in such unvested Restricted Stock Units.

SECTION 4. Issuance of Shares of Stock. As soon as practicable following each Vesting Date (but in no event later than two and one-half months after the end of the year in which the Vesting Date occurs), the Company shall issue to the Grantee the number of shares of Stock equal to the aggregate number of Restricted Stock Units that have vested pursuant to Paragraph 2 of this Agreement on such date and the Grantee shall thereafter have all the rights of a stockholder of the Company with respect to such shares.

SECTION 5. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Agreement shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

SECTION 6. Section 409A of the Code. This Agreement shall be interpreted in such a manner that all provisions relating to the settlement of the Award are exempt from the requirements of Section 409A of the Code as "short-term deferrals" as described in Section 409A of the Code.

SECTION 7. No Obligation to Continue as a Director. Neither the Plan nor this Award confers upon the Grantee any rights with respect to continuance as a Director.

SECTION 8. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Award and supersedes all prior agreements and discussions between the parties concerning such subject matter.

SECTION 9. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan or this Agreement (the "Relevant Information"). By entering into this Agreement, the Grantee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Grantee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Grantee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

SECTION 10. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Grantee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

POLARITYTE, INC.

By: _____

Name: _____

Title: _____

The foregoing Agreement is hereby accepted, and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

Dated: _____

_____
Grantee's Signature

Grantee's Name and address:

_____

_____

_____

_____

Exhibit 10.23

RESTRICTED STOCK UNIT AWARD AGREEMENT
FOR COMPANY EMPLOYEES
UNDER THE POLARITYTE, INC.
2020 STOCK OPTION AND INCENTIVE PLAN

Name of Optionee:

No. of Restricted Stock Units:

Grant Date:

Pursuant to the PolarityTE, Inc. 2020 Stock Option and Incentive Plan as amended through the date hereof (the "Plan"), PolarityTE, Inc. (the "Company") hereby grants an award of the number of Restricted Stock Units listed above (an "Award") to the Grantee named above. Each Restricted Stock Unit shall relate to one share of Common Stock, par value $0.001 per share (the "Stock") of the Company.

SECTION 1. Restrictions on Transfer of Award. This Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of by the Grantee, and any shares of Stock issuable with respect to the Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until (i) the Restricted Stock Units have vested as provided in Paragraph 2 of this Agreement and (ii) shares of Stock have been issued to the Grantee in accordance with the terms of the Plan and this Agreement.

SECTION 2. Vesting of Restricted Stock Units. The restrictions and conditions of Paragraph 1 of this Agreement shall lapse on the Vesting Date or Dates specified in the following schedule so long as the Grantee continues to have a Service Relationship with the Company or a Subsidiary on such dates. If a series of Vesting Dates is specified, then the restrictions and conditions in Paragraph 1 shall lapse only with respect to the number of Restricted Stock Units specified as vested on such date.

Incremental Number of Restricted Stock Units Vested	Vesting Date
_____ (___%)	
_____ (___%)	
_____ (___%)	
_____ (___%)	

The Administrator may at any time accelerate the vesting schedule specified in this Paragraph 2.

SECTION 3. Termination of Service Relationship. If the Grantee's Service Relationship with the Company and its Subsidiaries terminates for any reason (including death or disability) prior to the satisfaction of the vesting conditions set forth in Paragraph 2 above, any Restricted Stock Units that have not vested as of such date shall automatically and without notice terminate and be forfeited, and neither the Grantee nor any of his or her successors, heirs, assigns, or personal representatives will thereafter have any further rights or interests in such unvested Restricted Stock Units.

SECTION 4. Issuance of Shares of Stock. As soon as practicable following each Vesting Date (but in no event later than two and one-half months after the end of the year in which the Vesting Date occurs), the Company shall issue to the Grantee the number of shares of Stock equal to the aggregate number of Restricted Stock Units that have vested pursuant to Paragraph 2 of this Agreement on such date and the Grantee shall thereafter have all the rights of a stockholder of the Company with respect to such shares.

SECTION 5. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Agreement shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

SECTION 6. Tax Withholding. The Grantee shall, not later than the date as of which the receipt of this Award becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Administrator for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Company shall have the authority to cause the required tax withholding obligation to be satisfied, in whole or in part, by withholding from shares of Stock to be issued to the Grantee a number of shares of Stock with an aggregate Fair Market Value that would satisfy the withholding amount due; provided, however, that the amount withheld does not exceed the maximum statutory tax rate or such lesser amount as is necessary to avoid adverse accounting treatment or as determined by the Administrator.

SECTION 7. Section 409A of the Code. This Agreement shall be interpreted in such a manner that all provisions relating to the settlement of the Award are exempt from the requirements of Section 409A of the Code as "short-term deferrals" as described in Section 409A of the Code.

SECTION 8. No Obligation to Continue Service Relationship. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Grantee in the Service Relationship and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the Service Relationship of the Grantee at any time.

SECTION 9. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Award and supersedes all prior agreements and discussions between the parties concerning such subject matter.

SECTION 10. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the "Relevant Companies") may process any and all personal or professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan or this Agreement (the "Relevant Information"). By entering into this Agreement, the Grantee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Grantee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Grantee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

SECTION 11. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Grantee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

POLARITYTE, INC.

By: _____

Name: _____

Title: _____

The foregoing Agreement is hereby accepted, and the terms and conditions thereof hereby agreed to by the undersigned. Electronic acceptance of this Agreement pursuant to the Company's instructions to the Grantee (including through an online acceptance process) is acceptable.

Dated: _____

_____

Grantee's Signature

Grantee's Name and address:

_____

_____

_____

_____

Exhibit 10.28

SUBLEASE

KEY PROVISIONS

Sublease Date:	April 12, 2019	
Sublandlord:	JOSEPH M. STILL BURN CENTERS, INC., a Georgia corporation	
Subtenant:	POLARITYTE MD, INC., a Nevada corporation	
Premises:	Those certain premises containing approximately 7,000 rentable square feet of space located at 3647 J. Dewey Grey Circle, Augusta, Richmond County, Georgia, known as Suite 251 and as more particularly shown on Exhibit B attached hereto. Subtenant approves and accepts the aforementioned square footage of the Premises.	
Master Landlord:	DOC-MOB AUGUSTA II, LLC, a Georgia limited liability company	
Master Lease:	Lease between Master Landlord, as landlord, and Sublandlord, as tenant, dated June 24, 2016, for the lease of the Premises and certain other premises by Master Landlord to Sublandlord, all as more particularly set forth in the Master Lease. The Master Lease is attached hereto as Exhibit A. The "Master Lease" shall also include any future amendments, modifications and/or extensions of the Master Lease.	
Notice Addresses:	Sublandlord:	Subtenant:
	Joseph M. Still Burn Centers, Inc. 3651 Wheeler Road, Suite 300 Augusta, Georgia 30909 Attention: Fred Mullins, MD	PolarityTE MD, Inc. c/o PolarityTE, Inc. 123 N Wright Brothers Drive Salt Lake City, UT 84116 Attn: General Counsel phone: 800-560-3983 email: legal@polarityte.com
Commencement Date:	The Sublease Date	
Rent Commencement Date:	The earlier of (i) the date of Subtenant's receipt of a certificate of occupancy allowing Subtenant to use and occupy the Premises, or (ii) the date that is one hundred twenty (120) days after the Sublease Date.	
Expiration Date:	The date five (5) years after the Rent Commencement Date, provided that if such date falls during the middle of a month, then the Expiration Date shall be the last day of such month.	
Renewal Terms:	One (1) renewal term of three (3) years, followed by one (1) renewal term of two (2) years.	
Base Rent:	Period	Monthly Base Rent
	Initial Term	$11,083.34
	1st Renewal Term	$11,415.84
	2nd Renewal Term	$11,758.32
	For the purpose of this Sublease, "Lease Year" means each successive consecutive twelve (12) month period during the Sublease Term commencing on the Rent Commencement Date, provided that if the Rent Commencement Date is not on the first (1st) day of a calendar month, then the first (1st) Lease Year shall commence on the Rent Commencement Date and shall end on the last day of the calendar month one (1) year after the Rent Commencement Date.	
Additional Rent:	See Section 4 of this Sublease.	
Subtenant's Share:	15.19%	
Permitted Use:	Subject to (and to the extent permitted by) any restrictions and limitations in the Master Lease and/or in this Sublease and subject to (and to the extent permitted by) all applicable laws, ordinances, regulations and other governmental and quasi-governmental requirements, only for operating a biomedical manufacturing facility, laboratory and related office use, and/or other legitimate business purpose of Subtenant.	
Brokers:	None.	
Exhibits/Attachments:	Exhibit A – Master Lease Exhibit B – Floor Plan Consent of Master Landlord	

Sublandlord's Initials _____ Subtenant's Initials _____

SUBLEASE AGREEMENT

THIS SUBLEASE is made as of the Sublease Date between Sublandlord and Subtenant, and is consented to by Master Landlord pursuant to the Consent of Master Landlord attached to this Sublease.

Recitals

A. Sublandlord leases the Premises from Master Landlord pursuant to the Master Lease. Sublandlord desires to sublease to Subtenant the Premises pursuant to this Sublease and Subtenant desires to sublease from Sublandlord the Premises pursuant to this Sublease, all upon the terms and conditions set forth in this Sublease.

For good and valuable consideration, the receipt and sufficiency of which is acknowledged, Sublandlord subleases unto Subtenant, and Subtenant subleases from Sublandlord, the Premises upon the following terms and conditions:

1. Master Lease. Each reference in this Sublease to any Key Provision shall incorporate all of the terms provided for under such Key Provision and shall be read in conjunction with all other provisions of this Sublease applicable thereto. Subtenant acknowledges and agrees that Subtenant has received and reviewed the Master Lease, a copy of which is attached hereto and made a part hereof as Exhibit A. Subtenant covenants and agrees that this Sublease is made upon, and shall be subject and subordinate to: (A) all of the terms, covenants and conditions of the Master Lease, except Sections 1, 2.1, 8, 12, 20, 24.14, 25, and 26 and Exhibits B, C, D, and E (including all future amendments, modifications and extensions of the Master Lease made by Sublandlord from time to time; provided that no such amendment, modification or extension shall be binding upon Subtenant if such amendment, modification or extension would decrease the rights of Subtenant (other than to a de minimis extent) or increase the obligations of Subtenant under this Sublease (other than to a de minimis extent) unless consented to by Subtenant (which consent shall not be unreasonably withheld, conditioned or delayed), and Sublandlord shall provide notice to Subtenant of all other non-material amendments and modifications of the Master Lease), (B) all mortgages, leases and other documents to which the Master Lease is (or may hereafter become) subject and subordinate in accordance with the terms and conditions of the Master Lease, and (C) all easements, covenants, conditions, restrictions and other matters of record. Subtenant shall, within ten (10) business days of request, execute such commercially reasonable certificates and/or instruments requested by Sublandlord to confirm such subordination. Except as otherwise provided in this Sublease, Subtenant covenants and agrees to and for the benefit of Sublandlord, and Subtenant represents and warrants to Sublandlord, (a) to assume, faithfully perform and comply with, observe and be bound by all of the terms, covenants, obligations, agreements and conditions required to be performed or observed by Sublandlord (as the "Tenant" under the Master Lease) under the Master Lease with respect to the Premises, all of which shall constitute terms of this Sublease; (b) to faithfully comply with, observe and be bound by all rules and regulations (if any) promulgated by Master Landlord pursuant to the Master Lease or otherwise attached to the Master Lease, all of which shall constitute terms of this Sublease; (c) to indemnify, protect, defend, hold harmless and reimburse Sublandlord from, for and against any and all liabilities, penalties, demands, claims, damages (including, without limitation, consequential damages), costs and expenses (including, without limitation, attorneys' fees and court costs) incurred under or pursuant to the Master Lease or otherwise by reason of Subtenant's failure to fully comply with or observe any of the terms, covenants, obligations, agreements or conditions required to be performed or observed by Sublandlord (as the "Tenant" under the Master Lease) under the Master Lease with respect to the Premises unless arising from the gross negligence or willful misconduct of Sublandlord; (d) that any default by Master Landlord under the Master Lease shall not affect this Sublease or waive or defer the performance of any of Subtenant's obligations or covenants under this Sublease; (e) that Subtenant shall not do or cause to be done any act which would or might cause the Master Lease or the rights of Sublandlord as "Tenant" under the Master Lease to be endangered, canceled, terminated, forfeited or surrendered, or which would or would reasonably be expected to cause Sublandlord to be in default or breach under the Master Lease or liable for any damage, claim or penalty under the Master Lease; and (f) to obtain Sublandlord's consent whenever Master Landlord's consent is required under the Master Lease; provided that such consent shall not be unreasonably withheld, conditioned or delayed. If there is any conflict between the provisions of this Sublease and the provisions of the Master Lease which would (or may) permit Subtenant to do or cause to be done any act which is (or may be) prohibited by the Master Lease, then, unless otherwise specified by Sublandlord in Sublandlord's sole discretion, the provisions of the Master Lease shall prevail. Subtenant acknowledges and agrees that: (1) Sublandlord does not covenant or agree to do or perform any obligations or covenants undertaken or assumed by Master Landlord under the Master Lease, provided that in the event that Subtenant determines in good faith that Master Landlord has not performed its obligations under the Master Lease and such failure materially interferes with Subtenant's use of the Premises, then upon receipt of written notice from Subtenant, Sublandlord shall, at Subtenant's expense to the extent such failure relates to the Premises (including Subtenant reimbursing Sublandlord for Sublandlord's reasonable attorneys' fees), be obligated to use commercially reasonable efforts to cause such breaches, defaults or failures of Master Landlord under the Master Lease to be resolved or otherwise settled to Sublandlord's and Subtenant's reasonable satisfaction, provided that in no event shall Sublandlord be required or obligated to terminate the Master Lease, and (2) Sublandlord shall not be liable to Subtenant for any early termination of, or any default under, the Master Lease which is not caused by a default on the part of Sublandlord. Notwithstanding anything contained in this Sublease or otherwise, Subtenant shall not have any right or privilege (and Subtenant shall not have the right or ability to exercise any right or privilege) granted to Sublandlord under or pursuant to the Master Lease, including, without limitation, any consent or approval right, any right to renew or extend the term of the Master Lease, right of first refusal to purchase, right of first refusal to lease, right of first offer, option to purchase, option to lease or any other similar right or option granted in the Master Lease or any other right or option granted to Sublandlord in the Master Lease or otherwise. In addition, nothing contained in this Sublease or otherwise shall obligate (or be deemed to obligate) Sublandlord to exercise any renewal or extension right or option. Notwithstanding anything to the contrary contained in this Sublease, if the Master Lease is terminated for any reason or otherwise expires, then this Sublease shall automatically terminate and be of no further force or effect (except for Subtenant's obligations, liabilities and indemnities under this Sublease which survive any such termination or expiration) without any liability to Sublandlord, and Subtenant shall vacate the Premises prior to the expiration or termination of the Master Lease, and Subtenant shall have no further rights or interest in or to the Premises or under this Sublease.

Further, except as otherwise stated herein, the parties understand that (i) references in the Master Lease to the "Premises" shall be deemed to refer to the Premises defined under this Sublease, (ii) references in the Master Lease to the "Landlord" and to the "Tenant" shall be deemed to refer to "Sublandlord" and "Subtenant" under this Sublease, respectively, (iii) references in the Master Lease to the "Term" shall be deemed to refer to the "Sublease Term", (iv) references in the Master Lease to the "Base Rent," shall be deemed to refer to the Base Rent defined under this Sublease, (v) references in the Master Lease to the "Additional Rent," shall be deemed to refer to the Additional Rent defined in this Sublease, and (vi) references in the Master Lease to "Tenant's Proportionate Share" shall be deemed to refer to Subtenant's Share as defined under this Sublease. It is further understood that, except as otherwise stated herein, where reference is made in the Master Lease to "this Lease" the same shall be deemed to refer to "this Sublease." All capitalized and other terms not otherwise defined herein shall have the meanings ascribed to them in the Master Lease, unless the context clearly requires otherwise. Notwithstanding the foregoing provisions of this paragraph, Sublandlord is not assuming (and Sublandlord shall not be liable or obligated for) any of Master Landlord's obligations, covenants, agreements or liabilities under the Master Lease.

2. Sublease Term. Unless terminated earlier pursuant to the terms of this Sublease, the term of this Sublease shall begin on the Commencement Date and shall continue until the Expiration Date (the "**Sublease Initial Term**"). Subtenant shall have the right to extend the Sublease Initial Term for the Renewal Terms, provided that (i) Subtenant is not in default under this Sublease at the time Subtenant exercises each Renewal Term or at the commencement of each Renewal Term, (ii) the Master Lease and this Sublease are both in full force and effect, and (iii) Subtenant provides to Sublandlord written notice exercising the Renewal Term at least one hundred eighty (180) days prior to the expiration of the then current Sublease Term (time being of the essence). The Sublease Renewal Terms, if exercised by Subtenant, shall be upon all the terms and conditions set forth in this Sublease, except as to the Renewal Term being exercised. "**Sublease Term**" means the Sublease Initial Term and the Sublease Renewal Terms (if exercised). Base Rent during each Lease Year shall increase by three percent (3%) as set forth under "Base Rent" in the Key Provisions of this Sublease.

3. Rent. Subtenant shall pay to Sublandlord the Base Rent (plus applicable sales tax thereon), in advance, on the first day of each month, without notice, demand, deduction, abatement or offset, commencing on the Rent Commencement Date and continuing during the remainder of the Sublease Term. The first monthly installment of Base Rent (plus applicable sales tax thereon) shall be paid to Sublandlord by Subtenant on the Commencement Date. Base Rent for any partial calendar month shall be prorated on a per diem basis. Subtenant shall pay any other amounts due under this Sublease within ten (10) business days of demand. If Sublandlord pays any amounts, sums or payments required to be paid by Subtenant under this Sublease or for which Subtenant is otherwise responsible or liable for, then Subtenant shall reimburse Sublandlord for such amounts, sums or payments within ten (10) business days of demand. In addition, any additional rent and other sums payable by Subtenant under this Sublease for any partial calendar year or month during the Sublease Term shall be prorated accordingly. Sublandlord and Subtenant acknowledge and agree that the Base Rent as set forth herein and any additional rent payable hereunder (including any Base Rent increases, if any such increases are contemplated under this Sublease or are otherwise agreed upon by the parties), was determined by a reputable third-party valuation consultant to be at fair market value and was determined to be commercially reasonable and without taking into account the volume or value of any referrals or other business generated between the parties or affiliates of the parties.

4. Additional Rent; Repairs; Utilities.

(a) In addition to Subtenant's obligation to pay Base Rent and Subtenant's other obligations under this Sublease, Subtenant shall: (i) commencing on the Commencement Date and continuing during the remainder of the Sublease Term, at Subtenant's own cost and expense and without notice, deduction, abatement or offset, perform, complete and pay for all repairs, replacements, maintenance, restorations and other work required of Sublandlord (as the "Tenant" under the Master Lease) under the Master Lease with respect to the Premises, all in accordance with the terms and provisions of the Master Lease, (ii) commencing on the Rent Commencement Date and continuing during the remainder of the Sublease Term, pay to Sublandlord Subtenant's Share of all Operating Expenses (as defined in the Master Lease, which amounts shall be estimated and reconciled as set forth in the Master Lease), and (iii) commencing on the Commencement Date and continuing during the remainder of the Sublease Term, pay, prior to delinquency and to the appropriate utility company or other provider (or to Sublandlord if any such utility is submetered, Subtenant acknowledging and agreeing that electricity will be submetered), for all utilities and services consumed in, at or from the Premises (including, without limitation, water, sewer, power, electricity, telephone, internet and cable) to the extent such amounts are not included in Operating Expenses.

(b) Subtenant's Share of Operating Expenses shall be paid in monthly installments beginning on the date of the first payment of Base Rent, and thereafter on the first day of each month, in such amounts as are reasonably estimated by Sublandlord. Subtenant acknowledges and agrees that that any statements received from Master Landlord with respect to Operating Expenses shall be conclusive and binding upon Subtenant.

(c) Subtenant shall pay and be responsible for paying directly to the utility provider all utilities which are separately metered to the Premises. If any utilities provided to the Premises are separately submetered, then Sublandlord will provide Subtenant with monthly invoices for the costs of such utilities and Subtenant shall pay such invoices within thirty (30) days after receipt thereof. Subtenant shall pay and be responsible for paying all costs of telephone, television, internet and security installations and service serving the Premises solely. Subtenant shall also pay and be responsible for all costs, expenses and fees of all heat, ventilation and air conditioning supplied to the Premises. Subtenant acknowledges and agrees that the heat, ventilation and air conditioning for the Premises may not be separately metered to the Premises and that the heat, ventilation and air conditioning system that serves the Premises may serve other space in the Building. In such event, Subtenant shall pay to Sublandlord (or as Sublandlord shall otherwise direct), and Subtenant shall be liable and responsible for, Subtenant's proportionate share of the costs, expenses and fees of such heat, ventilation and air conditioning (including the costs, expenses and fees of all electricity for the heat, ventilation and air conditioning system), but excluding the costs, expenses and fees of operating, maintaining, repairing and replacing the heat, ventilation and air conditioning system; provided that Subtenant shall not be liable for such costs, expenses and fees to the extent such costs, expenses and/or fees are already included as an Operating Expense. For the purpose of this Section 4(c), Subtenant's proportionate share shall be a fraction, the numerator of which shall be the total rentable square footage of the Premises and the denominator of which shall be the total rentable square footage of all space served by the heat, ventilation and air conditioning system (including the Premises).

(d) Sublandlord shall have no obligation under this Sublease or otherwise to, and shall not be responsible for the failure of any other party to, maintain, repair, replace or restore the Premises (or any portion thereof); provided that in the event that Subtenant determines in good faith that Master Landlord has not performed its obligations under the Master Lease and such failure materially interferes with Subtenant's use of the Premises, then upon receipt of written notice from Subtenant, Sublandlord shall, at Subtenant's expense to the extent such failure relates to the Premises (including Subtenant reimbursing Sublandlord for Sublandlord's reasonable attorneys' fees), be obligated to use commercially reasonable efforts to cause such breaches, defaults or failures of Master Landlord under the Master Lease to be resolved or otherwise settled to Sublandlord's and Subtenant's reasonable satisfaction, provided that in no event shall Sublandlord be required or obligated to terminate the Master Lease. On or before the Commencement Date, Subtenant shall, at Subtenant's own cost and expense, have all utilities for the Premises transferred into Subtenant's name and pay to the applicable utility provider any and all deposits and fees required in connection with all utilities solely serving the Premises. Subtenant's obligations under this Section 4 that accrued prior to the expiration or earlier termination of this Sublease shall survive the expiration or any earlier termination of this Sublease.

5. Insurance.

(a) Subtenant shall, at Subtenant's own cost, maintain throughout the Sublease Term all of the insurance coverage required to be maintained by Sublandlord (as the "Tenant" under the Master Lease) under the Master Lease, all pursuant to and in accordance with the terms and requirements of the Master Lease. Subtenant covenants and agrees that all such insurance shall comply with all of the terms and requirements of the Master Lease. In addition, Subtenant shall, at Subtenant's own cost, also maintain throughout the Sublease Term commercial general liability insurance covering bodily injury, death and property damage (including a contractual liability endorsement), with limits of not less than $2,000,000.00 per occurrence and with a $4,000,000.00 general aggregate limit, and with Sublandlord, Master Landlord and their respective designees named as additional insureds thereunder.

(b) Subtenant shall (i) name Sublandlord and Master Landlord as additional insureds under all insurance policies required to be maintained by, or actually maintained by, Subtenant, and (ii) provide Sublandlord and Master Landlord, immediately upon demand, with certificates of insurance evidencing the insurance required to be maintained by Subtenant under this Sublease. In addition, all insurance policies required to be maintained by Subtenant hereunder shall (A) provide that such insurance shall not be canceled, terminated or changed or the coverage reduced without thirty (30) days' prior written notice to Sublandlord and Master Landlord, (B) contain a waiver of subrogation provision in favor of Sublandlord and Master Landlord in form and substance reasonably acceptable to Sublandlord and Master Landlord, (C) be issued by insurance companies authorized and licensed to do business in the State where the Premises are located and by insurance companies who have a general policy holder's rating of not less than "A XII" as stated in the most current available Best's Insurance Reports and who are also authorized to issue such policies, (D) contain deductibles acceptable to Sublandlord in Sublandlord's reasonable discretion, and (E) otherwise be in form and substance acceptable to Sublandlord in Sublandlord's reasonable discretion.

(c) Notwithstanding anything contained in this Sublease or otherwise, (i) Sublandlord shall not be liable to Subtenant for (and Subtenant hereby unconditionally waives all claims against Sublandlord in connection with) any loss or damage to any property (including, without limitation, any property, equipment or contents of the Premises or located on the Premises) from any cause whatsoever, including, without limitation, the negligence or misconduct of Sublandlord or any of Sublandlord's agents, invitees, employees, contractors or representatives; and (ii) Master Landlord shall not be liable to Subtenant for (and Subtenant hereby unconditionally waives all claims against Master Landlord in connection with) any loss or damage to any property (including, without limitation, any property, equipment or contents of the Premises or located on the Premises) from any cause whatsoever, including, without limitation, the negligence or misconduct of Master Landlord or any of Master Landlord's agents, invitees, employees, contractors or representatives. All policies of fire and extended coverage or other property damage insurance maintained (or required by this Sublease to be maintained) by Subtenant shall contain an endorsement in which the insurer recognizes this release by its insured and waives all rights of legal and conventional subrogation against the other party, and Subtenant agrees that no insurer shall hold any right of subrogation against Sublandlord or Master Landlord.

(d) Subtenant's obligations and agreements under this Section 5 shall survive the expiration or any earlier termination of this Sublease.

6. Use; Indemnification; Waiver. During Subtenant's use of the Premises during the Sublease Term, Subtenant shall be afforded the right to use the Premises on an exclusive basis (subject to the other terms of this Sublease and the terms of the Master Lease). Subtenant shall (a) use the Premises for the Permitted Use only and for no other use or purpose; (b) not conduct in or on the Premises (nor permit to be conducted in or on the Premises) waste or any business which is in violation of any governmental or quasi-governmental law, rule, regulation, ordinance or requirement or any insurance requirement or in violation of the Master Lease; and (c) maintain the Premises in a sanitary, clean, safe and operable condition and otherwise in a manner and condition acceptable to Sublandlord in Sublandlord's reasonable discretion subject to ordinary wear and tear and casualty damage. Subtenant represents and warrants to Sublandlord that Subtenant is authorized to enter into this Sublease, and that Subtenant is a validly existing entity authorized to do business in the State where the Premises are located. Sublandlord represents and warrants to Subtenant that (i) Sublandlord is authorized to enter into this Sublease and (ii) as of the date hereof, to the actual knowledge of Sublandlord, Sublandlord and Master Landlord are in compliance with the terms, conditions and covenants of the Master Lease in all material respects. Without limiting any other indemnification set forth in this Sublease and except to the extent arising from the gross negligence or willful misconduct of Sublandlord or Master Landlord, Subtenant shall indemnify, protect, defend, reimburse and hold harmless Sublandlord and Master Landlord from, for and against any and all damages (including, without limitation, consequential damages), losses, liabilities, judgments, costs, claims, liens, expenses, penalties, suits, demands, actions, fines and expenses (including, without limitation, attorneys' fees and court costs) directly or indirectly arising out of or relating to (i) any act or omission of Subtenant or any of Subtenant's employees, agents, invitees, customers or contractors, (ii) the use or occupancy of the Premises, or (iii) any default or breach by Subtenant under this Sublease. Without limiting any other indemnification set forth in this Sublease, Sublandlord shall indemnify, protect, defend, reimburse and hold harmless Subtenant from, for and against any and all damages (excluding consequential damages which both parties agree not to seek), losses, liabilities, judgments, costs, claims, liens, expenses, penalties, suits, demands, actions, fines and expenses (including, without limitation, attorneys' fees and court costs) directly or indirectly arising out of or relating to (A) the gross negligence or willful misconduct of Sublandlord or any of Sublandlord's employees, agents, invitees, customers or contractors, or (B) any default or breach by Sublandlord under this Sublease. This Section 6 shall survive the expiration or earlier termination of this Sublease.

7. Condition of Premises; Alterations; Repairs.

(a) Subtenant has examined the Premises and accepts the Premises in **"AS IS"** and **"WHERE IS"** condition, with all faults and defects, both known and unknown, and Subtenant acknowledges and agrees that neither Sublandlord nor any of Sublandlord's agents, employees or representatives have made any representation or warranty, either express or implied, with respect to the Premises or the use thereof by Subtenant or the condition of the Premises or the size or square footage of the Premises; provided that Sublandlord represents, to its actual knowledge without a duty to investigate, that the Premises are not in violation of any applicable laws in any material respect and that there are no material damages or material defects with respect to the Premises that would not be detected during a physical inspection. Subtenant further acknowledges and agrees that no representations or promises to alter, remodel or improve the Premises have been made by Sublandlord or Master Landlord or any other person or entity, and Sublandlord shall have no obligation under this Sublease or otherwise to, and shall not be responsible for the failure of any other party to, maintain, repair or replace the Premises. Subtenant shall use the Premises at Subtenant's own risk. Sublandlord shall not be liable to Subtenant or any of Subtenant's employees, licensees, invitees or guests or any other person for any loss, injury or damage to property or person occasioned by theft, casualty, force majeure or any other cause.

(b) Subtenant shall not make (or permit or allow to be made) any alterations, additions, improvements, repairs or replacements to the Premises without the prior written consent of Sublandlord (and Master Landlord if required by the Master Lease), provided that such consent of Sublandlord shall not be unreasonably withheld, conditioned or delayed. If Subtenant desires to perform any alterations, additions, improvements, repairs or replacements to the Premises, then Sublandlord shall have the right to require Subtenant to prepare, at Subtenant's expense, plans and specifications for such alterations, additions, improvements, repairs or replacements and such plans and specifications shall be subject to the prior written consent of Sublandlord (and Master Landlord if required by the Master Lease), provided that such consent of Sublandlord shall not be unreasonably withheld, conditioned or delayed. If any alterations, additions, improvements, repairs or replacements are consented to by Sublandlord (and by Master Landlord if required by the Master Lease), then Subtenant shall (a) comply with all requirements of the Master Lease with respect to such alterations, additions, improvements, repairs or replacements, (b) promptly (and in any event prior to its due date) pay in full all costs and expenses incurred or associated with any such alterations, additions, improvements, repairs or replacements, (c) deliver to Sublandlord, within ten (10) business days of Sublandlord's written or oral request, detailed proof acceptable to Sublandlord showing that all outstanding invoices for all alterations, additions, improvements, repairs and replacements have been paid in full, (d) complete and perform such alterations, additions, improvements, repairs and replacements in a good and workmanlike manner and in compliance with all laws, codes and ordinances and all insurance requirements, and (e) complete and perform such alterations, additions, improvements, repairs and replacements in accordance with the plans and specifications (if any) approved by Sublandlord and otherwise in a manner acceptable to Sublandlord. Any alterations, additions, improvements, repairs or replacements made by or for (or at the request of) Subtenant and consented to by Sublandlord (and Master Landlord if required by the Master Lease) shall remain on and be surrendered with the Premises upon the expiration or earlier termination of the Sublease Term and Subtenant shall not be required to remove any such alterations, additions, improvements, repairs or replacements, unless required to be removed pursuant to the Master Lease, in which case Subtenant shall, at Subtenant's own cost, promptly and diligently remove such alterations, additions, improvements, repairs and replacements and repair all damage caused by such removal.

(c) Subtenant's obligations and liabilities under this Section 7 shall survive the expiration or earlier termination of this Sublease.

8. Default. The occurrence of one or more of the following events (each, an "**Event of Default**") shall constitute an immediate default and Event of Default by Subtenant under this Sublease: (a) the failure to pay Base Rent or any other sum due under this Sublease within five (5) days after receipt of notice of such failure, (b) the failure to maintain the insurance required to be maintained by Subtenant under this Sublease; (c) the failure to perform or observe any other covenant, condition or agreement of this Sublease (other than (a) or (b) above) required to be performed or observed by Subtenant which is not cured within thirty (30) days of Subtenant's notice thereof; provided that if such failure cannot be cured within such thirty (30) day period, Subtenant shall have such additional time as needed to cure such failure so long as Subtenant commences such cure within such thirty (30) day period and diligently prosecuted such cure to completion; or (d) any act, occurrence, matter, circumstance or omission which does or would (or may) constitute a breach, a default or an event of default under the terms of the Master Lease.

9. Sublandlord's Remedies on Event of Default. Upon the occurrence of an Event of Default, Sublandlord shall have the immediate right to (i) terminate this Sublease and/or Subtenant's right to possession of the Premises at any time and reenter the Premises and remove Subtenant and all of Subtenant's property from the Premises (and Subtenant waives all claims against Sublandlord in connection therewith), and Subtenant shall vacate the Premises and remove all of Subtenant's property from the Premises as promptly as practicable, (ii) cure such Event of Default and Subtenant shall pay to Sublandlord upon demand all costs, expenses and fees incurred by or on behalf of Sublandlord in curing such Event of Default (together with an administrative fee equal to ten percent (10%) of such costs, expenses and fees), and/or (iii) pursue any other rights and remedies available under the Master Lease, at law and/or in equity and to recover from Subtenant all amounts then due or thereafter accruing and such other damages (including, without limitation, consequential damages) as are caused by such Event of Default. No course of dealing between Sublandlord and Subtenant or any delay on the part of Sublandlord in exercising any rights or remedies Sublandlord may have under this Sublease shall operate as a waiver of any of Sublandlord's rights or remedies, nor shall any waiver of a prior default operate as a waiver of any subsequent default. In exercising Sublandlord's rights and remedies under this Sublease, Sublandlord shall be entitled to recover from Subtenant all costs incurred in connection therewith, including, without limitation, attorneys' fees and court costs.

10. Brokers. Except for the Brokers listed in the Key Provisions, each Party represents and warrants to the other Party that such Party has not used (or dealt with) any broker in connection with this Sublease, and each Party agrees to indemnify, protect, defend and hold the other Party harmless from and against any and all damages, liabilities, judgments, costs, claims, liens, expenses (including attorneys' fees), penalties, suits, demands, actions and fines for or arising out of any brokerage commissions (or claims therefor) arising out of or involving such Party's actions in connection with this Sublease or any breach of the foregoing representation or warranty.

11. No Assignment and No Subletting.

(a) Subtenant shall not assign, transfer, encumber, mortgage or pledge this Sublease or any interest in this Sublease or in the Premises or sublet all or any part of the Premises or permit the Premises to be used or occupied by any other person or entity (each, a "**Transfer**") without the prior written consent of Sublandlord and Master Landlord, provided that such consent of Sublandlord shall not be unreasonably withheld, conditioned or delayed. In addition, Subtenant shall not (i) use or occupy the Premises for (or permit the Premises to be used or occupied for) any use other than the Permitted Use, or (ii) use or occupy the Premises for (or permit the Premises to be used or occupied for) any business operation or trade name other than Subtenant's trade name set forth in the Key Provisions above, it being the intent of the parties that Subtenant's rights, benefits and privileges under this Sublease are personal to the named Subtenant herein and cannot be assigned, transferred, encumbered, mortgaged or pledged. Consent by Sublandlord and Master Landlord to a Transfer shall not destroy or operate as a waiver of the prohibitions contained in this Section 11 or in the Master Lease as to future Transfers, and all such future Transfers shall be made only with the prior written consent of Sublandlord and Master Landlord. If Sublandlord and Master Landlord consent to a Transfer, then Subtenant shall remain liable for payment of all Base Rent and other sums provided for under this Sublease and for the faithful performance of all of the covenants, obligations, liabilities and conditions in and under this Sublease. Subtenant agrees to reimburse Sublandlord for all costs and expenses (including attorneys' fees) incurred by Sublandlord in connection with any Transfer or any Transfer request. Sublandlord may assign or transfer this Sublease and/or any of Sublandlord's rights or obligations under this Sublease and may delegate any of Sublandlord's duties under this Sublease. If Sublandlord assigns or transfers this Sublease, then Sublandlord shall be unconditionally released of all obligations and liabilities under this Sublease from and after the effective date of such assignment or transfer, as applicable.

(b) Notwithstanding the foregoing, but provided that Subtenant is not in default under this Sublease, Subtenant shall have the right, without Sublandlord's consent (but with at least fifteen (15) days advance written notice to Sublandlord), to assign this Sublease in its entirety to a Permitted Transferee (as defined below) (a "**Permitted Transfer**"), provided that (and on the condition that) (i) as of the date of the Permitted Transfer, the Permitted Transferee has the financial capacity to promptly and fully perform all of the obligations of the subtenant under this Sublease (including the prompt and full payment of all Base Rent due under this Sublease), (ii) the Permitted Transferee assumes in writing for Sublandlord's benefit all of the obligations and covenants to be performed and/or observed by Subtenant under this Sublease and all of Subtenant's liabilities under this Sublease, (iii) such Permitted Transfer shall be for the Permitted Use only, (iv) Sublandlord receives an executed copy of the applicable Permitted Transfer document within seven (7) business days of the date of such Permitted Transfer, and (v) such Permitted Transfer shall be subject to this Sublease and to all of the terms and provisions of this Sublease. "**Permitted Transferee**" means an entity that is controlling, controlled by, or under common control with, Subtenant or to an entity that acquires all or substantially all of the business or assets of Subtenant. For purposes of this Section, the term "**control**" shall mean the ability to direct the affairs of the entity either by way of ownership interest, management agreement or otherwise, without approval of any other person or entity. No Permitted Transfer shall release the original Subtenant from any obligations and liabilities under this Sublease or release any guarantor of this Sublease.

12. Entry. Master Landlord and Sublandlord shall have the same rights to enter the Premises as are provided to Master Landlord to enter the Premises pursuant to the Master Lease, and Master Landlord and Sublandlord shall be accompanied at all times (except in the case of an emergency) by a representative of Subtenant, if requested by Subtenant.

13. Surrender; Holding Over. Upon the expiration or earlier termination of this Sublease (time being of the essence), Subtenant shall, at Subtenant's sole cost and expense, (i) remove from the Premises all of Subtenant's equipment, trade fixtures, inventory and other personal property and repair any and all damage caused by such removal, and (ii) deliver and surrender the Premises to Sublandlord in broom clean condition (subject to ordinary wear and tear and casualty damage), free and clear of all liens, charges and encumbrances and in compliance with all laws, ordinances, rules, regulations and other governmental requirements and otherwise in the same condition as the Premises existed on the Rent Commencement Date and in the condition required by the Master Lease. Subtenant shall have no right to occupy the Premises or any portion thereof after the expiration or earlier termination of this Sublease. If Subtenant or any party claiming by, through or under Subtenant holds over or occupies the Premises after the expiration or earlier termination of this Sublease, then Sublandlord may exercise any and all rights and remedies available under the Master Lease, at law and/or in equity to recover possession of the Premises and to recover all damages in connection with such holdover, including, without limitation, all consequential damages and all damages and amounts payable by Sublandlord to Master Landlord by reason of such holdover (including any holdover rent paid by Sublandlord to Master Landlord). In addition, for each and every month or partial month that Subtenant or any party claiming by, through or under Subtenant holds over or occupies all or any portion of the Premises after the expiration or earlier termination of this Sublease, Subtenant shall also pay Sublandlord, as minimum damages and not as a penalty, monthly rent at a rate equal to 125% of the rate of monthly Base Rent payable by Subtenant under this Sublease immediately prior to the expiration or earlier termination of this Sublease. The acceptance by Sublandlord of any lesser sum shall be construed as payment on account and not in satisfaction of damages for such holding over. This provision shall survive the expiration or earlier termination of the Sublease Term.

14. Hazardous Materials.

(a) In addition to the obligations, restrictions and covenants set forth in the Master Lease, Subtenant and Subtenant's employees, agents, invitees, licensees or contractors shall not cause, permit or allow any substances, chemicals or materials (whether solid, liquid or gaseous) that are regulated, governed, restricted or prohibited by, form the basis of liability under, or are defined as a contaminant, pollutant, dangerous, designated or controlled substance product, solid or hazardous waste, hazardous substance, or toxic substance under any federal, state or local law (including common law), statute, code, ordinance, rule, regulation or permit relating to pollution or occupational health or safety or protection of human health or the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) (collectively, "**Environmental Laws**") or by any federal, state or local agency or authority, including, without limitation, any oil, gasoline, petroleum, petroleum by-products, car batteries, polychlorinated biphenyls, asbestos or asbestos containing materials, or any other material or substance which constitutes a health, safety or environmental hazard to any person or the environment (collectively, "**Hazardous Materials**"), to be handled, placed, stored, dumped, dispensed, released, discharged, disposed, deposited, distributed, manufactured, generated, treated, recycled, processed, used, transported or otherwise located on, in, under or about the Premises, except as specifically permitted pursuant to Section 14(b) below.

(b) Subtenant, at Subtenant's sole cost and expense, shall be responsible for medical, special and infectious waste removal for the Premises and the maintenance and storage thereof pending removal, all in accordance with all applicable laws, regulations and orders. Subtenant shall, at Subtenant's expense, comply with all federal, state and local laws, regulations and ordinances which govern the use, storage, handling and disposal of Hazardous Materials, wastes or materials and medical, special or infectious wastes. Subtenant shall indemnify, defend and hold Sublandlord harmless from and against any claims or liability arising out of or connected with Subtenant's failure to comply with the terms of this Section 14(a), which terms shall survive the expiration or earlier termination of this Sublease.

(c) Upon the expiration or earlier termination of this Sublease, Subtenant, at Subtenant's expense, shall remove all Hazardous Materials from the Premises introduced by Subtenant or any of Subtenant's employees, agents, customers, vendors or invitees, all in compliance with Environmental Laws and in a manner acceptable to Sublandlord.

(d) Subtenant shall give Sublandlord immediate written notice of any (1) problem, spill, release, discharge, threatened release or discharge, or discovery of any Hazardous Materials on or about the Premises, or (2) claim or notification by any person or governmental authority relating to the use, presence, discharge or release of Hazardous Materials on or about the Premises (collectively, the "**Environmental Condition**"). If the Environmental Condition was caused, in whole or in part, by Subtenant or Subtenant's employees, agents, contractors, invitees or licensees or otherwise arises or occurs during the Sublease Term, then such notice shall include a description of measures proposed to be taken by Subtenant to contain, remove and/or remediate such Hazardous Materials and any relating damage or impact to the Premises, persons and/or the environment (including any offsite property). Upon Sublandlord's and Master Landlord's approval and at Subtenant's own expense, Subtenant shall promptly take all steps necessary to clean up and remediate the Environmental Condition caused by Subtenant or any of its agents, employees, contractors or invitees in strict compliance with all Environmental Laws and to report and/or coordinate with Sublandlord and all appropriate governmental agencies with respect to Subtenant's efforts to address the Environmental Condition.

(e) Except to the extent arising from the gross negligence or willful misconduct of Sublandlord and/or Master Landlord, Subtenant hereby protects, defends, saves, indemnifies, releases and holds Sublandlord and Master Landlord harmless from and against all Liabilities (as defined below), whether or not resulting from third party claims, suffered by, incurred by or assessed against Sublandlord or Master Landlord or their representatives, affiliates or subsidiaries and all of their respective agents, employees, officers, directors, contractors, successors, assigns, attorneys or representatives as a result of the presence, disturbance, discharge, release, threatened release, removal, remediation or cleanup of any Hazardous Materials located at, on, under or about the Premises during the Sublease Term by Subtenant or any of its agents, employees, contractors or invitees or any of its agents, employees, contractors or invitees from any cause whatsoever. The term "**Liabilities**" as used herein is hereby defined as any and all obligations, fines, suits, liabilities, expenses, demands, fees, sums, amounts, judgments, damages (including, without limitation, punitive, exemplary and consequential damages and personal injury and property damages), expenses, costs (including, without limitation, attorneys', accountants' and consultants' fees and expenses, costs and services of any investigation, assessment, laboratory analysis, treatment, cleanup, containment, response action or remedial action), liabilities, losses, causes of action, claims for relief, court costs, alternative dispute resolution expenses and other legal fees and professional fees.

Subtenant's obligations and liabilities under this Section 14 shall survive the expiration or earlier termination of this Sublease.

15. Intentionally Omitted.

16. Notice. All notices required or permitted to be given under this Sublease shall be in writing and delivered by certified U.S. mail, return receipt requested, or by a national overnight courier service (such as Fed Ex), and shall be deemed effective upon the earlier of (i) actual delivery, or (ii) refusal of delivery, and in all cases addressed to Subtenant or Sublandlord at their respective addresses set forth in the Key Provisions. Either party may change its notice address under this Sublease by giving written notice to the other party in accordance with this Section 16.

17. Miscellaneous.

(a) Counterparts. This Sublease may be executed in two (2) or more counterparts with all being deemed collectively as one (1) sublease.

(b) Cumulative Remedies. All rights and remedies of Sublandlord under this Sublease, at law and in equity are cumulative, and the exercise of one or more rights or remedies shall not be taken to exclude or waive the right to the exercise of any other.

(c) Late Charge and Interest. If Subtenant fails to pay Sublandlord any sum required to be paid under this Sublease when due, then Subtenant shall immediately pay to Sublandlord a late charge equal to the greater of (i) three percent (3%) of such late sum, or (ii) $500.00; provided that no such late charge shall be due for the first late payment in any twelve (12) month period during the Sublease Term. In addition, if Subtenant fails to pay Sublandlord any sum required to be paid under this Sublease within fifteen (15) business days of when due, then such unpaid sum shall accrue interest until paid in full at the lesser of (i) the maximum rate permitted by law, or (ii) eighteen (18%) percent per annum, compounded monthly, and such interest shall begin to accrue from the due date of such sum. Such late charge and interest shall be due and payable immediately and without notice from Sublandlord. Subtenant acknowledges that the aforementioned late charge and interest are in addition to Sublandlord's other rights and remedies available under this Sublease, at law or in equity. In addition, if any financial institution returns more than one of Subtenant's checks due to insufficient funds, then Sublandlord shall have the right to require Subtenant to make all future payments under this Sublease by certified bank check.

(d) Entire Agreement. This Sublease represents the entire agreement between Sublandlord and Subtenant with respect to Sublandlord subleasing the Premises to Subtenant, and all prior and contemporaneous discussions and documents with respect thereto are superseded by this Sublease. Any statement or representation not contained herein shall not be binding on either party. All subsequent amendments hereto must be in writing and signed by the parties hereto.

(e) Governing Law. This Sublease shall be construed and enforced in accordance with the laws of the State where the Premises are located.

(f) Invalidity. The invalidity or unenforceability of any term in this Sublease shall not affect the validity or enforceability of any other term or provision of this Sublease.

(g) Non-Waiver. No right or remedy under this Sublease shall be waived unless the waiver is in writing and signed by the party claimed to have made the waiver, and such waiver shall not be interpreted as a continuing waiver.

(h) Successors and Assigns. This Sublease shall inure to the benefit of, and shall be binding upon, the parties hereto and their respective successors and assigns.

(i) Condemnation Awards. Subtenant shall have no right in or to any award or proceeds with respect to the Premises in connection with any taking of the Premises by condemnation or deed in lieu thereof, and Subtenant unconditionally relinquishes and releases any right, title and interest Subtenant has (or may have) in or to any such award or proceeds.

18. Signage. Any signage Subtenant desires to install on the Premises shall be installed in compliance with all laws and ordinances and all the terms and provisions of the Master Lease. Such signage shall be subject to Sublandlord's (and Master Landlord's if required by the Master Lease) prior written approval (which approval of Sublandlord shall not be unreasonably withheld) and shall be installed and maintained at Subtenant's own cost and in a good and workmanlike manner and in compliance with all laws and ordinances and all the terms and provisions of the Master Lease. Prior to the expiration or earlier termination of the Sublease Term, Subtenant shall remove all such signage from the Premises and repair all damage caused by such removal (which obligation of Subtenant shall survive the expiration or earlier termination of this Sublease).

19. Liens. Subtenant shall not permit or suffer any lien to attach to the Premises or to the interest of Master Landlord or Sublandlord in the Premises or to Subtenant's interest in this Sublease or in the Premises. Subtenant shall indemnify, defend (with counsel acceptable to Sublandlord) and hold Master Landlord and Sublandlord harmless from and against any such lien or claim of lien and any costs, expenses and liabilities relating thereto. If any such lien is filed, then Subtenant shall fully pay and discharge or bond over such lien within ten (10) business days from the filing of such lien and in a manner acceptable to Sublandlord and Master Landlord. If Subtenant fails to fully pay and discharge such lien or bond over such lien within ten (10) business days from the filing of such lien, then Sublandlord shall have the immediate right (but not the obligation) to pay and/or discharge such lien at Subtenant's sole cost, and Subtenant shall, within ten (10) business days of Sublandlord's demand, pay all costs and expenses incurred by Sublandlord in paying and/or discharging such lien. Subtenant's failure to fully pay and discharge any such lien within such ten (10) business day time period shall also constitute an immediate Event of Default under this Sublease. Subtenant's indemnities and obligations under this Section 19 shall survive any termination of this Sublease and the expiration of this Sublease.

20. Recording; Confidentiality. Neither this Sublease nor any short form or memorandum of this Sublease shall be recorded, unless requested or required by Sublandlord. Subtenant covenants and agrees that Subtenant and Subtenant's employees, agents, lenders, attorneys, representatives, officers, accountants and members shall keep confidential and shall not disclose the financial terms of this Sublease or other terms of this Sublease or any matters related to this Sublease (including the Master Lease) without Sublandlord's prior written consent (which consent Sublandlord may withhold or condition in Sublandlord's sole discretion).

21. Consent of Master Landlord. The Consent of Master Landlord executed by Master Landlord with respect to this Sublease (the "**Consent**") is attached hereto and made a part hereof and this Sublease shall not be effective unless and until such Consent has been obtained.

22. Regulatory Matters.

(a) Sublandlord and Subtenant enter into this Sublease with the intent of conducting their relationship and implementing the agreements contained herein in full compliance with applicable federal, state and local law, including without limitation, the Medicare/Medicaid Anti-Kickback statute (the "**Anti-Kickback Law**") and Section 1877 of the Social Security Act (the "**Stark Law**"), as amended. Notwithstanding any unanticipated effect of any of the provisions of this Sublease, neither party will intentionally conduct itself under the terms of this Sublease in a manner that would constitute a violation of the Anti-Kickback Law or the Stark Law. Without limiting the generality of the foregoing, Sublandlord and Subtenant expressly agree that nothing contained in this Sublease shall require either party or any of their affiliates to refer any patients to the other, or to any affiliate or subsidiary of the other.

(b) If any legislation, regulation or government policy is passed or adopted, the effect of which would cause either party to be in violation of such laws due to the existence of any provision of this Sublease, then Sublandlord and Subtenant agree to negotiate in good faith for a period of ninety (90) days to modify the terms of this Sublease to comply with applicable laws and keeping the underlying economic terms of this Sublease as close as possible to the original economic terms of this Sublease.

(c) For purposes of this Section of this Sublease, "protected health information", or PHI, shall have the meaning defined by the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160 and Subparts A and E of Part 164 (the " **Privacy Standards**"), as promulgated by the Department of Health and Human Services ("**HHS**") pursuant to the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**"). The parties agree that neither the Sublandlord nor its contractors, subcontractors or agents shall need access to, nor shall they use or disclose, any PHI of Subtenant. However, in the event PHI is disclosed by Subtenant or its agents to Sublandlord, its, contractors, subcontractors or agents, regardless as to whether the disclosure is inadvertent or otherwise, Sublandlord agrees to take reasonable steps to maintain, and to require its contractors, subcontractors and agents to maintain, the privacy and confidentiality of such PHI. The parties agree that the foregoing does not create, and is not intended to create, a "business associate" relationship between the parties as that term is defined by the Privacy Standards.

[SIGNATURES ON FOLLOWING PAGE]

The parties have executed this Sublease as of the Sublease Date.

SUBLANDLORD:

Witnesses:

JOSEPH M. STILL BURN CENTERS, INC., a Georgia corporation

By: */s/ Robert F. Mullins*
Print Name: Robert F. Mullins
Title: As its President

/s/ Annette Waters
Print Name

SUBTENANT:

Witnesses:

POLARITYTE MD, INC., a Nevada corporation

By: */s/ Paul Mann*
Print Name: Paul Mann
Title: CFO

/s/ Cameron Hoyler
Print Name

Excluded Exhibits: The following exhibits have been excluded from this document as filed with the Securities and Exchange Commission:

Exhibits A – Master Lease

Exhibit B – Floor Plan

CONSENT OF MASTER LANDLORD

DOC-MOB AUGUSTA II, LLC, a Georgia limited liability company (the "**Master Landlord**"), as the landlord under the Master Lease, hereby consents to the subletting of the Premises by Sublandlord to Subtenant pursuant to the Sublease to which this Consent is attached; provided, however, nothing in this Consent or in the Sublease shall (i) constitute approval or ratification by Master Landlord of any of the terms or provisions of the Sublease or constitute a representation or warranty by or on behalf of Master Landlord; (ii) waive or release Sublandlord from any of Sublandlord's obligations, agreements or liabilities under the Master Lease and Sublandlord is and shall remain primarily liable for all rent, additional rent and charges incurred with respect to the Premises and under the Master Lease and for the full performance of all covenants, obligations and conditions set forth in the Master Lease (including, without limitation, all insurance and indemnity obligations, all surrender obligations, the obligation to cure any default under or breach of the Master Lease (whether such default is caused by Sublandlord or Subtenant) and the obligation to make all payments under the Master Lease); (iii) modify, waive, amend or affect any of the terms, provisions, covenants or conditions of the Master Lease or any rights or remedies of Master Landlord thereunder; or (iv) expand the rights of Sublandlord beyond the rights specifically granted to Sublandlord in the Master Lease. In addition, in no event shall Master Landlord be deemed to be in privity of contract with Subtenant or owe any obligation or duty, under the Master Lease, the Sublease or otherwise, to Subtenant, and Master Landlord shall be under no obligation to collect rent from Subtenant (even though Master Landlord may have the right to do so, in which case Master Landlord reserves the right to do so in Master Landlord's sole discretion). Consent by Master Landlord to the Sublease shall not operate as a waiver of Master Landlord's rights to consent to any subsequent assignments or sublettings, Landlord specifically reserving such right.

MASTER LANDLORD:

DOC-MOB AUGUSTA II, LLC, a Georgia limited liability company

By: */s/ Frank Mullins*
Frank Mullins, Manager

Exhibit 21.1

List of Subsidiaries

Name	State of Formation
PolarityTE, Inc.	Nevada
PolarityTE MD, Inc.	Nevada
Arches Research, Inc.	Nevada
Utah CRO Services, Inc.	Nevada
IBEX Preclinical Research, Inc.	Nevada
IBEX Property, LLC	Nevada

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of PolarityTE, Inc. on Form S-3 (Nos. 333-234280 and 333-229584) and Form S-8 (Nos. 333-227721, 333-225264, 333-203501, 333-211959 and 333-200841) of our reports dated March 12, 2020, on our audits of the consolidated financial statements as of December 31, 2019 and 2018, for the year ended December 31, 2019, the transition period from November 1, 2018 through December 31, 2018, and the year ended October 31, 2018, and the effectiveness of PolarityTE, Inc.'s internal control over financial reporting as of December 31, 2019, which reports are included in the Annual Report on Form 10-K to be filed on or about March 12, 2020. Our report includes an explanatory paragraph that refers to a change in the method of accounting for leases due to the adoption of ASU 2016-02 - Leases. Our report on the effectiveness of the Company's internal control over financial reporting as of December 31, 2019, expresses an adverse opinion because of material weaknesses.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Iselin, NJ
March 12, 2020

EXHIBIT 31.1

CERTIFICATION

I, David Seaburg, certify that:

1. I have reviewed this Annual Report on Form 10-K of PolarityTE, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15 (f) and 15 (d)-15(f)) for the registrant and we have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) designed such internal control over financing reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect the registrant's internal control over the financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting that are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: March 12, 2020

/s/ David Seaburg
President
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Richard Hague, certify that:

1. I have reviewed this Annual Report on Form 10-K of PolarityTE, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15 (f) and 15 (d)-15(f)) for the registrant and we have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) designed such internal control over financing reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect the registrant's internal control over the financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting that are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: March 12, 2020

/s/ Richard Hague

Chief Operating Officer
(Principal Executive Officer)

EXHIBIT 31.3

CERTIFICATION

I, Paul Mann, certify that:

1. I have reviewed this Annual Report on Form 10-K of PolarityTE, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15 (f) and 15 (d)-15(f)) for the registrant and we have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

b) designed such internal control over financing reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect the registrant's internal control over the financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting that are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: March 12, 2020

/s/ Paul Mann

Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

Certification Pursuant to Rule 13a-14(b) and Section 1350, Chapter 63 of Title 18, United States Code

Pursuant to Section 1350, Chapter 63 of Title 18, United States Code, the undersigned officers of PolarityTE, Inc. (the "Company"), do hereby certify, to such officers' knowledge, that:

The Annual Report on Form 10-K for the period ending December 31, 2019 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 12, 2020

/s/ Richard Hague
Richard Hague
Chief Operating Officer

/s/ David Seaburg
David Seaburg
President

/s/ Paul Mann
Paul Mann
Chief Financial Officer