UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

☒ Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2020

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.)

1960 S. 4250 West
Salt Lake City, Utah 84104
(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

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☒

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 ☒

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☒ 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 ☒ 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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The aggregate market value of the common stock held by non-affiliates as of June 30, 2020, was $6,135,894.

The outstanding number of shares of common stock as of March 25, 2021, was80,319,378.

Documents incorporated by reference: Portions of the registrant's proxy statement for the 2021 Annual Meeting of Stockholders (2021 Proxy Statement) are incorporated into Part III hereof. The 2021 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the registrant's fiscal year ended December 31, 2020.

TABLE OF CONTENTS

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 in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). 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 timing or success of obtaining regulatory licenses or approvals for marketing our products;
- the initiation, timing, progress, and results of our pre-clinical studies or clinical trials;
- sufficiency of our working capital to fund our operations over the next 12 months;
- infrastructure required to support operations in future periods, including the expected costs thereof;
- estimates associated with revenue recognition, asset impairments, and cash flows;
- variance in our estimates of future operating costs;
- future vesting and forfeitures of compensatory equity awards;
- the effectiveness of our disclosure controls and our internal control over financial reporting;
- the impact of new accounting pronouncements;
- size and growth of our target markets; and
- the initiation, timing, progress, and results of our research and development programs.

Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, without limitation:

- the ability to comply with regulations applicable to the manufacture and distribution of our products and delivery of our services;
- the ability to meet demand for our products and services;
- the ability to deliver our products and services if employees are quarantined due to the impact of COVID-19;
- the scope of protection we can establish and maintain for intellectual property rights covering our product candidates and technology;

- developments relating to our competitors and industry;
- new discoveries or the development of new therapies or technologies that render our products or services obsolete or unviable;
- outbreaks of disease, including the COVID-19 pandemic, and related stay-at-home orders, quarantine policies and restrictions on travel, trade, and business operations;
- political and economic instability, whether resulting from natural disasters, wars, terrorism, pandemics, or other sources;
- the ability to gain adoption by healthcare providers of our products for patient care;
- the ability to find and retain skilled personnel;
- the need for, and ability to obtain, additional financing in the future;
- general economic conditions;
- inaccuracies in estimates of our expenses, future revenues, and capital requirements;
- future accounting pronouncements;
- unauthorized access to confidential information and data on our information technology systems and security and data breaches; and
- the other risks and uncertainties described in this report under Item 1A. Risk Factors, beginning on page 20.

Forward-looking statements relate to future events or to our future financial performance and involve 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 these forward-looking statements. Any forward-looking statement in this Annual Report on Form 10-K and the documents incorporated by reference herein reflects our current view

with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, industry, and future growth. Given these uncertainties, 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.

PART I

Item 1. Business

Overview

PolarityTE, Inc., headquartered in Salt Lake City, Utah, is a biotechnology company developing regenerative tissue products and biomaterials. We also operate a laboratory testing and clinical research business using equipment, personnel, and facilities we acquired to advance our development of regenerative tissue products.

Regenerative Tissue Product

Our first regenerative tissue product is SkinTE, which is intended 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. SkinTE was registered and listed with the United States Food and Drug Administration ("FDA") in August 2017 based on our determination that 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 was required. We proceeded to develop sales and manufacturing capabilities for SkinTE and focused on advancing commercialization of SkinTE. We began a regional commercial rollout of SkinTE in October 2018.

Following informal, voluntary discussions between us and the FDA we were advised by the FDA in April 2020 that its preliminary assessment is that SkinTE does not meet the requirements to be regulated solely as a 361 HCT/P. Rather, the FDA's preliminary assessment was that SkinTE is a biological product that should be regulated under Section 351 of the Public Health Service Act. We re-evaluated our regulatory approach and determined it is prudent to submit an investigational new drug application ("IND") for SkinTE and an eventual biologics license application ("BLA") because we believe it will create a more valuable asset with a greater likelihood of achieving widespread commercial adoption, and to avoid the possibility of a protracted dispute with the FDA. As a result of the change in the regulatory approach for SkinTE, we decided to adjust our SkinTE commercial operations accordingly.

The FDA developed and published in November 2017 a regenerative medicine policy framework to help facilitate regenerative medicine therapies. Under the framework, the FDA stated its intent to exercise enforcement discretion until November 2020 with respect to the FDA's IND and premarket approval requirements, which was subsequently extended through May 2021. We continued to sell SkinTE as a 361 HCT/P in 2020 and into 2021 in reliance on our view that there is a reasonable basis for regulating SkinTE as a 361 HCT/P and also in reliance on the enforcement discretion position stated in the policy framework. In May 2020, we effectuated a reduction in force within our regenerative medicine business segment to reduce historical monthly cash burn and preserve capital for pursuing the filing of an IND. Since then we have focused our commercial effort for SkinTE on the territories where we have current and repeat users of SkinTE.

We have evaluated the question of whether the FDA may extend enforcement discretion on regenerative medical products, and as of the date of this report the FDA has not taken any action on extending enforcement discretion. Following the end of the FDA's period of enforcement discretion, we may need to cease selling SkinTE until the FDA approves a BLA, and then we will only be able to market the product for indications that have been approved in a BLA. We cannot predict at this time when we may decide on continuing SkinTE sales because of the uncertainty around the decisions the FDA may make in this area.

We plan to focus our SkinTE activity on the preparation and submission of an IND in the second half of 2021, and the commencement of clinical trials under that IND once it is open. We believe that the network of physicians and other healthcare providers who have treated more than 1,100 patients to date with SkinTE will provide valuable support for our clinical development program as we work towards a BLA for SkinTE.

Testing and Research Services

Beginning in 2017 we developed internally a laboratory and research capability to advance the development of SkinTE and related technologies, which we operate through our subsidiary, Arches Research, Inc. ("Arches"). At the beginning of May 2018, we acquired a preclinical research and veterinary sciences business to be used, in part, for preclinical studies on our regenerative tissue products, which we operate through our subsidiary IBEX Preclinical Research, Inc. ("IBEX"). Through Arches and IBEX, we also offer research and laboratory testing services to unrelated third parties on a contract basis.

There was a substantial surge in COVID-19 testing throughout the United States as a result of the COVID-19 pandemic, which began in the spring of 2020. In the course of its operations, Arches maintains equipment and staff capable of performing molecular polymerase chain reaction testing for COVID-19, which made it possible for Arches to begin providing COVID-19 testing services at the end of May 2020. We believe that COVID-19 testing offers an opportunity to use existing resources to generate additional revenue in the contract services segment and thereby help defray our operating expenses. We provided COVID-19 testing services through the end of 2020, which we expect will continue in 2021.

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. Skin is an active immune organ functioning as a first line of defence against a wide spectrum of common pathogens encountered on a regular basis. Biosynthesis of melanin in the skin reduces the harmful effects of ultraviolet light. Skin is a ready source of vitamin D, which plays an important role in maintaining healthy levels of serum calcium and resorption of bone.

The clinical significance of skin is illustrated by the morbidity associated with chronic wounds, burns, and cutaneous defects. A 12-month prospective observational study of diabetic foot ulcers first published in *Diabetic medicine : a journal of the British Diabetic Association* in 2018 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. And according to statistics collected by the National Burn Repository, the mortality rate from 2008

to 2017 among burn patients treated at surveyed burn centers is approximately 3%. 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 grafting ("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 STSG 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.

Because of 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 often results in dysfunctional, painful scar tissues and lifelong morbidities.

Due to 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 skin. 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. To our knowledge, 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

The core technology of SkinTE is minimally polarized functional units ("MPFUs"). MPFUs are multi-cellular segments created from a piece of the patient's healthy skin. 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. The process begins with the collection of a skin sample from the patient and shipping the sample in a temperature-controlled shipping box to our FDA-regulated biomedical manufacturing facility. The harvested skin is used to manufacture SkinTE, which is expeditiously returned for application to the patient's wound. Processing of the skin creates multi-cellular segments that are optimized for grafting, which retain the progenitor cells found throughout the skin, including 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 engrafts within 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.

Given our significant real-world experience with SkinTE in clinical settings for a variety of wounds and several supporting publications, we believe SkinTE can be successful in closing full-thickness complex wounds, such as DFUs penetrating to tendon, capsule, and bone classified Wagner Grades 2 through 4; Stage 3 and 4 pressure injuries; and, acute wounds. Full-thickness DFUs that penetrate to deep structures are best classified as University of Texas Grades 2 and 3, corresponding to Wagner Grades 2 through 4, and are at the highest risk for progressing to amputation with very few treatment options and a paucity of high-level data related to current treatment options. Similarly, Stage 3 pressure injuries involve the entire thickness of the skin and Stage 4 pressure injuries have exposed muscle, tendon, or bone. Due to limited reliable solutions, these injuries affect a large number of people for extended periods of time. We believe that focusing our efforts in these hard-to-treat wound types, where there are significant unmet needs, can deliver substantial positive impacts in patients' lives and value for the SkinTE franchise for several reasons.

- Although these distinct wound types may occur in patients with different demographics and have different etiologies, they have common characteristics including significant wound depth, significant wound volume, frequent presence of tunneling and undermining, and exposure of critical structures.
- Wounds with these characteristics often require multiple treatment stages in order to fill volume and cover exposed structures before proceeding to traditional skin grafts or more invasive reconstruction. There is a paucity of high-level data to guide the progression through these treatment options.
- In our experience, wound care providers are focused on finding better treatments due to their unaddressed challenges and the seriousness of their outcomes, where failure of treatments may result in both the acute occurrence and elevated lifetime risk of amputation, long-term disability, and death.

Clinically, we believe SkinTE is highly differentiated from current treatment alternatives in these hard-to-treat wound types. In real-world experience and data from preliminary studies conducted to date, we believe that SkinTE has covered exposed critical structures, completely filled in wound depth including tunnelling, and ultimately provided complete and durable wound closure with the regenerated tissue having many of the important characteristics of native skin such as pliability, strength, sensation, ability to sweat, and hair growth. In contrast to a multi-staged approach combining numerous treatments in an algorithm dictated by wound progression, SkinTE can be applied directly into deep wounds with exposed structures, typically requires only a single application in the vast majority of cases and, unlike other products in this space, may not require a skin graft to achieve final closure. In our experience, providers treating complex wounds are most concerned with reliably covering deep structures, as this mitigates a substantial risk factor for the patient and converts the wound to a lower grade that is more manageable. We believe that covering deep structures and filling wound volume with newly generated vascular tissue is an important advantage of SkinTE and differentiates SkinTE from other treatments that have increased failure rates in these hard-to-treat wound settings. Another valuable aspect of SkinTE clinically is that it is created from a relatively small skin harvest that is well tolerated by the patient.

We believe that patients with complex wounds face significant unmet needs, and that providers are motivated to better address them. If our future clinical trials conducted under an IND demonstrate outcomes similar to those observed in real-world experience and preliminary clinical studies, we believe that SkinTE has the potential to shift practice patterns, accelerate adoption, and capture a significant portion of these hard-to-treat wound markets.

Clinical Trials

We have initiated and completed several clinical trials and have additional clinical trials underway. All clinical trials to date have been conducted on a post-marketing basis with SkinTE as a 361 HCT/P. As we transition to a BLA, and as discussed in more detail under "Our Plan for Advancing SkinTE" below, we will be conducting additional clinical trials once we have an open IND for SkinTE with the FDA, and we expect that those registration trials will be used to support our eventual BLA submission. We believe that the data from our clinical trials to date, however, are valuable as robust evidence of the strong safety and efficacy profile of SkinTE, and plan to include information from

these trials in our IND submission to the FDA.

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 was graft take. Data from the trial was published in the *Journal of Burn Care & Research* in September 2020. Eight patients with deep-partial/full thickness burns had a portion of their wounds treated with SkinTE and the remainder of their burn treated with split-thickness skin grafting. The SkinTE treated wounds had graft take and achieved closure by their last follow-up with a single application. There were no related adverse events pertaining to the SkinTE applications in the trial.

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 DFUs 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 plus standard of care (SOC) versus SOC alone in treatment of DFU (the DFU RCT). The size of the study is 100 patients and the final patient was enrolled in January 2021. The primary endpoint is percentage of ulcers closed at 12 weeks. Secondary endpoints include percent area reduction (PAR) at 4, 6, 8, and 12 weeks, quality of life assessment at 12 weeks, pain assessment at 12 weeks, peripheral neuropathy assessment at 12 weeks, and cost-effectiveness.

In July 2020, we reported data from an interim analysis of the DFU RCT. The analysis was based on 25 SkinTE/SOC patients and 25 SOC patients at 13 sites across the United States. All patients received only one application of SkinTE, except two patients who received reapplication due to inadvertent removal of the original product (mean 1.08 applications per SkinTE/SOC subject). Key demographics included:

Mean wound area (cm2):		Mean wound age (weeks):	
SkinTE/SOC:	4.3	SkinTE/SOC:	25.3
SOC:	3.3	SOC:	22.1

For the primary endpoint, 18 of 25 DFUs (72%) in the SkinTE/SOC group closed at 12 weeks, 8 of 25 DFUs (32%) in the SOC group closed at 12 weeks, and the associated p-value for these results is 0.005. For the PAR secondary endpoint, the interim analysis showed:

Week	SkinTE/SOC	SOC	p-value
4	78.6%	24.0%	0.00021
6	83.2%	43.8%	0.004
8	86.6%	47.2%	0.002
12	88.2%	49.6%	0.012

Furthermore, there was no significant difference between SkinTE/SOC closed wounds and SOC closed wounds with respect to the quality of life assessment at 12 weeks, pain assessment at 12 weeks, and peripheral neuropathy assessment at 12 weeks. In our interim analysis for the DFU RCT we calculated mean total product cost per patient by multiplying current pricing for SkinTE by the number of applications required per patient (1.08 mean applications per patient), resulting in a SkinTE mean total product cost per treated wound of $1,311.20.

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 started a multicenter, randomized controlled trial evaluating SkinTE versus standard of care in treatment of VLU, but decided in the first quarter of 2021 to suspend that trial after 30 patients were enrolled because we believed that our resources would be better used in future clinical trials conducted under an open IND that can be used in our eventual planned BLA submission.

Market Opportunity

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

- We believe SkinTE is suitable for treating a number of acute wounds. In 2017 the inpatient traumatic injury rate was 524.3 persons for every 100,000 people. This resulted in an estimated 1.8 million traumatic injuries per year requiring inpatient hospitalization of which approximately 5% are directly related to open wounds.
- The National Diabetes Statistics Report published in 2020 by the Centers for Disease Control stated that there are approximately 34.2 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.
- The American Burn Association estimates that every year over 450,000 serious burn injuries occur in the United States that require medical treatment and that approximately 40,000 of these resulted in hospitalization.

Our Plan for Advancing SkinTE

As discussed above under "Overview," we decided in April 2020 to pursue the preparation and filing with the FDA of an IND and BLA for SkinTE. Consequently, in May 2020 we effectuated a reduction in force within our regenerative medicine business segment to reduce monthly cash burn. At the end of 2020 we had approximately 10 salespeople and six clinical science staff that supported the sales team. In the coming months we will pursue the preparation of an IND filing with the FDA, which we believe we will be able to file in the second half of 2021.

In August 2020 we submitted a Type B Pre-IND meeting request to FDA regarding an indication for SkinTE to treat DFUs, and we received written responses to our meeting request and questions in October 2020. FDA's responses included, among other things, feedback, and recommendations on SkinTE manufacturing, preclinical studies, and clinical data submitted in the Company's briefing package, and guidance on additional information for the Company to include in its IND submission. Consistent with published FDA guidance documents, including "Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products," the Agency stated that for a condition like DFUs, it would generally expect at least two adequate and well-controlled studies to provide substantial evidence of effectiveness and evidence of safety to support a future marketing application. The Agency noted that our ongoing DFU RCT has elements of an adequate and well-controlled study but stated that it would not accept our ongoing post-marketing DFU RCT as one of the two adequate and well-controlled studies to support a future marketing application.

Based on FDA's feedback and our real-world experience with SkinTE, we plan to pursue multiple indications addressing complex wounds, including wounds with exposed critical structures. The initial indications we plan to pursue are DFUs penetrating to tendon, capsule, and bone classified Wagner Grades 2 through 4 (corresponding to University of Texas Grades 2 and 3), Stage 3 and 4 pressure injuries, and acute wounds. These wound types occur in patients with different demographics and have different etiologies, but they have common characteristics including significant wound depth, significant wound volume, frequent presence of tunnelling and undermining, and exposure of critical structures. We believe much of the chemistry, manufacturing, and controls (CMC) work, as well as preclinical work, that we would do for our initial IND in the DFU indication can be leveraged for multiple subsequent indications. Our present intention is to focus our efforts on an initial IND submission for the above-referenced DFU indication and make further IND submissions to develop the indications for pressure injuries and acute wounds either in parallel or a tight sequential process.

The Company has maintained a collaborative dialogue with the FDA and will continue to work closely with the FDA as it progresses towards its BLA submission. Upon BLA approval, we believe that SkinTE we will have 12 years of data exclusivity with regard to potential biosimilars.

Biological Product License Application (BLA) Pathway

Biological products subject to BLA requirements are approved under the Public Health Service Act. Biological products require FDA approval of a BLA to be marketed. In order to be approved, a BLA must demonstrate the safety, purity and potency of the product candidate based on results of preclinical studies and clinical trials. A BLA must also contain extensive CMC and other manufacturing information, and the applicant must pass an FDA pre-approval inspection of the manufacturing facility or facilities at which the biologic product is produced to assess compliance with the FDA's current Good Manufacturing Practices (cGMP). Satisfaction of FDA approval requirements for biologics typically takes several years and the actual time required may vary substantially based on the type, complexity, and novelty of the product. We cannot be certain that any BLA approvals for our products will be granted on a timely basis, or at all.

The steps for obtaining FDA approval of a BLA to market a biologic product in the U.S. ordinarily include:

- completion of preclinical laboratory tests, animal studies and formulation studies under the FDA's good laboratory practices regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin and include independent Institutional Review Board (IRB) approval before the trials may be initiated;
- performance of one or more adequate and well-controlled clinical trials in accordance with Good Clinical Practices to establish the safety and efficacy of the product for each indication;
- submission to the FDA of a BLA, which contains detailed information about CMC for the product, reports of the outcomes, and full data sets of the clinical trials, and proposed labeling and packaging for the product;
- satisfactory review of the contents of the BLA by the FDA, including the satisfactory resolution of any questions raised during the review;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP regulations, to assure that the facilities, methods and controls are adequate to ensure the product's identity, strength, quality, and purity; and
- FDA approval of the BLA including agreement on post-marketing commitments, if applicable.

Preclinical tests typically include laboratory evaluations of product chemistry, toxicity, and formulation, as well as animal studies, and an IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. In our communications with the FDA, the FDA has informed us that its current position is that additional preclinical studies are not required to support initiation of a clinical trial once the IND is effective, but this is not a final determination, and the Company still expects to conduct certain additional preclinical work as part of its SkinTE development program, including a toxicology study conducted under Good Laboratory Practices with a three-month terminal timepoint.

The IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials and or supporting preclinical data as outlined in the IND. In that case, the sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. In other words, submission of an IND may not result in the FDA allowing clinical trials to commence.

We plan to submit an IND for SkinTE for the treatment of certain DFUs in the second half of 2021, and plan to commence clinical trials for this indication shortly after the IND becomes effective.

Our SkinTE Sales Activity in 2020

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 first part of 2020 the sales process for SkinTE met a new challenge with the COVID-19 pandemic that broke out in March 2020, which grew rapidly in the United States as spring began. Throughout the country, healthcare assets in terms of facilities and providers were marshalled and dedicated to the care and treatment of COVID-19 patients while still trying to meet the acute and traumatic care needs of the general population. Consequently, medical care and procedures that are considered "elective" were put on hold in many regions across the country. Many of the initial economic effects in the healthcare industry of the early stages of the COVID-19 outbreak in the United States and the shift in healthcare resources occurred during the last three weeks of the quarter ended March 31, 2020, and we observed that some SkinTE procedures planned for the second calendar quarter were postponed, cancelled, or not scheduled as a direct result of the COVID-19 pandemic. The impact was most evident in chronic wounds without amputation risk. As a result of the shift in patient care due to COVID-19, other challenges in the sales offering, and the shift in our regulatory pathway for SkinTE, beginning in May 2020, our commercial team focused the sales effort on regions where we had repeat customers that are hospital groups or large facilities that treat acute and traumatic wounds conditions. Consequently, in 2020 38% of our net revenues from SkinTE sales were generated at one hospital system.

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. Our practice has been to work closely with our customers to ensure that pricing is not a barrier to use of SkinTE for patient care.

We have continued to sell SkinTE in 2021, but as discussed above under "Overview" we may need to cease selling SkinTE if FDA enforcement discretion ends and while a BLA is pending until the FDA approves a BLA, and then we will only be able to market SkinTE for the indications that have been approved in the BLA.

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 Payment Classification (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. 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.

Development Projects

Preparing and filing our IND with the FDA and beginning necessary clinical trials are the focus of our operational activity. We have development projects, however, that we believe will add value to SkinTE if and when we obtain pre-market approval.

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 product offering for several reasons. Using one harvest for multiple deployments may improve 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. SkinTE Cryo is in the development stage and is a long-term development project.

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 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 cannot predict when that phase may be complete.

Other Potential Products

We believe our innovative technologies may be platforms for developing therapies that address a variety of indications, including bone, cartilage, muscle, blood vessels, and neural elements, as well as solid and hollow organ composite tissue systems. For the foreseeable future, however, we intend to apply our business and financial resources to the SkinTE IND and BLA, and SkinTE-related projects described above, and we have at this time put on hold further development work on OsteoTE and products related to other tissue substrates so that we can focus our resources on SkinTE.

Manufacturing

Throughout 2020 we maintained at our facility in Salt Lake City, Utah, manufacturing processes and quality systems that allow us to receive a skin specimen, qualify the incoming tissue, process and manufacture the SkinTE tissue product, and perform outgoing quality control and quality assurance work prior to shipping. We 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 ("cGTP") under 21 C.F.R. Part 1271.

In connection with the preparation of our IND we are making plans to modify our manufacturing practices and facility so that we comply with current Good Manufacturing Practices ("cGMP") under 21 C.F.R. Parts 210 and 211, and other applicable regulations, which are in addition to cGTP referenced above.

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 foreign patent protection in selected jurisdictions 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. We have a number of patents issued and pending applications allowed in the United States and abroad related to our MPFU technology, including U.S. Patent No. 10,926,001 which issued on February 23, 2021. U.S. Patent No. 10,926,001 was filed on November 30, 2015 as Application No. 14/954,335 and thus has an estimated expiration date of November 30, 2035.

Patent terms extend for varying periods of time according to the date of patent filing or grant and the pertinent law in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends upon the type of patent, the scope of its coverage, and the availability of legal remedies in the country. Further, patent term extension may be available in certain countries to compensate for a regulatory delay in approval of certain products.

The U.S. healthcare legislation enacted in 2010 created an approval pathway for biosimilar versions of innovative biological products that did not previously exist. Prior to that time, innovative biologics had essentially unlimited regulatory exclusivity. Under the new regulatory mechanism, the FDA can approve products that are similar to (but not generic copies of) innovative biologics on the basis of less extensive data than is required by a full BLA. After an innovator has marketed its product for four years, any manufacturer may file an application for approval of a "biosimilar" version of the innovator product. However, although an application for approval of a biosimilar may be filed four years after approval of the innovator product, qualified innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. The law also provides a mechanism for innovators to enforce the patents that protect innovative biological products and for biosimilar applicants to challenge the patents. Such patent litigation may begin as early as four years after the innovative biological product is first approved by the FDA.

In the United States, the increased likelihood of generic and biosimilar challenges to innovators' intellectual property has increased the risk of loss of innovators' market exclusivity. First, generic companies have increasingly sought to challenge innovators' basic patents covering major pharmaceutical products. Second, statutory and regulatory provisions in the United States limit the ability of an innovator company to prevent generic and biosimilar drugs from being approved and launched while patent litigation is ongoing. As a result of all of these developments, it is not possible to predict the length of market exclusivity for a particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity.

In striving to protect the 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, WHERE SELF REGENERATES SELF, and SKINTE.

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. 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 products that we develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, 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 preclinical research facility that that complies with Good Laboratory Practices and 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 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 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.

There was a substantial surge in COVID-19 testing throughout the United States as a result of the COVID-19 pandemic, which began in the spring of 2020. In the course of its operations, Arches maintains equipment and staff capable of performing molecular polymerase chain reaction ("PCR") testing for COVID-19. We had the opportunity to use our research facilities to offer laboratory testing services for COVID-19, and to that end registered under the Clinical Laboratory Improvement Amendments ("CLIA") in May 2020, and we began providing COVID-19 testing services on May 27, 2020. We believe that COVID-19 testing offers an opportunity to use existing resources to generate additional revenue and thereby help defray our operating expenses. We pursued this opportunity through the end of 2020 and expect to continue to do so as long as we believe COVID-19 testing services are beneficial to supporting our operations.

On September 2, 2020, Arches entered into two agreements with Co-Diagnostics, Inc. ("Co-Diagnostics"). The COVID-19 Laboratory Services Agreement between the parties provides that Arches will perform specimen testing services for customers referred by Co-Diagnostics to Arches. Co-Diagnostics will arrange all logistics for delivering specimens to Arches for COVID-19 testing for those customers of Co-Diagnostics electing to use the service. Arches bills Co-Diagnostics for the testing services and Co-Diagnostics manages all customer billing. The Rental Agreement for LGC Genomics Oktopure Extraction Machine between Arches and Co-Diagnostics provides that Co-Diagnostics will make available to Arches the Oktopure high throughput extraction machine that Arches will use to perform COVID-19 testing. The term of the agreement is 12 months, requires Arches to use Co-Diagnostics tests exclusively in the machine, and establishes for Arches a minimum monthly purchase obligation for Co-Diagnostics tests and related consumables used in the testing process.

Competition for COVID-19 testing is intense with a large number of participants providing testing services. Many of our current competitors, either alone or with their collaboration partners, have significantly greater financial resources, testing resources, laboratory personnel, expertise, and marketing resources than we do. We are only able to offer our testing services in states where Arches is licensed or registered to provide laboratory testing services or where an emergency order or authorization allows unlicensed laboratories to provide COVID-19 testing, which limits the geographical market we can serve. We are a relatively unknown testing laboratory, so we have relied on word of mouth and management relationships to connect with prospects and vied for new business on the basis of price and service. During 2020 we had testing agreements with multiple nursing home and pharmacy facilities in the state of New York controlled by a single company that accounted for 96% of COVID-19 testing revenues in 2020. We were fortunate to obtain our major customer for testing services, which was a result of a direct relationship with management, and we have been able to retain this customer on the basis of price and service. We provide testing services in New York in reliance on monthly executive orders and authorizations that require regular testing of staff in these facilities and permit laboratories not licensed in New York to provide those services. On March 26, 2021, we were advised by the company that controls the New York nursing homes and pharmacy facilities we service that the state of New York is allowing on-site employee testing and that on-site testing will be implemented for the New York facilities we service, which will likely have the effect of substantially diminishing our revenues from COVID-19 testing after the first quarter of 2021.

We offer PCR testing for COVID-19, which is the current industry standard for accuracy of results. A number of companies, as well as academic research institutions, governmental agencies, and public and private research institutions, are pursuing the development of new COVID-19 tests that purport to be faster, easier, and less expensive than PCR testing. The successful development of such a test could substantially diminish the demand for the PCR testing we offer.

Government Regulation

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 biologics. Manufacturers of new biologics must complete extensive clinical trials, which must be conducted pursuant to an effective IND. In addition, the FDA must review and approve a BLA before a new biologic may be marketed.

If 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 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 qualifies as a 361 HCT/P. Following informal, voluntary discussions between us and the FDA we were advised by the FDA in April 2020 that its preliminary assessment is that SkinTE does not meet the requirements to be regulated solely as a 361 HCT/P. Rather, the FDA's preliminary assessment was that SkinTE is a biological product that should be regulated under Section 351 of the Public Health Service Act. We re-evaluated our regulatory approach and determined it is prudent to submit an IND for SkinTE and an eventual BLA because we believe it will create a more valuable asset with a greater likelihood of achieving widespread commercial adoption, and to avoid the possibility of a protracted dispute with the FDA. As a result of the change in the regulatory approach for SkinTE, we decided to adjust our SkinTE commercial operations accordingly.

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 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. During the enforcement discretion period, the FDA is permitting products that will become regulated under Section 351 to be manufactured in compliance with cGTP regulations. After the end of the enforcement discretion period, however, these products will be subject to cGMP compliance. The transition from cGTP to cGMP compliance includes development and enhancement of production processes, procedures, tests, and assays, and it requires extensive validation work. It can also involve the procurement and installation of new production or lab equipment. These efforts require expertise and resources.

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.

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, though we have had informal interactions with 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."

Regulation of Clinical Laboratories

Virtually all clinical laboratories operating in the United States must be certified by the federal government or by a federally-approved accreditation agency. In most cases, that certification is regulated by the Centers for Medicare & Medicaid Services of the U.S. Department of Health and Human Services ("HHS") through CLIA, which requires that applicable clinical laboratories meet quality assurance, quality control, and personnel standards. Laboratories also must undergo proficiency testing and are subject to inspections.

Arches has been issued a CLIA Certificate of Registration ("CLIA Certificate") to accept human specimens for the purpose of performing laboratory examinations or procedures. The CLIA Certificate was issued on April 20, 2020 and is valid until April 19, 2022, but is subject to revocation, suspension, limitation, or other sanctions for violations of applicable laws or regulations.

Arches is also subject to state and local laboratory regulation. CLIA provides that a state may adopt laboratory regulations different from or more stringent than those under federal law, and a number of states have implemented their own laboratory regulatory requirements. State laws may require that laboratory personnel meet certain qualifications, specify certain quality controls, or require maintenance of certain records.

We believe Arches is in compliance with all applicable laboratory requirements. Its laboratory has continuing programs to ensure that Arches' operations meet all such regulatory requirements, but no assurances can be given that the laboratory will pass all future licensure or certification inspections.

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 sometimes open to interpretation. We could potentially face legal risks if our interpretation differs from those of enforcement authorities. Further, from time to time we could be at a competitive disadvantage if our interpretation differs from that of our 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 HHS ("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 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.

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, and if we receive a BLA approval, we will be required to report certain information under applicable transparency laws.

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 80 full-time employees and five part-time employees as of December 31, 2020, 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 stockholder of PolarityTE NV. The asset acquisition was subject to stockholder 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 IBEX. 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.

Summary Risk Factors

The risk factors described below are a summary of the principal risk factors associated with an investment in us. These are not the only risks we face. You should carefully consider these risk factors, together with the risk factors set forth in "Item 1A. Risk Factors" of this Report and the other reports and documents filed by us with the U.S. Securities and Exchange Commission ("SEC").

Risks Related to Our Financial Condition

- We have a history of losses and may incur additional losses in the future.
- We will need additional funding in the future, which may not be available on acceptable terms, or at all, and, if available, may result in dilution to our stockholders. If we are unable to successfully raise additional capital, our future clinical trials and product development could be limited, and our long-term viability may be threatened.
- We plan to devote a majority of our financial and human resources to pursue an IND and BLA for SkinTE, which means we may fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.
- Our wholly owned subsidiary accepted a loan under the CARES Act pursuant to the Paycheck Protection Program, or the PPP, and the loan may not be forgiven or may subject us to challenges, audits, or investigations regarding qualification for the loan, any of which could reduce our liquidity and have a material adverse effect on our business, financial condition and results of operations.
- Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited, which could adversely affect future cash flows.

Risks Related to our Research & Development, Clinical, and Commercialization Activities

- We are pursuing an IND and BLA for SkinTE, so we are an early-stage biotechnology company subject to the risks associated with such companies, which may make it difficult to evaluate our current business and predict our success and viability.
- Our ability to timely submit an IND or BLA to the FDA may depend on circumstances outside of our control.
- Clinical trials are expensive, time-consuming, and difficult to design and implement, and as a result there is significant uncertainty with respect to successful completion.
- Biotechnology and pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. While we have generated revenue from sales of SkinTE, we have never achieved profitable operating results in our regenerative medicine product segment, and we may never be able to do so.
- We are dependent on third parties to conduct our clinical trials and the failure of such third parties to perform or delays in performance could increase our costs or prevent us from being able to use the results of the trials.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Any adverse developments that occur during any clinical trials conducted by academic investigators or other entities conducting clinical trials under independent INDs may negatively affect the conduct of our clinical trials or our ability to obtain regulatory approvals or commercialize our product candidates.
- Adverse side effects or other safety risks associated with our product candidates could cause us to suspend or discontinue clinical trials or delay or preclude approval.
- We may form or seek strategic alliances, enter into additional licensing arrangements, or participate in acquisition transactions in the future, and we may not succeed in realizing the benefits of such alliances, licensing arrangements, or acquisition transactions.
- Even if we obtain regulatory approval of SkinTE or future product candidates may not gain market acceptance among physicians, patients, hospitals, third-party payors, and others in the medical community.
- If we are required to withdraw or we voluntarily recall a product from the market, it could significantly increase our costs, damage our reputation, and disrupt our business.
- We face significant uncertainty in the industry due to government healthcare reform.
- We face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance.
- We operate in a highly competitive and evolving field and face competition from regenerative medicine, biotechnology, and pharmaceutical companies, tissue engineering entities, tissue processors, and medical device manufacturers, as well as new market entrants, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

Risks Related to our Operating Activities

- We may be required to discontinue sales of SkinTE, which would adversely affect our revenues, financial condition, and results of operations.
- We have a limited history of operation with our laboratory testing service so we are unable to predict with any certainty what contribution it will make to defraying our operating expenses in the future, which could adversely affect our ability to plan for the use of our resources to achieve our goals.
- Our manufacturing and COVID 19 testing operations depend primarily on one facility. If this facility is destroyed or we experience any manufacturing or laboratory difficulties, disruptions, or delays, this could adversely affect our ability to conduct our clinical trials or perform laboratory testing services.
- 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.
- The ongoing COVID-19 pandemic could materially affect our operations, as well as the business or operations of third parties with whom we conduct business. Our business could be adversely affected by the effects of other future health pandemics in regions where we or third parties on which we rely have significant business operations.

Risks Related to Our Intellectual Property

- 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.
- 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 may be subject to claims that our employees have wrongfully appropriated, used, or disclosed intellectual property of their former employers.
- If we are unable to protect the confidentiality of our proprietary information and know-how related to SkinTE or any of our product candidates, our competitive position would be impaired and our business, financial condition, and results of operations could be adversely affected.
- We may become subject to claims of infringement of the intellectual property rights of others, which could prohibit us from developing our products, 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.
- We have a number of patents issued and applications pending in the United States and other foreign jurisdictions, however we may not be able to enforce those patent rights against third parties.
- We may not be able to protect our intellectual property in countries outside of the United States.

Risks Related to Our Common Stock

- An active trading market for our common stock may not continue to develop or be sustained.
- We are pursuing a plan to advance regulatory approval of SkinTE, so delay or failure in achieving our milestones could adversely affect our prospects and the value of ownership of our common stock.
- 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.
- Future sales of our common stock in the public market could cause our stock price to fall.
- Our Restated Certificate of Incorporation, our Restated Bylaws, and Delaware law could deter a change of our management, which could discourage or delay offers to acquire us.
- 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.
- We incur costs and demands upon management because of being a public company.

Contact and Available Information

Our principal executive offices are located at 1960 S. 4250 West, Salt Lake City, UT 84104, and our telephone number is (800) 560-3983.

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 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. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at http://www.sec.gov.

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 Financial Condition

We have a history of losses and may incur additional losses in the future

On a cumulative basis we have sustained substantial losses and negative cash flows from operations since we embarked on our regenerative tissue product business at the beginning of 2017. As of December 31, 2020, our accumulated deficit was $478.2 million. As of December 31, 2020, we had $25.5 million in cash and cash equivalents, and working capital of approximately $22.7 million. In January 2021, we raised an additional $17.7 million in gross proceeds before offering expenses in a registered direct offering and through a warrant exercise agreement. In fiscal year 2020, we incurred losses of $42.9 million and we experienced negative cash flows from operations of $37.8 million. We expect to continue incurring material general and administrative expenses in connection with our operations, including the costs associated with preparing and filing our IND and BLA for SkinTE and beginning clinical trials as part of those applications. As a result, we anticipate that we will incur losses in the future.

We will need additional funding in the future, which may not be available on acceptable terms, or at all, and, if available, may result in dilution to our stockholders. If we are unable to successfully raise additional capital, our future clinical trials and product development could be limited, and our long-term viability may be threatened.

In 2020 our net revenues from product sales and services contributed $10.1 million to defray cost of sales and total operating costs and expenses in the amount of $56.1 million. Our net revenues reduce the rate at which we burn our capital resources in the pursuit of our IND and BLA for SkinTE, but we have no expectation that product sales and services will be a major contributor to the capital resources we will need to advance SkinTE through the FDA regulatory process over the next several years.

Based on currently available information as of the date we file this report, we believe that our existing cash and cash equivalents will be sufficient to fund our activities through the end of 2021 and into the third quarter of 2022. However, our projections of future cash needs may differ from actual results. Furthermore, finite resources may inhibit our ability to respond to competitive pressures or unanticipated capital needs, or may force us to reduce operating expenses, which would significantly harm our business. We will need to seek additional working capital, which may be through sales of our equity securities or through bank credit facilities or public or private debt from various financial institutions or through future arrangements with strategic partners. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we do identify sources for additional funding, the sale of additional equity securities or convertible debt could result in dilution to our stockholders. Additionally, the sale of equity securities or issuance of debt securities may be subject to certain security holder approvals under applicable Nasdaq rules or may result in the downward adjustment of the exercise or conversion price of our outstanding securities. We can give no assurance that sources of funding, such as sales of equity or debt, or strategic relationships would be available or would be approved by our security holders, if needed, on favorable terms or at all. If we fail to obtain additional working capital as and when needed, such failure could have a material adverse impact on our business, results of operations and financial condition.

We plan to devote a majority of our financial and human resources to pursue an IND and BLA for SkinTE, which means we may fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited resources, we plan to forego or delay pursuit of opportunities with other product candidates or for indications that later could prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for product candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate for which it would have been more advantageous to enter into a partnering arrangement.

Our wholly owned subsidiary accepted a loan under the CARES Act pursuant to the Paycheck Protection Program ("PPP"), and the loan may not be forgiven or may subject us to challenges, audits, or investigations regarding qualification for the loan, any of which could reduce our liquidity and have a material adverse effect on our business, financial condition and results of operations.

On April 12, 2020, our subsidiary PolarityTE MD, Inc. (the "Borrower") entered into a promissory note offered by a bank (the "Lender") evidencing an unsecured loan in the amount of $3,576,145 made to the Borrower under the PPP (the "Loan"). The PPP was established under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and is administered by the U.S. Small Business Administration (the "SBA"). The interest rate on the Loan is 1.00%. Beginning seven months from the date of the Loan the Borrower is required to make 24 monthly payments of principal and interest in the amount of $150,563. The promissory note evidencing the Loan contains customary events of default relating to, among other things, payment defaults, making materially false and misleading representations to the SBA or Lender, or breaching the terms of the Loan documents. The occurrence of an event of default may result in the repayment of all amounts outstanding, collection of all amounts owing from the Borrower, or filing suit and obtaining judgment against the Borrower. Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of a loan granted under the PPP.

On October 15, 2020, the Borrower applied to the Lender for forgiveness of the Loan in its entirety based on the Borrower's use of the PPP loan for payroll costs, rent, and utilities. On October 26, 2020, the Borrower was advised that the Lender approved the application and that the Lender was submitting the application to the SBA for a final decision. The Company classified the principal balance of the PPP loan within "Current portion of long-term notes payable" and "Long-term notes payable" on the consolidated balance sheet as of December 31, 2020. If the Borrower's application for forgiveness of the PPP loan is not approved or approved only in part, it will be obligated to repay the unforgiven portion of the loan after the SBA makes its decision on the application for forgiveness, in which case our liquidity could be reduced and our business, financial condition, and results of operations may be adversely affected.

Pursuant to the requirements under the CARES Act, in connection with the Loan, the Borrower certified that current economic uncertainty makes the Loan request necessary to support the ongoing operations of the Borrower. We believe that the Borrower made such certification in a manner consistent with SBA guidance that borrowers must make the certification in good faith, taking into account their current business activity and their ability to access other sources of liquidity sufficient to support their ongoing operations in a manner that is not significantly detrimental to the business. While we believe any certification by the Borrower's certification was supported in light of the understandings of the requirements and the assessment made on the certification date, we cannot be certain that SBA or any other governmental entity or third party will concur with the Borrower, especially in light of the press scrutiny and SBA's evolving guidance and views, our change in strategy triggered, in part, on regulatory developments occurring after the Loan was made, and the eventual extent of the impact of current economic uncertainties on Borrower's operations.

Subsequent to the Borrower's application for the loan, SBA issued various interpretive guidelines in connection with the PPP, including guidance on how SBA interprets certain of the certification requirements. One of the interpretations appears to be in response to various press reports that well-established or well capitalized private and public companies were able to secure PPP loans that were meant for smaller companies. SBA's interpretive guidelines published on April 23, 2020, set forth that public companies with substantial market value and access to capital markets would likely not qualify to participate in the PPP and SBA advised any such public company to be prepared to provide the basis for the certifications upon SBA request. Subsequently, on April 28, 2020 the Secretary of the Treasury and SBA announced that the government will conduct a full audit of all PPP loans of more than $2 million for which the borrower applies for forgiveness. Consistent with that announcement the SBA established an audit procedure for obtaining additional information from PPP borrowers regarding the loan application certification and use of PPP loan proceeds. The Borrower completed and submitted the additional information in December 2020 and plans to continue to provide information to SBA in support of the Borrower's original Loan application and use of Loan proceeds. The Borrower has yet to receive any response from the SBA. There is no assurance the SBA will conclude the Borrower properly applied for, and used the proceeds of, the Loan. If there is any adverse finding in the SBA audit or if the Borrower were alleged, or determined, not to qualify for the Loan or alleged, or found, to have made false certifications in connection with the Loan, the Borrower could be required to return the full amount of the Loan, which would reduce its liquidity, and could subject it to fines and penalties, and exclusion from government contracts. In particular, the Borrower may become subject to actions under the FCA, including its qui tam provisions, which, among other things, prohibits persons from knowingly filing, or knowingly causing to be filed, a false statement, or knowingly using a false statement, to obtain payment from the federal government. Violations of the FCA are subject to treble damages and penalties. In the case of an SBA loan, the government could allege that single damages are the amount of the loan and interest thereon (or more), which under the FCA could then be trebled. Substantial penalties must also be imposed for each submitted false statement when a defendant loses an FCA trial. FCA cases may be initiated by the U.S. Department of Justice or by private persons or entities, often called "whistleblowers," who bring the action on behalf of the United States. The Borrower may also face enforcement arising under other federal statutes, including criminal laws, and administrative actions and investigations initiated by SBA or other governmental entities. Furthermore, if the Borrower is identified as an entity that the media, government officials, or others seek to portray as a business that should not have availed itself of PPP funding, the Borrower may face negative publicity, which could have a materially adverse impact on its business and operations and on our business and operations as its parent. Generally, the cost of defending claims under the FCA, regardless of merit, could be substantial, even as much as the PPP loan proceeds, so the Borrower may evaluate voluntarily repaying the loan on the basis of future circumstances to avoid these costs as well as the significant drain on management resources that accompanies litigation.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited, which could adversely affect future cash flows.

We have incurred net losses over the past several years, and we may never achieve or sustain profitability. Generally, losses incurred will carry forward until such losses expire or are used to offset future taxable income, if any. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"), if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss, or NOL, carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have not completed a study to assess whether an ownership change for purposes of Section 382 or 383 has occurred, or whether there have been multiple ownership changes in the past. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset such taxable income could be subject to limitations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. As a result, even if we attain profitability, we may be unable to use a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows.

Risks Related to our Research & Development, Clinical, and Commercialization Activities

We are pursuing an IND and BLA for SkinTE, so we are an early-stage biotechnology company subject to the risks associated with such companies, which may make it difficult to evaluate our current business and predict our success and viability.

Our primary focus for the foreseeable future will be shepherding SkinTE through the FDA regulatory process, which is a lengthy process with no assurance of success. Stockholders should understand that we are an early-stage biotechnology company with a limited history of revenue-generating operations. Therefore, we are subject to all the risks and uncertainties inherent in an early-stage biotechnology company, in particular those businesses engaged in the pursuit of tissue regenerative technologies.

Accordingly, you should evaluate our prospects in light of the costs, uncertainties, delays, and difficulties frequently encountered by early-stage companies, particularly those in the biotechnology field. In particular, stockholders should consider that there is a significant risk that we will not be able to:

- successfully complete any preclinical or other studies necessary to submit an IND to the FDA for SkinTE;
- successfully compile clinical, CMC, and other information necessary to submit an IND to the FDA for SkinTE;
- obtain FDA approval to commence human clinical trials of SkinTE;
- successfully enroll sufficient numbers of qualified patients to participate in our clinical trials;
- successfully meet the primary endpoints in our clinical trials;
- implement or execute our current business plan, or that our current business plan is sound;
- raise sufficient funds in the capital markets or otherwise to fully effectuate our business plan;
- maintain our management team;
- determine that the processes and technologies that we have developed or will develop are commercially viable; and/or
- attract, enter into, or maintain contracts with potential commercial partners, healthcare providers, licensors of technology, or licensees of our technologies.

Any of the foregoing risks may adversely affect us and result in the failure of our business. In addition, we expect to encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors.

Our ability to timely submit an IND to the FDA may depend on circumstances outside of our control.

Our ability to submit an IND to the FDA depends on a variety of factors. We must submit the results of various preclinical tests, together with manufacturing information, analytical data, any available past clinical data or literature, and a proposed clinical protocol to the FDA as part of the IND. Preclinical tests include laboratory evaluations of product chemistry and formulation, as well as other studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements, subject to any adjustments allowed by the FDA. The FDA may require that we conduct additional preclinical testing for any product candidate before it allows us to initiate the clinical testing under any IND, which may lead to additional delays and increase the costs of our preclinical and clinical development. An IND also involves considerable work from our employees and advisors. Difficulties or delays in the process will likely increase the costs associated with the IND and result in an unanticipated reduction in the working capital we have available to pursue the IND and BLA.

Clinical trials are expensive, time-consuming, and difficult to design and implement, and as a result there is significant uncertainty with respect to successful completion.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The costs of our clinical trials may increase if the FDA does not agree with our clinical development plans or requires us to conduct additional clinical trials, data analyses, or data audits to demonstrate the safety and efficacy of SkinTE or future product candidates. Should we be unable to cover the expense of our clinical trials or encounter difficulties in execution of our clinical trials it is unlikely we will be able to advance SkinTE or other product candidates to marketing approval, which would have a significant adverse effect on our business, prospects, financial condition, and results of operations.

Biotechnology and pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. While we have generated revenue from sales of SkinTE, we have never achieved profitable operating results in our regenerative medicine product segment, and we may never be able to do so.

Our ability to generate revenue depends in large part on our ability, alone or with partners, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize, product candidates. Following the end of the FDA's period of enforcement discretion (currently scheduled through May 2021) for regenerative tissue products, we may need to cease selling SkinTE until the FDA approves a BLA, and then we will only be able to market the product for indications that have been approved in a BLA. Our ability to generate future revenues from product sales of regenerative tissue products depends heavily on our success in:

- progressing our discovery-stage programs into pre-clinical testing;
- progressing our pre-clinical programs into human clinical trials;
- completing requisite clinical trials through all phases of clinical development of our product candidates;
- seeking and obtaining marketing approvals for our product candidates that successfully complete clinical trials, if any;
- launching and commercializing our product candidates for which we obtain marketing approval, if any, with a partner or, if launched independently, successfully establishing a manufacturing, sales force, marketing, and distribution infrastructure;
- identifying and developing new product candidates;
- establishing and maintaining supply and manufacturing relationships with third parties;
- maintaining, protecting, expanding, and enforcing our intellectual property; and
- attracting, hiring, and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with biologic and pharmaceutical product development, we are unable to predict the likelihood or timing for when we may receive regulatory approval of our product candidates or when we will be able to achieve or maintain profitability, if ever. If we are unable to establish a development and or commercialization partnership, or do not receive regulatory approvals, our business, prospects, financial condition, and results of operations will be adversely affected. Even if we or a partner obtain the regulatory approvals to market and sell one or more of our product candidates, we may never generate significant revenues from any commercial sales for several reasons, including because the market for our products may be smaller than we anticipate, or products may not be adopted by physicians and payors, or because our products may not be as efficacious or safe as other treatment options. If we fail to successfully commercialize one or more products, by ourselves or through a partner, we may be unable to generate sufficient revenues to sustain and grow our business and our business, prospects, financial condition, and results of operations will be adversely affected.

We are dependent on third parties to conduct our clinical trials and the failure of such third parties to perform or delays in performance could increase our costs or prevent us from being able to use the results of the trials.

We depend and will continue to depend upon independent investigators and collaborators, such as universities and medical institutions, to conduct our clinical trials under agreements with us. Negotiations of budgets and contracts with study sites may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory, and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices ("cGCPs"), which are regulations and guidelines enforced by the FDA for product candidates in clinical development. The FDA enforces these cGCPs through periodic inspections of clinical trial sponsors, principal investigators, and clinical trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA could

require us to perform additional clinical trials, undertake data analyses or audits, or adopt new or revised clinical study procedures and systems before approving our marketing applications. It is possible the FDA could determine that any of our clinical trials fail to comply with the cGCP regulations. In addition, our clinical trials must be conducted with a biologic product produced under current good manufacturing practices, or cGMPs, and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations, or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with these third parties, we cannot control whether they devote sufficient time and resources to our ongoing preclinical, clinical, and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for SkinTE or other product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Even if we are permitted to conduct clinical trials for SkinTE under an IND, we may experience difficulties in subject enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the clinical trial protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to the study site;
- the design of the clinical trial;
- our ability to retain clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion;
- competing clinical trials and approved therapies available for patients; and
- unexpected difficulties, complications, and delays that could arise at any stage of our clinical trials as a result of the COVID-19 pandemic or otherwise.

In particular, SkinTE clinical trials will be designed to test the treatment of wounds with specific characteristics and be conducted at a limited number of sites, so to a large extent we will have no control or influence on the number and timing of enrolling patients that are suitable for our trials.

Our clinical trials could compete with other companies' clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition could reduce the number and types of patients available to us, because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a trial being conducted by one of our competitors. It is possible we could conduct our clinical trials at the same clinical trial sites that some of our competitors may use, which could reduce the number of patients who are available for our clinical trial in these clinical trial sites. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials, which could prevent completion of the clinical trials and adversely affect our ability to advance the development of SkinTE.

Any adverse developments that occur during any clinical trials conducted by academic investigators or other entities conducting clinical trials under separate INDs may negatively affect the conduct of our clinical trials or our ability to obtain regulatory approvals or commercialize our product candidates.

Skin-based HCT/Ps and other HCT/Ps for wound care are being used, or may be used, by third parties in clinical trials that are completely independent of our plan for SkinTE. We have no control over the conduct of those clinical trials. If serious adverse events occur during those or any other clinical trials using technologies similar to ours, the FDA and other regulatory authorities may delay our clinical trial, or could delay, limit, or deny approval of SkinTE or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs. If we receive regulatory approval for SkinTE and a new and serious safety issue is identified in connection with clinical trials conducted by third parties, the applicable regulatory authorities may withdraw their approval of SkinTE or otherwise restrict our ability to market and sell our product. In addition, treating physicians may be less willing to administer our products due to concerns over such adverse events, which would limit our ability to commercialize our products.

Adverse side effects or other safety risks associated with our product candidates could cause us to suspend or discontinue clinical trials or delay or preclude approval.

During our DFU RCT and in the course of our commercial sales of SkinTE we did not observe undesirable side effects from the application of SkinTE. There is no assurance, however, that undesirable side effects will not be observed in our clinical trials, whether or not they are caused by SkinTE. Any such undesirable side effects could result in the delay, suspension, or termination of clinical trials by the FDA or us for a number of reasons. In addition, because the patients who will be enrolled in our clinical trials may be suffering from one or more serious chronic or life-threatening conditions it may be difficult to accurately assess the relationship between SkinTE and adverse events experienced by very ill patients. If we elect or are required to delay, suspend, or terminate any of our clinical trials, the commercial prospects of SkinTE could be harmed and our ability to generate product revenues from SkinTE could be delayed or eliminated. In addition, serious adverse events observed in clinical trials could hinder or prevent market acceptance of SkinTE. Any of these occurrences may harm our business, prospects, financial condition, and results of operations significantly.

We may form or seek strategic alliances, enter into additional licensing arrangements, or participate in acquisition transactions in the future, and we may not succeed in realizing the benefits of such alliances, licensing arrangements, or acquisition transactions.

We may form or seek strategic alliances, create joint ventures or collaborations, enter into licensing arrangements, or participate in an acquisition in which we are the acquirer or the target with third parties that we believe will complement or augment our development and commercialization efforts with respect to SkinTE or our other product candidates we may develop. Any of these relationships or transactions may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic opportunities and the negotiation process is time-consuming and complex. Moreover, we may not be successful in arranging a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or achieve commercial success. If we license or acquire products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. It is possible that,

following a strategic transaction or license, we may not achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.

Even if we obtain regulatory approval of SkinTE or future product candidates, they may not gain market acceptance among physicians, patients, hospitals, third-party payors, and others in the medical community.

The development and use of HCT/Ps for tissue regeneration therapies is a recently developed technology and may not become broadly accepted by physicians, patients, hospitals, third-party payors, and others in the medical community. Many factors will influence whether SkinTE or any other product candidates we may develop are accepted in the market, including:

- the clinical indications for which our product candidates are approved, if any;
- physicians, hospitals, and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the extent and quality of the clinical evidence supporting the efficacy and safety of our product candidates;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third-party payors and government authorities;
- the willingness and ability of patients to pay out-of-pocket in the absence of coverage by third-party payors, including government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our or any of our strategic partners' sales and marketing efforts.

If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Our ability to timely submit an IND to the FDA may depend on circumstances outside of our control.

Our ability to submit an IND to the FDA depends on a variety of factors. We must submit the results of various preclinical tests, together with manufacturing information, analytical data, all available past clinical data or literature, and a proposed clinical protocol to the FDA as part of the IND. Preclinical tests include laboratory evaluations of product chemistry and formulation, as well as other studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements, subject to any adjustments allowed by the FDA. The FDA may require that we conduct additional preclinical testing or for any product candidate before it allows us to initiate the clinical testing under any IND, which may lead to additional delays and increase the costs of our preclinical and clinical development. An IND also involves considerable work from our employees and advisors. Difficulties or delays in the process will likely increase the costs associated with the IND and result in an unanticipated reduction in the working capital we have available to pursue the IND and BLA.

If we are required to or voluntarily withdraw, recall, or cease product manufacturing, it 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, market withdrawal, or cessation of manufacturing or may be required to do so by a regulatory authority. A recall, market withdrawal, or cessation of manufacturing of one of our products would be costly and would divert management resources. Any such action involving 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 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 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 operate in a highly competitive and evolving field and face competition from regenerative medicine, biotechnology, and pharmaceutical companies, tissue engineering entities, tissue processors, and medical device manufacturers, as well as new market entrants, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

We operate in a competitive and continually evolving field. Competition from other regenerative medicine, biotechnology, 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. Many of our competitors have substantially greater financial, technical, and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove

to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring, or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized, or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. Our failure to compete effectively would have a material and adverse effect on our business, results of operations, and financial condition.

Risks Related to our Operating Activities

We may be required to discontinue sales of SkinTE, which would adversely affect our revenues, financial condition, and results of operations.

We continue to market SkinTE as a 361 HCT/P product and under the FDA's policy of enforcement discretion (currently scheduled through May 2021) as we work to transition SkinTE to a Section 351 product. Our net revenues from SkinTE sales in 2020 were $3.7 million. Following the end of the FDA's period of enforcement discretion, we may need to cease selling SkinTE until the FDA approves a BLA, and then we will only be able to market the product for indications that have been approved in a BLA. The loss of our ability to market and sell SkinTE would have an adverse impact on our revenues, financial condition, and results of operations.

We have a limited history of operation with our laboratory testing service so we are unable to predict with any certainty what contribution it will make to defraying our operating expenses in the future, which could adversely affect our ability to plan for the use of our resources to achieve our goals.

Net loss from our contract services segment was $39,000 for the year ended December 31, 2020 compared to a net loss of $1.2 million for the year ended December 31, 2019, and this reversal is directly attributable to the new source of revenue we found in COVD-19 testing. Net revenues from our historical clinical service offerings were $59,000 for the year ended December 31, 2020, compared to $4.3 million in net revenues generated by COVID-19 testing services. COVID-19 testing is a relatively new business activity that we started with existing equipment and personnel when the opportunity presented itself, which means there are substantial risks and uncertainties associated with this new business activity. We obtained 96% of COVID-19 testing revenues in 2020 under 30-day renewable testing agreements with multiple nursing home and pharmacy facilities in the state of New York controlled by a single company. On March 26, 2021, we were advised by the company that controls the New York nursing homes and pharmacy facilities we service that the state of New York is allowing on-site employee testing and that on-site testing will be implemented for the New York facilities we service, which will likely have the effect of substantially diminishing our revenues from COVID-19 testing after the first quarter of 2021. We are a relatively unknown testing laboratory, so we have relied on word of mouth and management relationships to connect with prospects and vied for new business on the basis of price and service, and we cannot predict how well this marketing approach will work in finding new customers for Arches' testing services. Even if we are able to find new customers for the COVID-19 testing business there remain substantial risks associated with the COVID-19 testing business, including the following:

- our plan is to commit our financial business resources to advancing our IND and BLA for SkinTE, not to develop or scale the COVID-19 testing business;
- competition from other COVID-19 testing facilities is intense, expected to increase, subject to rapid change, and could be significantly affected by the introduction of new testing products;
- there are a number of competitors for testing services that have substantially greater financial, marketing, testing, and managerial resources than we do;
- the United States is embarking on an aggressive vaccination program for the entire population against COVID-19 and this could impact the need or demand for testing in the future;
- we obtained CLIA registration for our laboratory because this is a prerequisite to providing testing services, and we must continue to comply with the practices and procedures required for registration in order to be able to continue to provide testing services;
- our ability to service our testing customers depends on the continuous operation of our testing equipment without significant disruption; and
- we need reliable sources of reagents and other supplies required for COVID-19 testing.

A significant decline or loss of the COVID-19 testing business in 2021 that we are unable to substantially replace with new customers could have a material and adverse effect on our business, results of operations, and financial condition.

Our manufacturing and COVID 19 testing operations depend primarily on one facility. If this facility is destroyed or we experience any manufacturing or laboratory difficulties, disruptions, or delays, this could adversely affect our ability to conduct our clinical trials or perform laboratory testing services.

All of the manufacturing of SkinTE and COVID-19 testing takes place at our single U.S. facility. If regulatory, manufacturing, or other problems require us to discontinue production or laboratory operations at our current facility, we would not be able to supply SkinTE for clinical trials or operate our COVID-19 testing business, 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 or laboratory 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 a third party or laboratory testing to our IBEX facility. Even if we could transfer manufacturing, the shift would likely be expensive and time-consuming, particularly since an alternative facility would need to comply with applicable FDA manufacturing and quality requirements and, if applicable, FDA approval would be required before any products manufactured at that facility could be used. Similarly, if we are able to transfer laboratory testing to IBEX, the transfer will likely be expensive and require CLIA registration.

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.

The ongoing COVID-19 pandemic could materially affect our operations, as well as the business or operations of third parties with whom we conduct business. Our business could be adversely affected by the effects of other future health pandemics in regions where we or third parties on which we rely have significant business operations.

COVID-19 has spread globally and the World Health Organization has declared it a pandemic. While still evolving, the COVID-19 pandemic has caused significant worldwide economic and financial turmoil and has fueled concerns that it will lead to a global recession. On March 13, 2020, the United States declared a national emergency with respect to COVID-19 and the majority of states, including the state of Utah, and local governments have since issued orders restricting the operations of non-essential businesses or restricting activities of residents. As the pandemic has evolved since March 2020, some restrictions have eased, however, if in the future there are surges of infection and hospitalization rates, more severe restrictions many be implemented by local government agencies. We are following the recommendations of local health authorities to minimize exposure risk for our employees and visitors, including requiring designated employees to work from home. The continued and prolonged implementation of restrictions by federal, state, and local authorities to slow the spread of COVID-19 have disrupted and, we expect, will continue to disrupt, our business and operations.

Depending upon the length of the COVID-19 pandemic and whether the FDA allows us to commence our clinical trials once we submit our proposed IND, our future clinical trials for SkinTE may be affected by the COVID-19 pandemic. If COVID-19 continues to spread in the U.S. and elsewhere, we may experience additional disruptions that could adversely impact our business and clinical trials, including: (i) delays or difficulties in enrolling patients in our clinical trials approved under our IND; (ii) delays or difficulties in clinical site activation, including difficulties in recruiting clinical site investigators and clinical site personnel; (iii) delays in clinical sites receiving the supplies and materials needed to conduct our clinical trial, including interruption in shipping that may affect the transport of our clinical trial product; (iv) changes in local regulations as part of a response to the COVID-19 pandemic that may require us to change the ways in which our clinical trial is to be conducted, which may result in unexpected costs, or to discontinue the clinical trial altogether; (v) diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trial; (vi) interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers, and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data; (vii) risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; (viii) delays in necessary interactions with local regulators, ethics committees, and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; (ix) limitations in employee resources that would otherwise be focused on the conduct of our clinical trial because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; (x) refusal of the FDA to accept data from clinical trials in affected geographies; and (xi) interruption or delays to our clinical trial activities.

The extent to which the COVID-19 pandemic impacts our business, operations, and financial results will depend on numerous evolving factors that we may not be able to accurately predict, including: the duration and scope of the pandemic; governmental, business and individuals' actions that have been and continue to be taken in response to the pandemic; the impact of the pandemic on economic activity and actions taken in response; our ability to continue daily operations, including as a result of travel restrictions and people working from home; and any closures of our and our business partners' offices and facilities.

Risks Related to Our Intellectual Property

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, patents, and patent applications. We currently have one issued patent and one allowed patent application in the United States relating to our MPFU technology. We intend to continue 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 already filed or that may be filed or acquired 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 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 have obtained or 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 have obtained or ultimately 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 have obtained or ultimately 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 for patent enforcement 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 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 SkinTE or 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 SkinTE 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, SkinTE, 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 SkinTE, our product candidates, procedures, or processes will infringe. There may be existing patents that SkinTE, 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.

We may not be able to enforce our 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 or applications 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 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.

We are pursuing a plan to advance regulatory approval of SkinTE, so delay or failure in achieving our milestones could adversely affect our prospects and the value of ownership of our common stock.

While a positive contributor to operating results, we do not plan to commit any meaningful amount of capital to scale our testing and research services business because we plan to devote our capital resources to the advancement of SkinTE through the regulatory process. We believe growth in stockholder value will follow if and when we achieve milestones in the process of pursuing our IND and BLA for SkinTE. To the extent that we encounter problems or delays in this process, our growth prospects and stockholder value could be materially, adversely affected.

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 28, 2021, with closing stock prices ranging from a high of $1.85 per share to a low of $0.61 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:

- the timing or success of obtaining regulatory licenses or approvals for marketing our products;
- the initiation, timing, progress, and results of our pre-clinical studies or clinical trials;
- sufficiency of our working capital to fund our operations over the next 12 months and beyond;
- infrastructure required to support operations in future periods, including the expected costs thereof;
- estimates associated with revenue recognition, asset impairments, and cash flows;
- variance in our estimates of future operating costs;
- the impact of new accounting pronouncements;
- size and growth of our target markets;
- the initiation, timing, progress, and results of our research and development programs;
- issues in manufacturing our product candidates or future approved products;
- 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.

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. As of March 25, 2021, we had 80,319,378 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 March 25, 2021, we also had a significant number of securities convertible into, or allowing the purchase of, our common stock, including 19,314,143 warrants to purchase shares of our common stock, 6,079,210 options and rights to acquire shares of our common stock that are outstanding under our equity incentive plans, and 4,271,350 shares of common stock reserved for future issuance under our equity incentive plans.

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

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

- we have a classified Board requiring that members of the Board be elected in different years, which lengthens the time needed to elect a new majority of the Board;
- our Board is authorized to issue up to 25,000,000 shares of preferred stock without stockholder approval, which could be issued by our Board to increase the number of outstanding shares or change the balance of voting control and thwart a takeover attempt;
- stockholders are not entitled to remove directors other than by a two-thirds vote and only for cause;
- stockholders cannot call a special meeting of stockholders;
- we require all stockholder actions be taken at a meeting of our stockholders, and not by written consent; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

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.

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, Utah. 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.

On June 26, 2018, a class action complaint alleging violations of the federal securities laws was filed in the U.S. 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"). On November 28, 2018, the court consolidated the *Moreno* and *Lawi* cases under the caption *In re PolarityTE, Inc. Securities Litigation* with Case No. 2:18-cv-00510 (the "Consolidated Securities Litigation"). The gravamen of the consolidated complaint in the Consolidated Securities Litigation was that defendants made statements or disseminated information to the public through reports filed with the SEC 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 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. 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. Following a hearing on the Company's motion to dismiss the court issued an order on November 22, 2020, dismissing the complaint in the Consolidated Securities Litigation with prejudice.

In November 2018, a shareholder derivative lawsuit was filed in the U.S. 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. After disposition of the Consolidated Securities Litigation described above the parties to the shareholder derivative lawsuit agreed to dismiss the lawsuit without prejudice, and the lawsuit was dismissed on January 29, 2021.

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. At December 31, 2020, 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 March 29, 2021, there were approximately 104 holders of record of our common stock.

The following table provides information on our compensation plans at December 31, 2020, 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	4,649,567	$ 10.02	3,603,057

Equity compensation plans not approved by security holders (1)	145,000	$	10.38	-0-
Total	4,794,567			3,603,057

(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
02/08/2017	50,000	$	4.72
04/06/2017	75,000	$	13.12
04/10/2017	10,000	$	14.25
04/10/2017	10,000	$	14.25

Shares Forgone by Employees or Reacquired by Us to Satisfy Tax Withholding Liability

During the year ended December 31, 2020, we withheld or acquired from employees shares of common stock to satisfy statutory withholding tax liability upon the vesting of share-based awards. The following table sets forth information on our acquisition of these shares for each month in 2020 in which an acquisition occurred.

Issuer Purchases of Equity Securities

Period	(a) Total number of shares (or units) purchased		(b) Average price paid per share (or unit)	(c) Total number of shares (or units) purchased as part of publicly announced plans or programs	(d) Maximum number (or approximate dollar value) of shares (or units) that may yet be purchased under the plans or programs
March 2020	4,587	$	1.052	N/A	N/A
April 2020	545	$	1.050	N/A	N/A
May 2020	1,090	$	0.898	N/A	N/A
June 2020	5,283	$	1.370	N/A	N/A
July 2020	52,190	$	1.520	N/A	N/A
August 2020	13,254	$	1.547	N/A	N/A
September 2020	5,283	$	1.040	N/A	N/A
October 2020	29,664	$	1.076	N/A	N/A
December 2020	6,091	$	0.700	N/A	N/A
Total	117,987	$	1.315		

Item 6. Selected Financial Data

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

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

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

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

Overview

We are a biotechnology company developing regenerative tissue products and biomaterials. Our first regenerative tissue product is SkinTE, which is intended 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. Given our significant real-world experience with the application of SkinTE and several supporting publications, we believe SkinTE can be successful in closing full-thickness complex wounds, such as DFUs penetrating to tendon, capsule, and bone classified Wagner Grades 2 through 4; Stage 3 and 4 pressure injuries; and, acute wounds. We believe that SkinTE could significantly improve clinical outcomes versus the standards of care for these wounds.

Since the beginning of 2017, we have incurred substantial operating losses and our operations have been financed primarily by public equity financings. Our plan is to file an IND for SkinTE in the second half of 2021 and commence clinical trials under our BLA by the first quarter of 2022, but this timing will depend on when we obtain FDA approval of our IND. The clinical trials and regulatory process will likely result in an increase in our expenses. We will continue to incur substantial operating losses as we pursue an IND and BLA, and we expect to seek financing from external sources over the next several years to fund our operations.

In May 2020 we reduced head count as a result of our decision to file an IND for SkinTE, and this decision was also influenced by what we believed would be adverse effects of the COVID-19 pandemic. At the end of 2020 we had 85 full and part-time employees compared to 157 at the end of 2019. This 46% reduction in personnel is the primary driver for the 47% reduction of total operating costs and expenses in 2020. We will continue to search for opportunities to lower our operating expenses in 2021 and thereby lower the rate at which we use capital obtained from external sources.

We have generated revenue from the sale of SkinTE as a 361 HCT/P product since 2018. In addition, we have generated revenue from our laboratory testing and research service business. Revenue from these activities has been helpful in lowering the rate at which we use capital obtained from external sources.

Gross profit from the sale of SkinTE covered 5% of our total operating costs and expenses in 2020. However, if the FDA allows enforcement discretion for regenerative tissue products to expire at the end of May 2021, we may need to cease selling SkinTE until the FDA approves a BLA, and then we will only be able to market

SkinTE for the indications that have been approved in the BLA. Consequently, it is possible that SkinTE sales may not continue to contribute to our capital resources in 2022. We are actively seeking opportunities to continue the process of reducing our operating expenses, and if SkinTE sales end in the future we intend to re-double our efforts to reduce costs of operations to make up for the loss of revenues.

Revenues generated from our laboratory testing and research services have also been helpful in lowering the rate at which we use capital obtained from external sources. Gross margin from services in 2020 covered 6% of our total operating costs and expenses in 2020. Gross profit from services was 39% higher in 2020 than in 2019 due to the revenues generated through COVID-19 testing that began at the end of May 2020. COVID-19 testing is a relatively new business activity, and 96% of COVID-19 testing revenues in 2020 were obtained under 30-day renewable testing agreements with multiple nursing home and pharmacy facilities in the state of New York controlled by a single company. On March 26, 2021, we were advised by the company that controls the New York nursing homes and pharmacy facilities we service that the state of New York is allowing on-site employee testing and that on-site testing will be implemented for the New York facilities we service, which will likely have the effect of substantially diminishing our revenues from COVID-19 testing after the first quarter of 2021. We are a relatively unknown testing laboratory, so we have relied on word of mouth and management relationships to connect with prospects and vied for new business on the basis of price and service, and we cannot predict how well this marketing approach will work in finding new customers for Arches' testing services. Even if we are able to find new customers for the COVID-19 testing business there remain substantial uncertainties around the COVID-19 testing business due to rapid developments in testing and vaccines.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending upon the timing of our clinical trials and our expenditures for satisfying all the conditions of obtaining FDA market approval for SkinTE. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued research and development and other current liabilities.

Recent Developments

Capital Formation

We raised capital in December 2020 and January 2021 to fund our operations. We previously reported in November 2020 that at September 30, 2020, our cash and cash equivalents totaled $23.186 million, which would not be adequate to fund our operations beyond the first quarter of 2021. We embarked on a plan to raise capital to fund our operations that began with a restructuring in November 2020 of warrants sold in a public offering in February 2020, which we believed had a chilling effect on our ability to attract institutional investors and depressed the public trading price of our common stock.

After the warrant restructuring we sold 5,450,000 shares of common stock, pre-funded warrants to purchase up to 5,238,043 shares of common stock (with an exercise price of $0.001), and accompanying common warrants to purchase up to 10,688,043 shares of common stock to a single healthcare-dedicated institutional investor in a registered direct offering. Each common share and pre-funded warrant were sold together with a common warrant. The combined offering price of each common share and accompanying common warrant was $0.7485 and for each pre-funded warrant and accompanying common warrant was $0.7475. The pre-funded warrants were subsequently exercised in January 2021 and the net proceeds we received from the offering were $7.2 million. In January 2021, the holder of the common warrants exercised all 10,688,043 warrants at an exercise price of $0.624 per share resulting in gross proceeds of $6.7 million. In exchange for the agreement of the holder to exercise those common warrants we issued to the holder new common stock purchase warrants at a price of $0.125 per new warrant to purchase up to 8,016,033 shares of common stock at an exercise price of $1.20 per share. Gross proceeds from the sale of the new warrants was $1.0 million.

Also in January 2021 we sold to the same institutional investor who participated in the December registered direct offering 6,670,000 shares of common stock, pre-funded warrants to purchase up to 2,420,910 shares of common stock (with an exercise price of $0.001), and accompanying common warrants to purchase up to 9,090,910 shares of common stock in another registered direct offering. Each common share and pre-funded warrant were sold together with a common warrant. The combined offering price of each common share and accompanying common warrant was $1.10 and for each pre-funded warrant and accompanying common warrant was $1.099. The pre-funded warrants were subsequently exercised so the gross proceeds of the offering were $10.0 million. The common warrants sold in the registered direct offering have an exercise price of $1.20 per share.

We believe this capital infusion from the foregoing offerings will enable us to fund our IND filing and the start of at least two clinical trials under the BLA for SkinTE.

Business Effects of COVID-19

The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, clinicians, communities, and business operations, as well as the U.S. economy and financial markets. The full extent to which the COVID-19 pandemic will directly or indirectly impact the timing and cost of pursuing FDA approval of SkinTE under a BLA is highly uncertain and cannot be accurately predicted. We will need to engage contract research organizations ("CROs") for our future clinical trials and the COVID-19 pandemic and response efforts may have an impact on the ability of CROs to timely perform the trials we need for SkinTE.

We saw a decrease in SkinTE cases in March 2020 and procedures scheduled for April 2020 postponed or not being scheduled, which was a trend we expected would continue and adversely affect our results of operations. As a result of our decision to file an IND for SkinTE and the disturbing trend in SkinTE cases, in May 2020 we reduced our workforce within our regenerative medicine business segment, which is engaged primarily in the commercialization of SkinTE. We also refocused our commercialization effort on the territories where we have current and repeat users of SkinTE, and this new focus resulted in a quarter over quarter increase in the average wound size treated and a concomitant increase in revenues, which we did not expect.

In the contract services segment COVID-19 had a significant adverse effect on pre-clinical research business from March through the end of 2020, so we expected our contract services business would also suffer as a result of COVID-19. However, we unexpectedly received inquiries in April 2020 from third parties acquainted with our management team regarding our laboratory and its ability to perform COVID-19 testing, which we attribute to the surge in COVID-19 testing throughout the United States and what we believe to be a lack of laboratory testing capacity to meet the surging demand. Management evaluated Arches' resources and found that it has the capability of performing molecular polymerase chain reaction testing for COVID-19. Management decided that COVID-19 testing offered an opportunity to use existing resources to generate additional revenue in the contract services segment and thereby help defray our operating expenses. We began providing COVID-19 testing services at the end of May 2020, and from then to the end of 2020 COVID-19 testing generated $4.3 million in net revenues. These developments notwithstanding, there is great uncertainty around the COVID-19 pandemic that makes it impossible to accurately predict how the pandemic may directly or indirectly impact our business, results of operations, liquidity, and financial condition

The COVID-19 pandemic has caused us to modify our business practices including, but not limited to, curtailing or modifying employee travel, moving to partial remote work, and cancelling physical participation in meetings, events, and conferences. We may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, patients, clinicians, and business partners. The majority of our office-based employees have been working from home since March 2020, while ensuring essential staffing levels to support our operations remain in place, including maintaining key personnel in our laboratories.

Liquidity and Capital Resources

As of December 31, 2020, we had $25.5 million in cash and cash equivalents, and working capital of approximately $22.7 million. In January 2021, we raised an additional $17.7 million in gross proceeds before offering expenses in a registered direct offering and through a warrant exercise agreement.

We believe the net revenues we generate internally together with the cash and cash equivalents on our balance sheet will fund our business activities through the end of 2021 and into the third quarter of 2022. In the fourth quarter of 2020 cash used in operating activities was $5.6 million, or an average of $1.9 million per month. After our IND is filed and then accepted by the FDA, we will move to begin clinical trials as soon as possible. Preliminary estimates indicate one clinical trial could cost approximately $5.0 million over two years, and we believe we will need to conduct at least two clinical trials for SkinTE. Clinical trials are the major expense we see in the near and long term, and while we are pursuing clinical trials we will continue to incur the costs of maintaining our business. In addition to clinical trials, the most significant uses of cash to maintain our business going forward are compensation and costs of occupying our facilities. If we need to discontinue commercial sales of SkinTE, we will lose net revenues from the sale of SkinTE, but we will also focus on eliminating operating expenses related to the SkinTE service. We cannot predict how this will impact our cash flows and working capital.

We will need to raise additional capital to fund our effort to obtain FDA approval of SkinTE and maintain our operations in the future. Although we have been successful in raising capital in the past, financing may not be available on terms favorable to us, if at all, so there is no assurance that we will be successful in obtaining additional financing. For the foreseeable future we will continue to pursue fundraising opportunities when available. If adequate funds are not available to us in the future, we may be required to delay, reduce the scope of, or eliminate our plans for obtaining regulatory approval for SkinTE or be unable to continue operations over a longer term.

Results of Operations

	For the Year Ended		Increase (Decrease)	
(in thousands)	December 31, 2020	December 31, 2019	Amount	%
Net revenues				
Products	$ 3,730	$ 2,353	$ 1,377	59%
Services	6,396	3,299	3,097	94%
Total net revenues	10,126	5,652	4,474	79%
Cost of sales				
Products	1,068	1,365	(297)	(22)%
Services	3,356	1,114	2,242	201%
Total cost of sales	4,424	2,479	1,945	78%
Gross profit	5,702	3,173	2,529	80%
Operating costs and expenses				
Research and development	11,532	16,397	(4,865)	(30)%
General and administrative	27,557	63,189	(35,632)	(56)%
Sales and marketing	8,719	16,980	(8,261)	(49)%
Restructuring and other charges	3,834	-	3,834	*
Total operating costs and expenses	51,642	96,566	(44,924)	(47)%
Operating loss	(45,940)	(93,393)	47,453	(51)%
Other income (expense), net				
Change in fair value of common stock warrant liability	2,914	-	2,914	*
Interest (expense) income, net	(182)	151	(333)	(221)%
Other income, net	354	749	(395)	(53)%
Net loss	$ (42,854)	$ (92,493)	$ 46,639	(54)%

* Not meaningful

Net Revenues

Net revenues increased by 79% to $10.126 million in 2020. The increase in net revenues for sale of products was the result of a sales strategy adopted in May 2020 to focus on regions and facilities where we had repeat users of SkinTE. For 2020 the average wound size treated with SkinTE was 219 cm^2 compared to 120 cm^2 in 2019, which corresponds with the difference in revenue between those years. The increase in net revenues for services was the result of $4.324 million in new COVID-19 testing services we began to offer through Arches at the end of May 2020. In 2019 services net revenues was derived primarily from pre-clinical testing services provided through IBEX, which were adversely impacted by COVID-19 in 2020.

Cost of Sales

Cost of sales increased by 78% to $4.424 million in 2020, which is attributable to the cost of sales of $2.417 million for providing COVID-19 testing services that were added in 2020. The cost of sales for products were lower in 2020 by 22% over 2019 due to the economies of scale gained from selling SkinTE for larger wounds.

Operating Costs and Expenses

Total operating costs and expenses decreased to $51.642 million in 2020 from $96.566 million in 2019, or 47%. This is the most significant change in our results of operations period over period and is attributable to the 46% reduction in personnel from the end of 2019 to the end of 2020. The reduction in personnel substantially reduced salary and benefit costs across the Company. Salary and benefits totaled $19.721 in 2020 compared to $28.812 in 2019. In addition, stock-based compensation decreased by 77% from $31.402 million in 2019 to $7.258 million in 2020. The decrease in salary and benefits in 2020 accounts for 20% of the decrease in total operating costs and expenses in 2020 compared to 2019. The decrease in stock-based compensation in 2020 accounts for 54% of the decrease in total operating costs and expenses in 2020 compared to 2019. The reduction in personnel also allows us to make incremental reductions in the cost of infrastructure required to support the activities of employees.

Research and Development

Research and development expenses decreased by 30% in 2020 to $11.532 million, which is attributable to the reduction in salary and benefits and stock compensation costs from 2019.

General and Administrative Expenses

General and administrative expenses decreased by 56% in 2020 to $27.557 million. In addition to reductions in salary and benefits and stock compensation costs from 2019, travel and related costs decreased to $0.243 million in 2020 from $1.318 million in 2019. Expenses for our leased facilities were $2.094 million in 2020. Lease expenses for our corporate office facility was $0.357 million in 2020, which will not recur in 2021 because the lease expired in 2020. Our lease expense for our manufacturing facility in Utah was $1.251 million in 2020, and we remain obligated under the terms of the lease for that facility until the end of November 2022.

Sales and Marketing

Sales and marketing expenses decreased by 49% in 2020 to $8.719 million. In addition to reductions in salary and benefits and stock compensation costs from 2019, promotional consulting and expense was reduced to $0.834 million in 2020 from $5.270 in 2019, and travel and related costs decreased to $0.444 million in 2020 from $1.440 million in 2019.

Restructuring and other charges

We recorded $3.834 million in restructuring and other charges in 2020. The main components of the restructuring charges are capitalized costs in the amount of $0.518 million for the development of a vivarium project at our Salt Lake City facility we abandoned in 2020, abandonment of equipment purchased in prior periods in the amount of $1.014 million, and severance payments in the amount of $1.025 million associated with the reduction of personnel in 2020.

In addition, when we were pursuing an aggressive commercialization plan for SkinTE in 2019 we entered into a lease agreement for establishing a manufacturing node at the Joseph M. Still Burn Center in Augusta, Georgia. The node lease has a term of five years and a monthly base rent of $10,286. In 2020 we spent $0.606 million on node operations, including rent of $0.119 million. In the fourth quarter of 2020 we decided to abandon operations at the node, which resulted in the recognition of a charge in the amount of $1.175 million comprised of equipment, leasehold improvements, and a right of use asset. We continue to make payments on the lease for the node and are seeking opportunities to sublease the space.

Other income (expense), net – Change in Fair Value of Common Stock Warrants

We have issued and outstanding warrants classified as liabilities. The amount of the liabilities attributable to the warrants are remeasured as of the end of each fiscal quarter and adjusted accordingly through an increase or decrease recorded on our consolidated statement of operations for the period. At December 31, 2020, the total common stock warrant liability was $5.975 million reflecting a fair value change of $2.914 million under other income.

Critical Accounting Policies and Estimates

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

Revenue Recognition. With respect to revenue recognition in contract services provided by IBEX, revenues generally consist of a single performance obligation that IBEX 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. We believe 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 that our services personnel at IBEX make reasonable estimates of the extent of progress toward completion of the contract and, as a result, unbilled receivables and deferred revenue are recognized based on payment timing and work completed.

Stock-Based Compensation. 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 our historical stock prices.

Common Stock Warrant Liability. The fair value of the common stock warrant liability is estimated using the Monte Carlo simulation model, which involves simulated future stock price amounts over the remaining life of the commitment. The fair value estimate is affected by our stock price as well as estimated change of control considerations.

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

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

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on the evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2020, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

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 ("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 a 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, 2020. 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 effective as of December 31, 2020.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three-month period ended December 31, 2020.

Item 9B. Other Information.

"At the Market" Offering

On March 30, 2021, we entered into a sales agreement (the "Sales Agreement") with Cantor, Fitzgerald & Co. ("Cantor"), to sell shares of our common stock having aggregate sales proceeds of up to $50.0 million, from time to time, through an "at the market" equity offering program under which Cantor will act as sales agent.

Under the Sales Agreement, we will set the parameters for the sale of shares of our common stock, including the number of shares to be issued, the time period during which sales are requested to be made, and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sales Agreement, Cantor will use commercially reasonable efforts to sell the shares by methods deemed to be an "at the market offering" as defined in Rule 415 under the Securities Act, including sales made directly on The Nasdaq Global Market or any other trading market for our common stock. We will pay Cantor a commission of up to 4.0% of the aggregate gross proceeds of any common stock sold through Cantor under the Sales Agreement, if any. In the event the total amount of commissions paid to Cantor is not at least $400,000 as of March 30, 2022, we will pay to Cantor the difference between $400,000 and the total amount of commissions paid to Cantor as of that date. The Sales Agreement contains customary representations, warranties and agreements between us and Cantor, as well as customary indemnification rights, including for liabilities under the Securities Act.

We are not obligated to make any sales of common stock under the Sales Agreement. The offering of shares of common stock pursuant to the Sales Agreement will terminate upon the termination of the Sales Agreement in accordance with its terms. We and Cantor may terminate the Sales Agreement at any time by providing written notice to the other party.

The foregoing description of the Sales Agreement is qualified in its entirety by reference to the Sales Agreement, a copy of which is attached hereto as Exhibit 1.1 and incorporated herein by reference. The Sales Agreement contains representations, warranties, and covenants that were made only for purposes of such agreement and as of specific dates, are solely for the benefit of the parties to such agreement and may be subject to limitations agreed upon by the contracting parties. The Sales Agreement is not intended to provide any other factual information about us.

The legal opinion of King & Spalding LLP relating to the shares of common stock being offered pursuant to the Sales Agreement is filed as Exhibit 5.1 to this Annual Report on Form 10-K.

Keystone Equity Line

Pursuant to an Equity Purchase Agreement dated as of December 5, 2019 (the "Purchase Agreement") that we entered into with Keystone Capital Partners, LLC ("Keystone"), Keystone 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. In anticipation of the "at the market" equity offering program described above, we provided notice to Keystone of our decision to terminate the Purchase Agreement, which was effective on March 26, 2021. During the period from the date of the Purchase Agreement to the date of termination we sold 270,502 shares of our common stock under the Purchase Agreement generating total gross proceeds of $0.7 million.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information under the captions "Proposal No. 1 Election of Directors," "Corporate Governance and the Board of Directors," and "Board of Directors" in our proxy statement for our 2021 annual meeting of stockholders (our "2021 Proxy Statement") is incorporated herein by reference. There were no material changes to the procedures by which stockholders may recommend nominees to our board of directors. See also, "Part 1, Item 1- Contact and Available Information," above.

ITEM 11. EXECUTIVE COMPENSATION

The information under the captions "Board of Directors" and "Executive Compensation" in our 2021 Proxy Statement is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information under the captions "Security Ownership of Certain Beneficial Owners and Management" in our 2021 Proxy Statement is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information under the captions “Corporate Governance and the Board of Directors” and “Certain Relationships and Related Transactions” in our 2021 Proxy Statement is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information under the proposal pertaining to ratification of the appointment of EisnerAmper LLP as independent public accountant for the fiscal year ending December 31, 2021 in our 2021 Proxy Statement is incorporated herein by reference.

With the exception of the information specifically incorporated by reference in Part III of this Annual Report on Form 10-K from our 2021 Proxy Statement, our 2021 Proxy Statement will not be deemed to be filed as part of this report. Without limiting the foregoing, the information under the caption “Audit Committee Report” in our 2021 Proxy Statement is not incorporated by reference in this Annual Report on Form 10-K.

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:

1.1	Sales Agreement dated March 30, 2021, between the Company and Cantor Fitzgerald & Co.
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	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)
3.3	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 January 10, 2017)
3.4	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)
3.5	Certificate of Elimination to Restated Certificate of Incorporation eliminating the Series A Preferred Stock, Series B Preferred Stock, Series C Preferred Stock, Series D Preferred Stock, Series E Preferred Stock and Series F Preferred Stock in the Corporation’s Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to our Form 8-K filed with the SEC on March 7, 2018)
3.6	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)
3.7	Restated Bylaws (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on June 17, 2005).
3.8	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)
3.9	Articles of Merger (incorporated by reference to Exhibit 3.2 to our Form 8-K filed with the SEC on April 7, 2017)
4.1	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)
4.2	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)
4.3	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)
4.4	Form of letter agreement for repricing of common stock warrants issued February 14, 2020 (incorporated by reference to Exhibit 99.1 to our Form 8-K filed with the SEC on November 23, 2020)
4.5	Form of Series A Common Stock Purchase Warrant dated December 23, 2020 (incorporated by reference to Exhibit 4.1 to our Form 8-K filed with the SEC on December 23, 2020)
4.6	Form of Series B Pre-Funded Common Stock Purchase Warrant dated December 23, 2020 (incorporated by reference to Exhibit 4.2 to our Form 8-K filed with the SEC on December 23, 2020)
4.7	Form of Placement Agent Common Stock Purchase Warrant dated December 23, 2020 (incorporated by reference to Exhibit 4.3 to our Form 8-K filed with the SEC on December 23, 2020)
4.8	Form of Series A Common Stock Purchase Warrant – January 2021 (incorporated by reference to Exhibit 4.1 to our Form 8-K filed with the SEC on January 14, 2021)
4.9	Form of Series B Pre-Funded Common Stock Purchase Warrant – January 2021 (incorporated by reference to Exhibit 4.2 to our Form 8-K filed with the SEC on January 14, 2021)
4.10	Form of Placement Agent Common Stock Purchase Warrant – January 2021 (incorporated by reference to Exhibit 4.3 to our Form 8-K filed with the SEC on January 14, 2021)
4.11	Form of Common Stock Purchase Warrant – January 2021 (incorporated by reference to Exhibit 4.1 to our Form 8-K filed with the SEC on January 26, 2021)
4.12	Form of Placement Agent Common Stock Purchase Warrant – January 2021 (incorporated by reference to Exhibit 4.2 to our Form 8-K filed with the SEC on January 26, 2021)
*4.13	Description of Securities
*5.1	Opinion of King & Spalding relating to the Sales Agreement dated March 30, 2021
#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

#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 2017 Equity Incentive Plan (incorporated by reference to Appendix A of our proxy statement filed with the SEC on February 24, 2017)
#10.14	PolarityTE 2019 Equity Incentive Plan (incorporated by reference to Exhibit 99.2 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 99.1 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 99.1 to our Form 8-K filed with the SEC on December 29, 2020)
#10.17	Form of Incentive Stock Option Agreement – 2020 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.17 to our Form 10-K filed with the SEC on March 12, 2020)
#10.18	Form of Non-qualified Stock Option Agreement – Non-employee Directors – 2020 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.18 to our Form 10-K filed with the SEC on March 12, 2020)
#10.19	Form of Non-qualified Stock Option Agreement – Employees – 2020 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.19 to our Form 10-K filed with the SEC on March 12, 2020)
#10.20	Form of Non-qualified Stock Option Agreement – Consultants – 2020 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.20 to our Form 10-K filed with the SEC on March 12, 2020)
#10.21	Form of Restricted Stock Award – 2020 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.21 to our Form 10-K filed with the SEC on March 12, 2020)
#10.22	Form of Restricted Stock Unit Award – Non-employee Directors - 2020 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.22 to our Form 10-K filed with the SEC on March 12, 2020)
#10.23	Form of Restricted Stock Unit Award – Employees - 2020 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.23 to our Form 10-K filed with the SEC on March 12, 2020)
#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	Separation, Transition, and Release of Claims Agreement dated March 31, 2020, between Paul Mann and the Company (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on April 1, 2020)
#10.27	Form of Indemnification Agreement for directors and officers (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on March 25, 2020)
10.28	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)
10.29	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)
10.30	Sublease Agreement with Joseph M. Still Burn Centers, Inc., dated April 22, 2019 (incorporated by reference to Exhibit 10.28 to our Form 10-K filed with the SEC on March 12, 2020)
10.31	Commercial Lease Agreement by and Between the Company and Adcomp LLC (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on December 29, 2017)

10.32	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)
10.33	Note and Loan Agreement dated April 12, 2020, between PolarityTE MD, Inc., and KeyBank National Association (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on April 15, 2020)
10.34	COVID-19 Laboratory Services Agreement between Arches Research, Inc., and Co-Diagnostics, Inc., dated September 2, 2020 [service pricing information is redacted from the exhibit] (incorporated by reference to Exhibit 10.1 to our Form 10-Q filed with the SEC on November 9, 2020)
10.35	Rental Agreement for LGC Genomics Oktopure Extraction Machine between Arches Research, Inc., and Co-Diagnostics, Inc., dated September 2, 2020 [product pricing information is redacted from the exhibit] (incorporated by reference to Exhibit 10.2 to our Form 10-Q filed with the SEC on November 9, 2020)
10.36	Form of Securities Purchase Agreement dated December 21, 2020 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on December 23, 2020)
10.37	Form of Securities Purchase Agreement dated January 11, 2021 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on January 14, 2021)
10.38	Form of letter agreement for exercise of Series A Common Stock Purchase Warrant dated December 23, 2020 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on January 26, 2021)
21.1	Subsidiaries (incorporated by reference to Exhibit 21.1 to our Form 10-K filed with the SEC on March 12, 2020)
*23.1	Consent of Independent Registered Public Accounting Firm
*23.2	Consent of King & Spalding LLP (included in Exhibit 5.1)
*31.1	Certification Pursuant to Rule 13a-14(a)
*31.2	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.

Item 16. Form 10-K Summary.

Not Applicable.

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*
Chief Executive Officer
(Principal Executive Officer)

Date: March 30, 2021

By: */s/ Jacob Patterson*
Chief Financial Officer (Principal Financial and Accounting Officer)

Date: March 30, 2021

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 30, 2021
/s/ Jeffrey Dyer Jeffrey Dyer	Director	March 30, 2021
/s/ Chris Nolet Chris Nolet	Director	March 30, 2021
/s/ Minnie Baylor-Henry Minnie Baylor-Henry	Director	March 30, 2021
/s/ Willie C. Bogan Willie C. Bogan	Director	March 30, 2021
/s/ Jessica Shen Jessica Shen	Director	March 30, 2021

POLARITYTE, INC. AND SUBSIDIARIES

Consolidated Financial Statements

TABLE OF CONTENTS

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, 2020 and 2019 and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2020 and 2019 and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP).

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Equity Linked Instruments

As discussed in Notes 11 and 12, the Company has issued common stock warrants to purchasers of its common stock that are classified as a liability and are recorded at fair value in the Company's balance sheet and has granted stock-based awards in the form of stock options, restricted stock awards and restricted stock units to employees and non-employees for which compensation expense is recorded based on the fair value of the awards. In addition, equity linked instruments classified as liabilities are remeasured each period until settled or until classified as equity. Management utilized the Monte Carlo Simulation and Black Scholes models to estimate the fair value of these instruments which required assumptions for the inputs to those models.

We identified the accounting for equity linked instruments as a critical audit matter due to (i) the significant management judgment and subjectivity in developing the assumptions to the models utilized (ii) there was subjectivity in assessing the features of the common stock warrants in evaluating classification and the relevant accounting guidance for classification is complex, and (iii) the complexity of the Monte Carlo Simulation model.. This in turn led to a high degree of auditor judgment and subjectivity and significant audit effort was required in performing procedures to evaluate the accounting for equity linked instruments. Additionally, the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. We obtained an understanding and evaluated the design of controls relating to the Company's accounting for equity linked instruments. Our procedures also included, among others, (i) evaluating management's process for selecting the appropriate valuation models and techniques and assumptions used as inputs to those valuation models; (ii) testing the completeness, mathematical accuracy, and relevance of underlying data used in the models and calculations; and (iii) evaluating the features of the equity linked instruments and applying our understanding of the applicable provisions of U.S. GAAP in testing their classification. We involved a valuation specialist in auditing the estimated fair value of the common stock warrant liability, which utilized the Monte Carlo Simulation model. The valuation specialist assisted with evaluating the valuation models and related assumptions utilized, as well as performed a sensitivity analysis of the Monte Carlo Simulation.

/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 30, 2021

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

	December 31, 2020	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 25,522	$ 10,218
Short-term investments	–	19,022
Accounts receivable, net	3,819	1,731
Inventory	883	252
Prepaid expenses and other current assets	992	1,264
Total current assets	31,216	32,487
Property and equipment, net	10,550	14,911
Operating lease right-of-use assets	2,452	4,590
Intangible assets, net	542	731
Goodwill	278	278
Other assets	472	602
TOTAL ASSETS	$ 45,510	$ 53,599
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 4,148	$ 7,095
Other current liabilities	2,106	2,338

Current portion of long-term note payable	2,059	528
Deferred revenue	168	98
Total current liabilities	8,481	10,059
Common stock warrant liability	5,975	–
Operating lease liabilities	1,476	2,994
Other long-term liabilities	723	1,630
Long-term notes payable	1,517	–
Total liabilities	18,172	14,683
Commitments and Contingencies (Note 17)		
STOCKHOLDERS' EQUITY		
Preferred stock – 25,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2020 and 2019	–	–
Common stock - $.001 par value; 250,000,000 shares authorized; 54,857,099 and 27,374,653 shares issued and outstanding at December 31, 2020 and 2019, respectively	55	27
Additional paid-in capital	505,494	474,174
Accumulated other comprehensive income	–	72
Accumulated deficit	(478,211)	(435,357)
Total stockholders' equity	27,338	38,916
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 45,510	$ 53,599

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, 2020	For the Year Ended December 31, 2019
Net revenues		
Products	$ 3,730	$ 2,353
Services	6,396	3,299
Total net revenues	10,126	5,652
Cost of sales		
Products	1,068	1,365
Services	3,356	1,114
Total costs of sales	4,424	2,479
Gross profit	5,702	3,173
Operating costs and expenses		
Research and development	11,532	16,397
General and administrative	27,557	63,189
Sales and marketing	8,719	16,980
Restructuring and other charges	3,834	–
Total operating costs and expenses	51,642	96,566
Operating loss	(45,940)	(93,393)
Other income (expense), net		
Change in fair value of common stock warrant liability	2,914	–
Interest (expense) income, net	(182)	151
Other income, net	354	749
Net loss	$ (42,854)	$ (92,493)
Net loss per share attributable to common stockholders		
Basic	$ (1.11)	$ (3.70)
Diluted	$ (1.16)	$ (3.70)
Weighted average shares outstanding		
Basic	38,779,316	24,966,355
Diluted	39,367,390	24,966,355

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, 2020	For the Year Ended December 31, 2019
Net loss	$ (42,854)	$ (92,493)
Other comprehensive income (loss):		
Unrealized gain on available-for-sale securities	11	493

Reclassification of realized gain included in net loss	(83)	(457)
Comprehensive loss	$ (42,926)	$ (92,457)

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

POLARITYTE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share and per share amounts)

	Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Number	Amount	Number	Amount	Capital	Income	Deficit	Equity
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	–	–	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
Issuance of common stock, net of issuance costs of $1,319	–	–	10,854,710	11	12,589	–	–	12,600
Issuance of common stock and pre-funded warrants through underwritten offering, net of issuance costs of $251	–	–	5,450,000	5	2,261	–	–	2,266
Issuance of common stock upon exercise of warrants	–	–	10,073,298	10	9,263	–	–	9,273
Stock option exercise	–	–	10,208	–	31	–	–	31
Stock-based compensation expense	–	–	–	–	7,258	–	–	7,258
Purchase of ESPP shares	–	–	97,445	–	75	–	–	75
Vesting of restricted stock units	–	–	1,161,658	2	(2)	–	–	–
Shares withheld for tax withholding on vesting of restricted stock	–	–	(117,987)	–	(155)	–	–	(155)
Forfeiture of restricted stock awards	–	–	(46,886)	–	–	–	–	
Other comprehensive loss	–	–	–	–	–	(72)	–	(72)
Net loss	–	–	–	–	–	–	(42,854)	(42,854)
Balance - December 31, 2020	–	$ –	54,857,099	$ 55	$ 505,494	$ –	$ (478,211)	$ 27,338

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, 2020	For the Year Ended December 31, 2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (42,854)	$ (92,493)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	7,258	31,402
Depreciation and amortization	3,074	2,992
Change in allowance for doubtful accounts	148	26
Change in fair value of common stock warrant liability	(2,914)	–
Amortization of intangible assets	189	193
Amortization of debt discount	19	49
Change in fair value of contingent consideration	–	(36)
Loss on abandonment of property and equipment and ROU assets	2,806	914
Other non-cash adjustments	(21)	20
Changes in operating assets and liabilities:		
Accounts receivable	(2,236)	(1,045)
Inventory	(631)	84
Prepaid expenses and other current assets	272	193
Operating lease right-of-use assets	1,700	1,651
Other assets/liabilities, net	(200)	(249)
Accounts payable and accrued expenses	(2,761)	1,269
Other current liabilities	35	32
Deferred revenue	70	(72)
Operating lease liabilities	(1,708)	(1,578)

Net cash used in operating activities	(37,754)	(56,648)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(1,339)	(2,773)
Purchase of available-for-sale securities	(14,144)	(40,072)
Proceeds from maturities of available-for-sale securities	16,945	23,327
Proceeds from sale of available-for-sale securities	16,171	3,901
Net cash provided by/(used in) investing activities	17,633	(15,617)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from term note payable and financing arrangements	4,629	–
Principal payments on term note payable and financing arrangements	(1,675)	(534)
Payment of contingent consideration liability	–	(225)
Principal payments on financing leases	(508)	(453)
Net proceeds from the sale of common stock, warrants and pre-funded warrants	32,020	28,073
Proceeds from warrants exercised	1,008	–
Cash paid for tax withholdings related to net share settlement	(155)	(679)
Proceeds from stock options exercised	31	529
Proceeds from ESPP purchase	75	99
Net cash provided by financing activities	35,425	26,810
Net increase/(decrease) in cash and cash equivalents	15,304	(45,455)
Cash and cash equivalents - beginning of period	10,218	55,673
Cash and cash equivalents - end of period	$ 25,522	$ 10,218
Supplemental cash flow information:		
Cash paid for interest	$ 187	$ 199
Supplemental schedule of non-cash investing and financing activities:		
Property and equipment additions acquired through finance leases	$ –	$ 2,578
Property and equipment acquired through financing arrangements	$ –	$ 58
Unpaid liability for acquisition of property and equipment	$ 87	$ 273
Reclassification of stock-based compensation expense that was previously classified as a liability to paid-in capital	**$** –	**$** 38
Right-of-use asset obtained in exchange for new lease liability	**$** 82	**$** –
Allocation of proceeds from sale of common stock and warrants to warrant liability	**$** 17,154	**$** –
Reclassification of warrant liability to stockholders' equity upon exercise of warrant	**$** 8,265	**$** –

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

POLARITYTE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. PRINCIPAL BUSINESS ACTIVITY AND BASIS OF PRESENTATION

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

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, the valuation of warrant liabilities, and impairment and abandonment of assets. 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), the Chief Executive Officer (CEO), allocates resources to and assesses the performance of each operating segment using information about its revenue and operating income (loss).

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 (expense) 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, 2020 and 2019, the Company recorded an allowance of approximately $174,000 and

$26,000, respectively.

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.

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. 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.

The Company records product revenues primarily from the sale of its regenerative tissue products. The Company sells its products to healthcare providers (customers), 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. Contract services include research and laboratory testing services to unrelated third parties on a contract basis. These customer contracts generally consist of a single performance obligation that the Company satisfies at a point in time. The Company recognizes revenue upon delivery of testing results to the customer. As of December 31, 2020 and 2019, the Company had unbilled receivables of $0.2 million and $0.1 million, respectively, and deferred revenue of $0.2 million and $0.1 million, respectively. The unbilled receivables balance is included in consolidated accounts receivable. Revenue of $0.1 million was recognized during the year ended December 31, 2020 that was included in the deferred revenue balance as of December 31, 2019.

Any costs incurred to obtain a contract would be recognized as product is shipped.

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:

	Segment	For the Year Ended December 31, 2020 % of Revenue	For the Year Ended December 31, 2019 % of Revenue
Customer A	Contract Services	*	23%
Customer B	Regenerative Medicine	13%	*
Customer C	Contract Services	41%	*

Concentration of accounts receivable was as follows:

	Segment	December 31, 2020 % of Accounts Receivable	December 31, 2019 % of Accounts Receivable
Customer B	Regenerative Medicine	14%	14%
Customer C	Contract Services	46%	*
Customer D	Contract Services	*	15%
Customer E	Regenerative Medicine	*	11%

The following table contains revenues as presented in the Consolidated Statements of Operations disaggregated by services and products.

	December 31, 2020	December 31, 2019
Regenerative Medicine		
SkinTE Products	$ 3,730	$ 2,353
Contract Services		
Lab Testing Services	4,454	176
Preclinical Research Services	1,942	3,123
	6,396	3,299
Total Net Revenues	$ 10,126	$ 5,652

* 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 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.

Common Stock Warrant Liability. The Company accounts for common stock warrants issued as freestanding instruments in accordance with applicable accounting guidance as either liabilities or as equity instruments depending on the specific terms of the warrant agreement. Under certain change of control provisions, some warrants issued by the Company could require cash settlement which necessitates such warrants to be recorded as liabilities. Warrants classified as liabilities are remeasured each period until settled or until classified as equity. No reclassification occurred within the periods presented.

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.

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.

Net Loss Per Share. Basic net 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. Gains on warrant liabilities are only considered dilutive when the average market price of the common stock during the period exceeds the exercise price of the warrants. Further, in December 2020, in connection with the December 23, 2020 underwritten offering, the Company sold pre-funded warrants to purchases 5,238,043 shares of common stock. The pre-funded warrants are exercisable for shares of common stock at a price of $0.001 per share. The shares of common stock into which the pre-funded warrants may be exercised are considered outstanding for the purposes of computing fully diluted net loss per share because the shares may be issued for little or no consideration, are fully vested, and are exercisable after the original issuance date.

Recent Accounting Pronouncements

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.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes by removing certain exceptions to the current guidance, and improving the consistent application of and simplification of other areas of the guidance. The amendments in the ASU are effective for fiscal years beginning after December 15, 2020, including interim periods therein. Early adoption is permitted. The amendment to the ASU will not have a material impact to the Company.

Recently Adopted 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 was effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years with early adoption permitted. The ASU was adopted by the Company in the first quarter of fiscal year 2020. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. The ASU aligns the requirements of capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. Adoption of the ASU is either retrospective or prospective. The Company adopted this standard prospectively on January 1, 2020. The adoption of this ASU did not have a material 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, 2020, the Company has an accumulated deficit of $478.2 million. As of December 31, 2020, the Company had cash and cash equivalents of $25.5 million. The Company has been funded historically through sales of equity and debt.

During the first quarter of 2020, the Company effectuated four 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. 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.

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 public purchase price of $2.35 before underwriting discount and commission. The exercise price of each warrant was $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 were $22.5 million, after offering expenses payable by the Company. In connection with this agreement, the Company agreed not to sell any additional shares under the Keystone Purchase Agreement for a period of 90 days after the closing date of the offering. On November 19, 2020, the Company reduced the exercise price of the Warrants from $2.80 per share to $0.10 per share effective November 20, 2020. As of December 31, 2020, 10,073,298 of these Warrants were exercised into shares of common stock for proceeds of $1.0 million.

The Company entered into a promissory note for $3.6 million under the Paycheck Protection Program on April 12, 2020. Additional details are provided in Note 10.

In the second quarter of 2020 the Company took steps to reduce cash burn by reducing payroll expense, adopting a salary and wage reduction, and reducing discretionary spending across the organization to minimal levels.

On December 23, 2020, the Company completed a registered direct offering of 5,450,000 shares of its common stock, par value $0.001 per share, pre-funded warrants to purchase up to 5,238,043 shares of common stock and accompanying common warrants to purchase up to 10,688,043 shares of common stock. Each share of common stock and pre-funded warrant was sold together with a warrant. The combined offering price of each common stock share and accompanying warrant was $0.7485 and for each pre-funded warrant and accompanying warrant was $0.7475. The pre-funded warrants had an exercise price of $0.001 each and were exercised in full in January 2021. Each warrant is exercisable for one share of the Company's common stock at an exercise price of $0.624 per share. The net proceeds to the Company from the offering were $7.2 million, after offering expenses payable by the Company.

Following the end of 2020, the Company closed on two additional offerings:

On January 14, 2021, the Company completed a registered direct offering of 6,670,000 shares of its common stock, par value $0.001 per share, pre-funded warrants to purchase up to 2,420,910 shares of common stock and accompanying common warrants to purchase up to 9,090,910 shares of common stock. Each share of common stock and pre-funded warrant were sold together with a warrant. The combined offering price of each common share and accompanying warrant was $1.100 and for each pre-funded warrant and accompanying warrant was $1.099. The pre-funded warrants had an exercise price of $0.001 each and were exercised in full in January 2021. The Company received gross proceeds of approximately $10.0 million in connection with the offering, before deducting placement agent fees and related offering expenses.

On January 22, 2021, the Company entered into a letter agreement with the holder of warrants to purchase up to 10,688,043 shares of common stock at an exercise price of $0.624 per share that were issued to the holder in the registered direct offering that closed on December 23, 2020. Under the letter agreement the holder agreed to exercise the 10,688,043 warrants in full and the Company agreed to issue and sell to the holder common warrants to purchase up to 8,016,033 shares of the Company's common stock, par value $0.001 per share, at a price of $0.125. Each warrant is exercisable for one share of Common Stock at an exercise price of $1.20 per share. The warrants are

immediately exercisable and will expire five years from the date of issuance. The holder of the warrants may not exercise any portion of the warrants to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, which percentage may be changed at the holder's election to a lower percentage at any time or to a higher percentage not to exceed 9.99% upon 61 days' notice to the Company. The Company also issued to designees of the placement agent for the registered direct offering in December 2020 warrants to purchase up to 6.0% of the aggregate number of warrants issued under the letter agreement (or warrants to purchase up to 480,962 shares of common stock). The placement agent warrants have substantially the same terms as the warrants. The Company received gross proceeds of approximately $6.67 million from the exercise of the existing warrants and gross proceeds of approximately $1.0 million from the sale of the newly issued warrants, before deducting placement agent fees and related offering expenses.

Based upon the current status of product development and commercialization plans, the Company believes that its existing cash and cash equivalents and equity offerings completed subsequent to December 31, 2020 and prior to the filing of these financial statements will be adequate to satisfy its capital and operating needs for at least the next 12 months from the date of filing. 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. 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 valuation of the Company's common stock warrants, measurement of impairment, and 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.

For the year ended December 31, 2020, the Company transferred all available-for-sale securities to cash accounts.

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, 2020 and 2019 (in thousands):

	Fair Value Measurement as of December 31, 2020			
	Level 1	Level 2	Level 3	Total
Liabilities				
Common stock warrant liability	$ –	$ –	$ 5,975	$ 5,975
Total	$ –	$ –	$ 5,975	$ 5,975

	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

The following table presents the change in fair value of the liability classified common stock warrants (in thousands):

	Initial Fair Value at Issuance	Liability Reduction Due to Exercises	(Gain) Loss Upon Change in Fair Value	Fair Value on December 31, 2020
Warrant liabilities				
February 14, 2020 issuance	$ 11,677	$ (8,265)	$ (3,084)	$ 328
December 23, 2020 issuance	5,477	–	170	5,647
Total	$ 17,154	$ (8,265)	$ (2,914)	$ 5,975

The Company uses the Monte Carlo valuation model to determine the fair value of the liability classified warrants issued during 2020Input assumptions for these freestanding instruments are as follows:

	For the Year Ended December 31, 2020
Stock price	$ 0.65 - 1.69
Exercise price	$ 0.10 - 2.80
Risk-free rate	0.36 - 1.51%
Volatility	93.4 - 99.7%

Remaining term (years)	5.0 - 7.0

$31,000 of contingent consideration outstanding as of December 31, 2019 was paid during the first quarter of 2020.

5. Cash Equivalents and Short-Term Investments

For the year ended December 31, 2020, the Company transferred all available-for-sale securities to cash accounts.

Cash equivalents and short-term investments consisted of the following as of December 31, 2019 (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.

All investments of debt securities held as of December 31, 2019 had maturities of less than one year.For the year ended December 31, 2020 and 2019, the Company recognized net realized gains on available-for-sale securities of $0.1 million and $0.5 million, respectively.

6. PROPERTY AND EQUIPMENT, NET

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

	December 31, 2020	December 31, 2019
Machinery and equipment	$ 12,232	$ 12,083
Land and buildings	2,000	2,000
Computers and software	1,240	1,189
Leasehold improvements	2,107	2,282
Construction in progress	87	1,606
Furniture and equipment	148	470
Total property and equipment, gross	17,814	19,630
Accumulated depreciation	(7,264)	(4,719)
Total property and equipment, net	$ 10,550	$ 14,911

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, 2020	For the Year Ended December 31, 2019
General and administrative expense	$ 1,533	$ 1,562
Research and development expense	1,541	1,430
Total depreciation and amortization expense	$ 3,074	$ 2,992

As a result of management's restructuring efforts, management wrote down certain production assets and leasehold improvements due to asset abandonment in the amount of $2.4 million and right of use assets due to abandonment in the amount of $0.4 million. The write-downs were recorded within the Company's regenerative medicine business segment and are included in restructuring and other charges in the accompanying consolidated statement of operations.

7. LEASES

The Company leases facilities and certain equipment under noncancelable leases that expire at various dates through August 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.

Operating Leases

On December 27, 2017, the Company entered into a commercial lease agreement with Adcomp LLC, a Utah limited liability company, pursuant to which the Company leased approximately 178,528 rentable square feet of warehouse, manufacturing, office, and lab space in Salt Lake City, Utah from the landlord. The initial term of the lease is five years and it expires on November 30, 2022. The Company has 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. Because the rate implicit in the lease is not readily determinable, the Company has used an incremental borrowing rate of 10% to determine the present value of the lease payments.

Effective July 15, 2018, the Company entered into a commercial lease agreement with Salt Lake City Corporation, pursuant to which the Company leased approximately 44,695 rentable square feet of office space at 123 Wright Brothers Drive in Salt Lake City, Utah. The initial term of the lease wastwo years and provided the option to extend

the term for an additional five years by agreement of the parties. The initial base rent under this lease was $39,108 per month for the first year of the initial lease term and increased by 3.0% thereafter. Because the rate implicit in the lease is not readily determinable, the Company determined an incremental borrowing rate of 9% to determine the present value of the lease payments. On January 11, 2019, the lease was amended to extend the initial lease term to September 30, 2020. The Company did not exercise the option to extend the lease term and the lease expired September 30, 2020.

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 third quarter of 2020, the Company initiated a business analysis to determine the long-term strategy of the remote facility and cost to remain operational. During the fourth quarter of fiscal year 2020, it was determined that the Company would cease operations and vacate the facility. As a result, the Company determined that the approved plan to vacate the lease represented a triggering event requiring the long-lived assets attributable to the disposal group be assessed for impairment. Given the facts and circumstances, the Company determined that the carrying value of the related assets of the disposal group were not recoverable. As a result, the carrying values of $0.6 million, $0.1 million, $0.1 million and $0.4 million respectively for leasehold improvements, construction in progress, equipment, and right of use assets, were reduced to $0 as of December 31, 2020.

Financing Leases

In November 2018 and April 2019, the Company entered into financing leases primarily for laboratory equipment used in research and development activities. The financing leases have remaining terms that range from 15 to 40 months as of December 31, 2020 and include options to purchase equipment at the end of the lease. Because the rate implicit in the lease is not readily determinable, the Company has used an incremental borrowing rate of 10% to determine the present value of the lease payments for these leases.

As of December 31 2020, the maturities of operating and finance lease liabilities were as follows (in thousands):

	Operating leases	Finance leases
Year ending December 31:		
2021	$ 1,694	$ 656
2022	1,345	405
2023	132	336
2024	87	42
Total lease payments	3,258	1,439
Less:		
Imputed interest	(297)	(172)
Total	$ 2,961	$ 1,267

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

Finance leases

	December 31, 2020	December 31, 2019
Finance lease right-of-use assets included within property and equipment, net	$ 1,301	$ 2,177
Current finance lease liabilities included within other current liabilities	$ 556	$ 508
Non-current finance lease liabilities included within other long-term liabilities	711	1,267
Total	$ 1,267	$ 1,775

Operating leases

	December 31, 2020	December 31, 2019
Current operating lease liabilities included within other current liabilities	$ 1,485	$ 1,746
Operating lease liabilities – non current	1,476	2,994
Total	$ 2,961	$ 4,740

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

	For the Year Ended December 31, 2020	For the Year Ended December 31, 2019
Operating lease costs included within operating costs and expenses	$ 2,428	2,173
Finance lease costs:		
Amortization of right of use assets	$ 698	654
Interest on lease liabilities	151	152
Total	$ 849	806

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

	For the Year Ended December 31, 2020	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	$ 2,070	$ 2,100
Operating cash out flows from finance leases	$ 151	$ 152
Financing cash out flows from finance leases	$ 508	$ 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
Remeasurement of operating lease liability due to lease modification	$ 154	$ –

As of December 31, 2020, the weighted average remaining operating lease term is 2.1 years and the weighted average discount rate used to determine the operating lease liability was 9.75%. The weighted average remaining finance lease term is 2.6 years and the weighted average discount rate used to determine the finance lease liability was 9.78%.

8. INTANGIBLE ASSETS

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

	December 31, 2020	December 31, 2019
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	(515)	(326)
Total intangible assets, net	$ 542	$ 731

Amortization expense for the years ended December 31, 2020 and December 31, 2019 was approximately $0.2 million for each period.

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

Year ending December 31:	
2021	$ 189
2022	121
2023	87
2024	87
2025	35
Thereafter	23
	$ 542

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	December 31, 2020	December 31, 2019
Accounts payable	$ 1,193	$ 1,689
Salaries and other compensation	1,129	1,462
Legal and accounting	241	1,404
Accrued severance	330	1,053
Benefit plan accrual	659	557
Other	596	930
Total accounts payable and accrued expenses	$ 4,148	$ 7,095

Accrued severance as of December 31, 2020 and December 31, 2019 consists of accrued compensation owed to Dr. Denver Lough, a former officer and director, under a settlement terms agreement dated August 21, 2019 (Note 18).

Other current liabilities are primarily comprised of the current portion of operating lease liabilities and finance lease liabilities. The short-term lease components are disclosed in Note 7 above.

10. DEBT

PPP Loan

On April 12, 2020, our subsidiary PolarityTE MD, Inc. (the "Borrower") entered into a promissory note evidencing an unsecured loan in the amount of $3,576,145 made to it under the Paycheck Protection Program (the "Loan"). The Paycheck Protection Program (or "PPP") was established under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and is administered by the U.S. Small Business Administration. The Loan to the Borrower was made through KeyBank, N.A., a national banking association (the "Lender"). The interest rate on the Loan is 1.00%. Beginning seven months from the date of the Loan the Borrower is required to make 24 monthly payments of principal and interest in the amount of $150,563. The promissory note evidencing the Loan contains customary events of default relating to, among other things, payment defaults, making materially false and misleading representations to the SBA or Lender, or breaching the terms of the Loan documents. The occurrence of an event of default may result in the repayment of all amounts outstanding, collection of all amounts owing from the Borrower, or filing suit and obtaining judgment against the Borrower. Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of a loan granted under the PPP. On October 15, 2020, the Borrower applied to the Lender for forgiveness of the PPP loan in its entirety based on the Borrower's use of the PPP loan for payroll costs, rent, and utilities. On October 26, 2020, the Borrower was advised that the Lender approved the application, and that the Lender was submitting the application to the SBA for a final decision. The Company classified the principal balance of the PPP loan within "Current portion of long-term notes payable" and "Long-term notes payable" on the consolidated balance sheet as of December 31, 2020. If the Borrower's application for forgiveness of the PPP loan is not approved or approved only in part, it will be obligated to repay the unforgiven portion of the loan after the SBA makes its decision on the application for forgiveness. No assurance has been provided that the Company will obtain forgiveness of the Loan in whole or in part. The SBA adopted a procedure for auditing all PPP loans over $2 million and pursuant to that procedure the Company completed the SBA's form requesting information surrounding the Borrower's original application for the Loan and information on use of the Loan proceeds, which was submitted to the SBA in December 2020. The Borrower has yet to receive any response from the SBA. If the SBA makes a determination pursuant to its audit of the Borrower that it was not eligible to obtain the Loan or did not use the Loan for the purposes contemplated by the CARES Act, it is likely the Borrower will be required to promptly repay the Loan in full and may be subject to additional charges or penalties.

11. SALE OF COMMON STOCK, WARRANTS AND PRE- FUNDED WARRANTS

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. During the first quarter of 2020, 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. 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.

On February 14, 2020, the Company completed an underwritten offering of10,638,298 shares of its common stock and warrants to purchase10,638,298 shares of common stock. Each common share and warrant were sold together for a combined public purchase price of $2.35 before underwriting discount and commission. The exercise price of each warrant is $2.80 per share, the warrants were exercisable immediately, and they will expireFebruary 12, 2027. On November 19, 2020, the Company reduced the exercise price of the warrants from $2.80 per share to $0.10 per share effective November 20, 2020. As of December 31, 2020,10,073,298 of these warrants were exercised into shares of common stock for proceeds of $1.0 million. As the warrants could require cash settlement in certain scenarios, they wereclassified as liabilities and were initially recorded at an estimated fair value of $11.7 million upon issuance. The total proceeds from the offering were first allocated to the liability classified warrants, based on their fair values, with the residual $12.0 million allocated to the common stock. Issuance costs allocated to the common stock of $1.3 million were recorded as a reduction to paid-in capital. The Company measured the fair value of the liability classified warrants using the Monte Carlo simulation model at issuance, upon change in exercise price, and again at December 31, 2020 using the following inputs:

	February 14, 2020	November 20, 2020	December 31, 2020
Stock price	$ 1.69	$ 0.92	$ 0.68
Exercise price	$ 2.80	$ 0.10	$ 0.10
Risk-free rate	1.51%	0.53%	0.52%
Volatility	93.4%	99.4%	98.9%
Remaining term (years)	7.0	6.2	6.1

On December 23, 2020, the Company completed a registered direct offering of5,450,000 shares of its common stock, par value $0.001 per share, pre-funded warrants to purchase up to 5,238,043 shares of common stock and accompanying common warrants to purchase up to10,688,043 shares of common stock. Each share of common stock and pre-funded warrant was sold together with a warrant. The combined offering price of each common stock share and accompanying warrant was $0.7485 and for each pre-funded warrant and accompanying warrant was $0.7475. The pre-funded warrants had an exercise price of $0.001 each and were exercised in full in January 2021. Each warrant is exercisable for one share of the Company's common stock at an exercise price of $0.624 per share. The warrants are immediately exercisable and will expirefive years from the date of issuance. The holder of the warrants may not exercise any portion of the warrants to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, which percentage may be changed at the holder's election to a lower percentage at any time or to a higher percentage not to exceed 9.99% upon 61 days' notice to the Company. The Company also issued to designees of the placement agent for the registered direct offering warrants to purchase up to 6.0% of the aggregate number of common stock shares and pre-funded warrants sold in the offering (or warrants to purchase up to 641,283 shares of common stock). The placement agent warrants have substantially the same terms as the warrants, except that the placement agent warrants have an exercise price equal to 125% of the purchase price per share (or $0.9356 per share). The net proceeds to the Company from the offering were $7.2 million, after offering expenses payable by the Company.

As the common stock warrants and placement agent common stock warrants could each require cash settlement in certain scenarios, the common stock warrants and placement agent common stock warrants were classified as liabilities upon issuance and were initially recorded at estimated fair values of $5.2 million and $0.3 million, respectively. Since the pre-funded warrants did not contain the same cash settlement provision, these warrants are classified as a component of stockholders' equity within additional paid-in-capital. The pre-funded warrants are equity classified because they meet characteristics of the equity classification criteria.The total proceeds from the offering were first allocated to the liability classified warrants, based on their fair values, with the residual $2.5 million allocated on a relative fair value basis to the common stock and pre-funded common stock warrants. Issuance costs allocated to the equity classified pre-funded common stock warrants and common stock of $0.3 million were recorded as a reduction to paid-in capital. Issuance costs allocated to the liability classified warrants of $0.5 million were recorded as an expense. The Company measured the fair value of the accompanying common warrants and placement agent warrants using the Monte Carlo simulation model at issuance and again at December 31, 2020 using the following inputs:

Accompanying common warrants:

	December 23, 2020	December 31, 2020
Stock price	$ 0.65	$ 0.68
Exercise price	$ 0.62	$ 0.62
Risk-free rate	0.38%	0.36%
Volatility	99.7%	96.2%
Remaining term (years)	5.0	5.0

Placement agent warrants:

	December 23, 2020	December 31, 2020
Stock price	$ 0.65	$ 0.68
Exercise price	$ 0.94	$ 0.94
Risk-free rate	0.38%	0.36%
Volatility	99.7%	96.2%
Remaining term (years)	5.0	5.0

The following table summarizes warrant activity for the year ended December 31, 2020.

	Warrants Issued	Warrants Exercised	Outstanding December 31, 2020
Transaction			
February 14, 2020 common warrants	10,638,298	10,073,298	565,000
December 23, 2020 common warrants	10,688,043	–	10,688,043
December 23, 2020 placement agent warrants	641,283	–	641,283
Total	21,967,624	10,073,298	11,894,326

For information regarding warrants issued or exercised subsequent to December 31, 2020, see Subsequent Events below.

12. 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. On November 19, 2020, the 2020 Stock Option and Incentive Plan was amended to add 2,000,000 common shares to the number of shares available for awards. As of December 31, 2020, the Company had 2,092,556 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, 2020, the Company had 314,734 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, 2020, the Company had 1,195,767 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, 2019	4,529,988	$ 15.26
Granted	1,896,558	$ 1.23
Exercised (1)	(10,208)	$ 3.08
Forfeited	(1,621,771)	$ 14.35
Outstanding – December 31, 2020	4,794,567	$ 10.03
Options exercisable, December 31, 2020	3,509,574	$ 12.60

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

During the years ended December 31, 2020 and 2019, the estimated weighted-average grant-date fair value of options granted was $0.91 and $9.14, per share, respectively. The intrinsic value of options exercised for the years ended December 31, 2020 and 2019 was $0 and $3.5 million, respectively. During the years ended December 31, 2020 and 2019, the estimated total grant-date fair value of options vested was $8.4 million and $32.0 million, respectively.

The aggregate intrinsic value of options outstanding and exercisable at December 31, 2020 was $0. The weighted average remaining contractual term of options outstanding and exercisable at December 31, 2020 was 6.95 years.

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 of 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, 2020	For the Year Ended December 31 2019
Option grants		
Risk free annual interest rate	0.2% - 1.7%	1.4% - 2.7%
Expected volatility	94.3% - 100.9%	80.8% - 97.5%
Expected term of options (years)	4.4 - 4.6	5.0 - 7.0
Assumed dividends	-	-
ESPP		

Risk free annual interest rate	0.2% - 1.6%	2.1% - 2.5%
Expected volatility	100.5% - 143.2%	76.6% - 88.9%
Expected term of options (years)	0.5	0.5
Assumed dividends	-	-

Restricted Stock

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

	Number of shares
Unvested - December 31, 2019	1,843,001
Granted	3,676,504
Vested (1)	(1,955,348)
Forfeited	(95,188)
Unvested – December 31, 2020	3,468,969

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

The weighted-average per share grant-date fair value of restricted stock granted during the years ended December 31, 2020 and 2019 was $1.18 and $4.74 per share, respectively. The total fair value of restricted stock vested during the years ended December 31, 2020 and 2019 was approximately $9.0 million and $12.4 million, respectively.

As of December 31, 2020, there was approximately $2.6 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 2.0 years.

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, 2020	For the Year Ended December 31, 2019
General and administrative expense	$ 5,879	$ 27,692
Research and development expense	943	2,643
Sales and marketing expense	436	1,067
Total stock-based compensation expense	$ 7,258	$ 31,402

As of December 31, 2020, there was approximately $0.8 million of unrecognized compensation cost related to stock option awards, which is expected to be recognized over a remaining weighted-average vesting period of 1.9 years.

Stock-based compensation related to the ESPP for the year ended December 31, 2020 was $64,000. A total of 97,445 shares of common stock were purchased at a weighted-average purchase price of $0.76 for total proceeds of $0.1 million pursuant to the ESPP during the year ended December 31, 2020.

13. 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 ($19,500 for calendar year 2020). The Company contributes 3% of employee's eligible earnings. The Company recorded contribution expense related to its 401(k) Plan of $0.2 million and $0.3 million for the years ended December 31, 2020 and 2019, respectively.

14. 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, 2020	For the Year Ended December 31, 2019
Current:		
Federal	$ –	$ –
State	–	–
Deferred:		
Federal	(593)	(19,057)
State	(79)	(8,595)
Change in valuation allowance	672	27,652
Total provision (benefit) for income taxes	$ –	$ –

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, 2020		For the Year Ended December 31, 2019	
	Amount	Percent of Pretax Loss	Amount	Percent of Pretax Loss
Tax (benefit) at federal statutory rate	$ (8,999)	21%	$ (19,423)	21%
State income taxes, net of federal income taxes	(79)	–%	(8,595)	9%

Effect of warrant liability	(209)	1%	–	–%
Effect of other permanent items	65	–%	418	–%
Effect of stock compensation	9,032	(21)%	129	–%
Change in valuation allowance	672	(2)%	27,652	(30)%
Other	(482)	1%	(181)	%
	$ –	**–%**	**$ –**	**–%**

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

	As of December 31, 2020	As of December 31, 2019
Leases	$ 132	$ 38
Depreciation and amortization	(784)	(956)
Compensation expense not deductible until options are exercised	9,494	18,295
All other temporary differences	488	934
Net operating loss carry forward	41,766	32,113
Less valuation allowance	(51,096)	(50,424)
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 net operating loss carryforwards available for income tax purposes at December 31, 2020 amounts to approximately $158.6 million. Of this amount, $38.5 million will expire between 2037 and 2038 and $120.1 million will have an indefinite life. Approximately $168.6 million for state income taxes will begin to expire starting in 2032.

The Company files income tax returns in the U.S. and various states. As of December 31, 2020, the Company had no unrecognized tax benefits, which would impact its tax rate if recognized. As of December 31, 2020, the Company had no accrual for the potential payment of penalties. As of December 31, 2020, 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.

15. NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

The following tables present reconciliations for the numerators and denominators of basic and diluted net loss per share for the years ended December 31, 2020 and 2019.

	December 31, 2020	December 31, 2019
Numerator:		
Net loss, primary	$ (42,854)	$ (92,493)
Gain from change in fair value of warrant liabilities	2,914	–
Net loss, diluted	$ (45,768)	$ (92,493)

	December 31, 2020	December 31, 2019
Denominator:		
Basic weighted average number of common shares (1)	38,779,316	24,966,355
Potentially dilutive effect of warrants	588,074	–
Diluted weighted average number of common shares	39,367,390	24,966,355

(1) In December 2020, the Company sold 5,450,000 shares of common stock as well as pre-funded warrants to purchase up to 5,238,043 shares of common stock. The shares of common stock associated with the pre-funded warrants are considered contingently issuable shares and therefore are outstanding for the purposes of computing earnings per share because the shares may be issued for little or no consideration, are fully vested, and are exercisable after the original issuance date.

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, 2020	December 31, 2019
Stock options	4,794,567	4,529,988
Unvested restricted stock grants	3,468,969	1,843,001

16. RESTRUCTURING AND OTHER CHARGES

In the second quarter of 2020, management approved several actions as part of a restructuring plan designed to improve operational efficiency and financial results. Management approved a reduction in force, which affected 40 of the 126 employees in the regenerative medicine business segment, or approximately 31.7% of that workforce. The Company did not make any change in the workforce of its contract services segment. Total severance expense recorded for the year ended December 31, 2020 was $1.0 million. All severance was paid during 2020. Included in the restructuring plan, management recorded $1.5 million of asset abandonments within the Company's regenerative medicine business segment related to the restructuring.

In the fourth quarter of 2020, management recorded $0.9 million in write-downs related to the abandonment of certain production assets and leasehold improvements and $0.4 million in charges related to the abandonment of right of use assets. The charges were recorded within the Company's regenerative medicine business segment and are included in restructuring and other charges in the accompanying consolidated statement of operations.

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"). On November 28, 2018, the Court consolidated the *Moreno* and *Lawi* cases under the caption *In re PolarityTE, Inc. Securities Litigation* with Case No. 2:18-cv-00510 (the "Consolidated Securities Litigation"). The gravamen of the consolidated complaint in the Consolidated Securities Litigation was that defendants made statements or disseminated 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 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. 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. Following a hearing on the Company's motion to dismiss the Court issued an order on November 22, 2020, dismissing the complaint in the Consolidated Securities Litigation with prejudice.

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. After disposition of the Consolidated Securities Litigation described above the parties to the shareholder derivative lawsuit agreed to dismiss the lawsuit without prejudice and the lawsuit was dismissed on January 29, 2021.

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, 2020, 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.

On September 2, 2020, Arches Research, Inc., a subsidiary of PolarityTE, Inc. ("Arches") entered into two agreements with Co-Diagnostics, Inc. ("Co-Diagnostics"). The COVID-19 Laboratory Services Agreement between the parties provides that Arches will perform specimen testing services for customers referred by Co-Diagnostics to Arches. Co-Diagnostics will arrange all logistics for delivering specimens to Arches for COVID-19 testing for those customers of Co-Diagnostics electing to use the service. Arches bills Co-Diagnostics for the testing services and Co-Diagnostics manages all customer billing. The Rental Agreement for LGC Genomics Oktopure Extraction Machine between Arches and Co-Diagnostics provides that Co-Diagnostics will make available to Arches the Oktopure high throughput extraction machine that Arches will use to perform COVID-19 testing. The term of the agreement is 12 months, requires Arches to use Co-Diagnostics tests exclusively in the machine, and establishes for Arches a minimum monthly purchase obligation, valued at approximately $1.1 million annually for Co-Diagnostics tests and related consumables used in the testing process.

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. The fair value of the restricted stock units was $0.8 million. The Company expensed the cash portion and equity portion of these awards upon Dr. Lough's termination. As of December 31, 2020, the Company has recorded a liability of $0.3 million related to future cash payments under the agreement.

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.

In May 2020, the Company reduced the space from 6,232 to 4,554. During the fourth quarter of 2020, the Company increased the space leased from 4,554 square feet to 5,500 square feet. The Company is using 1,099 square feet, and Cohen LLC is using approximately 4,401 square feet as of December 31, 2020. The monthly lease payment for 5,500 square feet is $27,501. Of this amount $22,007 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 $0.3 million of sublease income related to this agreement for the years ended December 31, 2020 and December 31, 2019, respectively. The sublease income is included in other income, net in the accompanying consolidated statement of operations. As of December 31, 2020, and December 31, 2019, there were no amounts due from the related party under this agreement.

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.

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

	For the Year Ended December 31, 2020	For the Year Ended December 31, 2019
Net revenues:		
Reportable segments:		
Regenerative medicine	$ 3,730	$ 2,353
Contract services	6,396	3,299
Total net revenues	$ 10,126	$ 5,652
Net loss:		
Reportable segments:		
Regenerative medicine	$ (42,815)	$ (91,259)

Contract services	(39)	(1,234)
Total net loss	$ (42,854)	$ (92,493)

	December 31, 2020	December 31, 2019
Identifiable assets employed:		
Reportable segments:		
Regenerative medicine	$ 36,858	$ 48,615
Contract services	8,652	4,984
Total assets	$ 45,510	$ 53,599

20. SUBSEQUENT EVENTS

Pre-Funded Warrants Exercised

On December 23, 2020, the Company sold pre-funded warrants to purchase 5,238,043 shares of common stock at an exercise price of $0.001. As of January 7, 2021, all pre-funded warrants had been exercised into shares of common stock for total proceeds of $5,000.

January 14, 2021 offering

On January 14, 2021, the Company completed a registered direct offering of 6,670,000 shares of its common stock, par value $0.001 per share, pre-funded warrants to purchase up to 2,420,910 shares of Common Stock and accompanying common warrants to purchase up to 9,090,910 shares of Common Stock. Each share of common stock and pre-funded warrant were sold together with a warrant. The combined offering price of each common share and accompanying warrant was $1.100 and for each pre-funded warrant and accompanying warrant was $1.099. The pre-funded warrants had an exercise price of $0.001 each and were exercised in full on January 13, 2021. Each warrant is exercisable for one share of the Company's common stock at an exercise price of $1.20 per share. The warrants are immediately exercisable and will expire five years from the date of issuance. The holder of the warrants may not exercise any portion of the warrants to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, which percentage may be changed at the holder's election to a lower percentage at any time or to a higher percentage not to exceed 9.99% upon 61 days' notice to the Company. The Company also issued to designees of the placement agent for the registered direct offering warrants to purchase up to 6.0% of the aggregate number of common stock shares and pre-funded warrants sold in the offering (or warrants to purchase up to 545,455 shares of common stock). The placement agent warrants have substantially the same terms as the warrants, except that the placement agent warrants have an exercise price equal to 125% of the purchase price per share (or $1.375 per share). The Company received gross proceeds of approximately $10.0 million in connection with the offering, before deducting placement agent fees and related offering expenses.

January 22, 2021 exercise and subsequent offering

On January 22, 2021, the Company entered into a letter agreement with the holder of warrants to purchase up to 10,688,043 shares of common stock at an exercise price of $0.624 per share that were issued to the holder in the registered direct offering that closed on December 23, 2020. Under the letter agreement the holder agreed to exercise the 10,688,043 warrants in full and the Company agreed to issue and sell to the holder common warrants to purchase up to 8,016,033 shares of the Company's common stock, par value $0.001 per share, at a price of $0.125. Each warrant is exercisable for one share of Common Stock at an exercise price of $1.20 per share. The warrants are immediately exercisable and will expire five years from the date of issuance. The holder of the warrants may not exercise any portion of the warrants to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, which percentage may be changed at the holder's election to a lower percentage at any time or to a higher percentage not to exceed 9.99% upon 61 days' notice to the Company. The Company also issued to designees of the placement agent for the registered direct offering in December 2020 warrants to purchase up to 6.0% of the aggregate number of warrants issued under the letter agreement (or warrants to purchase up to 480,962 shares of common stock). The placement agent warrants have substantially the same terms as the warrants. In January 2021, the holder of the common warrants exercised all 10,688,043 warrants at an exercise price of $0.624 per share resulting in gross proceeds of $6.67 million and gross proceeds of approximately $1.0 million from the sale of the newly issued warrants, before deducting placement agent fees and related offering expenses.

"At the Market" Offering

On March 30, 2021, we entered into a sales agreement with Cantor, Fitzgerald & Co. ("Cantor"), to sell shares of our common stock having aggregate sales proceeds of up to $50.0 million, from time to time, through an "at the market" equity offering program under which Cantor will act as sales agent.

Termination of Keystone Purchase Agreement

Pursuant to an Equity Purchase Agreement dated as of December 5, 2019 (the "Purchase Agreement") that we entered into with Keystone Capital Partners, LLC ("Keystone"), Keystone 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. In anticipation of the "at the market" equity offering program described above, we provided notice to Keystone of our decision to terminate the Purchase Agreement, which was effective on March 26, 2021.

Exhibit 1.1

Execution Version

PolarityTE, Inc.
Shares of Common Stock
(par value $0.001 per share)

Controlled Equity Offering[SM]

Sales Agreement

March 30, 2021

Cantor Fitzgerald & Co.
499 Park Avenue
New York, NY 10022

Ladies and Gentlemen:

PolarityTE, Inc., a Delaware corporation (the "**Company**"), confirms its agreement (this "**Agreement**") with Cantor Fitzgerald & Co. (the "**Agent**"), as follows:

1. Issuance and Sale of Shares. The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through the Agent, shares of common stock (the "**Placement Shares**") of the Company, par value $0.001 per share (the "**Common Stock**"); *provided*, *however*, that in no event shall the Company issue or sell through the Agent such number or dollar amount of Placement Shares that would (a) exceed the number or dollar amount of shares of Common Stock registered on the effective Registration Statement (as defined below) pursuant to which the offering is being made, (b) exceed the number of authorized but unissued shares of Common Stock (less shares of Common Stock issuable upon exercise, conversion or exchange of any outstanding securities of the Company or otherwise reserved from the Company's authorized capital stock), (c) exceed the number or dollar amount of shares of Common Stock permitted to be sold under Form S-3 (including General Instruction I.B.6 thereof, if applicable) or (d) exceed the number or dollar amount of shares of Common Stock for which the Company has filed a Prospectus Supplement (as defined below) (the lesser of (a), (b), (c) and (d), the "**Maximum Amount**"). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitations set forth in this Section 1 on the amount of Placement Shares issued and sold under this Agreement shall be the sole responsibility of the Company and that the Agent shall have no obligation in connection with such compliance. The offer and sale of Placement Shares through the Agent will be effected pursuant to the Registration Statement filed by the Company and which was declared effective by the Securities and Exchange Commission (the "**Commission**") on February 22, 2019, although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement to issue Common Stock.

The Company has filed, in accordance with the provisions of the Securities Act of 1933, as amended (the "**Securities Act**") and the rules and regulations thereunder (the "**Securities Act Regulations**"), with the Commission a registration statement on Form S-3 (File No. 333-229584), including a base prospectus, relating to certain securities, including the Placement Shares to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), and the rules and regulations thereunder. The Company has prepared a prospectus or a prospectus supplement to the base prospectus included as part of the registration statement, which prospectus or prospectus supplement relates to the Placement Shares to be issued from time to time by the Company (the "**Prospectus Supplement**"). The Company will furnish to the Agent, for use by the Agent, copies of the prospectus included as part of such registration statement, as supplemented by the Prospectus Supplement, relating to the Placement Shares to be issued from time to time by the Company. The Company may file one or more additional registration statements from time to time that will contain a base prospectus and related prospectus or prospectus supplement, if applicable (which shall be a Prospectus Supplement), with respect to the Placement Shares. Except where the context otherwise requires, such registration statement(s), including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act Regulations or deemed to be a part of such registration statement pursuant to Rule 430B of the Securities Act Regulations, is herein called the "**Registration Statement**." The base prospectus or base prospectuses, including all documents incorporated therein by reference, included in the Registration Statement, as it may be supplemented, if necessary, by the Prospectus Supplement, in the form in which such prospectus or prospectuses and/or Prospectus Supplement have most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act Regulations, together with the then issued Issuer Free Writing Prospectus(es) (as defined below), is herein called the "**Prospectus**."

Any reference herein to the Registration Statement, any Prospectus Supplement, Prospectus or any Issuer Free Writing Prospectus shall be deemed to refer to and include the documents, if any, incorporated by reference therein (the "**Incorporated Documents**"), including, unless the context otherwise requires, the documents, if any, filed as exhibits to such Incorporated Documents. Any reference herein to the terms "amend," "amendment" or "supplement" with respect to the Registration Statement, any Prospectus Supplement, the Prospectus or any Issuer Free Writing Prospectus shall be deemed to refer to and include the filing of any document under the Exchange Act on or after the most-recent effective date of the Registration Statement, or the date of the Prospectus Supplement, Prospectus or such Issuer Free Writing Prospectus, as the case may be, and incorporated therein by reference. For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include the most recent copy filed with the Commission pursuant to its Electronic Data Gathering Analysis and Retrieval system, or if applicable, the Interactive Data Electronic Application system when used by the Commission (collectively, "**EDGAR**").

---

2. Placements. Each time that the Company wishes to issue and sell Placement Shares hereunder (each, a "**Placement**"), it will notify the Agent by email notice (or other method mutually agreed to by the parties) of the number of Placement Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Placement Shares that may be sold in any one day and any minimum price below which sales may not be made (a "**Placement Notice**"), the form of which is attached hereto as Schedule 1. The Placement Notice shall originate from any of the individuals from the Company set forth on Schedule 3 (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from the Agent set forth on Schedule 3, as such Schedule 3 may be amended from time to time. The Placement Notice shall be effective unless and until (i) the Agent declines to accept the terms contained therein for any reason, in its sole discretion, *provided* the Agent delivers written notice thereof to the Company within two (2) Business Days (as defined below) after receipt of such Placement Notice, (ii) the entire amount of the Placement Shares thereunder have been sold, (iii) the Company suspends or terminates the Placement Notice or (iv) this Agreement has been terminated under the provisions of Section 12. The amount of any discount, commission or other compensation to be paid by the Company to the Agent in connection with the sale of the Placement Shares shall be calculated in accordance with the terms set forth in Schedule 2. It is expressly acknowledged and agreed that neither the Company nor the Agent will have any obligation whatsoever with respect to a Placement or any Placement Shares unless and until the Company delivers a Placement Notice to the Agent and the Agent does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified therein and herein. In the event of a conflict between the terms of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice will control.

3. Sale of Placement Shares by the Agent. Subject to the provisions of Section 5(a), the Agent, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the Nasdaq

Capital Market (the "**Exchange**"), to sell the Placement Shares up to the amount specified in, and otherwise in accordance with the terms of, such Placement Notice. The Agent will provide written confirmation to the Company no later than the opening of the Trading Day (as defined below) immediately following the Trading Day on which it has made sales of Placement Shares hereunder setting forth the number of Placement Shares sold on such day, the compensation payable by the Company to the Agent pursuant to Section 2 with respect to such sales, and the Net Proceeds (as defined below) payable to the Company, with an itemization of the deductions made by the Agent (as set forth in Section 5(b)) from the gross proceeds that it receives from such sales. Subject to the terms of the Placement Notice, the Agent may sell Placement Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act Regulations, including sales made directly on or through the Exchange or any other existing trading market for the Common Stock, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices and/or any other method permitted by law. "**Trading Day**" means any day on which Common Stock is traded on the Exchange. While a Placement Notice is in effect, neither the Agent nor any of its subsidiaries shall, for its own account, engage in (i) any short sale of any security of the Company, as defined in Regulation SHO under the Exchange Act, or (ii) any market making bidding, stabilization or other trading activity with regard to the Common Stock or related derivative securities, in each case, if such activity would be prohibited under Regulation M under the Exchange Act or other anti-manipulation rules under the Securities Act. For the avoidance of doubt, this restriction shall not apply to transactions by or on behalf of any customer of the Agent or transactions by the Agent to facilitate any such transactions by or on behalf of any customer of the Agent.

4. Suspension of Sales. The Company or the Agent may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on Schedule 3, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by verifiable facsimile transmission or email correspondence to each of the individuals of the other party set forth on Schedule 3), suspend any sale of Placement Shares (a "**Suspension**"); *provided*, *however*, that such Suspension shall not affect or impair any party's obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. While a Suspension is in effect any obligation under Sections 7(l), 7(m), 7(n) and 7(o) with respect to the delivery of certificates, opinions, or comfort letters to the Agent, shall be waived. Each of the parties agrees that no such notice under this Section 4 shall be effective against any other party unless it is made to one of the individuals named on Schedule 3 hereto, as such Schedule may be amended from time to time.

5. Sale and Delivery to the Agent; Settlement.

(a) Sale of Placement Shares. On the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, upon the Agent's acceptance of the terms of a Placement Notice, and unless the sale of the Placement Shares described therein has been declined, suspended, or otherwise terminated in accordance with the terms of this Agreement, the Agent, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell such Placement Shares up to the amount specified, and otherwise in accordance with the terms of such Placement Notice. The Company acknowledges and agrees that (i) there can be no assurance that the Agent will be successful in selling Placement Shares, (ii) the Agent will incur no liability or obligation to the Company or any other person or entity if it does not sell Placement Shares for any reason other than a failure by the Agent to use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell such Placement Shares as required under this Agreement and (iii) the Agent shall be under no obligation to purchase Placement Shares on a principal basis pursuant to this Agreement, except as otherwise agreed by the Agent and the Company.

(b) Settlement of Placement Shares. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the third (3rd) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a "**Settlement Date**"). The Agent shall notify the Company of each sale of Placement Shares no later than the opening of the Trading Day immediately following the Trading Day on which it has made sales of Placement Shares hereunder. The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement Shares sold (the "**Net Proceeds**") will be equal to the aggregate sales price received by the Agent, after deduction for (i) the Agent's commission, discount or other compensation for such sales payable by the Company pursuant to Section 2 hereof, and (ii) any transaction fees imposed by any Governmental Authority (as defined below) in respect of such sales.

(c) Delivery of Placement Shares. On or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Placement Shares being sold by crediting the Agent's or its designee's account (provided the Agent shall have given the Company written notice of such designee at least one Trading Day prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto which in all cases shall be freely tradable, transferable, registered shares in good deliverable form. On each Settlement Date, the Agent will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. If the Company, or its transfer agent (if applicable), defaults in its obligation to deliver Placement Shares on a Settlement Date, through no fault of the Agent, the Company agrees that in addition to, and in no way limiting the rights and obligations set forth in Section 10(a) hereto, it will (i) hold the Agent harmless against any loss, claim, damage, or reasonable documented expense (including reasonable documented legal fees and expenses), as incurred, arising out of or in connection with such default by the Company or its transfer agent (if applicable) and (ii) pay to the Agent any commission, discount, or other compensation to which it would otherwise have been entitled absent such default.

(d) Denominations; Registration. Certificates for the Placement Shares, if any, shall be in such denominations and registered in such names as the Agent may request in writing at least one full Business Day before the Settlement Date. The certificates for the Placement Shares, if any, will be made available by the Company for examination and packaging by the Agent in The City of New York not later than noon (New York time) on the Business Day prior to the Settlement Date.

(e) Limitations on Offering Size. Under no circumstances shall the Company cause or request the offer or sale of any Placement Shares if, after giving effect to the sale of such Placement Shares, the aggregate gross sales proceeds of Placement Shares sold pursuant to this Agreement would exceed the lesser of (A) together with all sales of Placement Shares under this Agreement, the Maximum Amount, (B) the amount available for offer and sale under the currently effective Registration Statement and (C) the amount authorized from time to time to be issued and sold under this Agreement by the Company's board of directors, a duly authorized committee thereof or a duly authorized executive committee, and notified to the Agent in writing. Under no circumstances shall the Company cause or request the offer or sale of any Placement Shares pursuant to this Agreement at a price lower than the minimum price authorized from time to time by the Company's board of directors, a duly authorized committee thereof or a duly authorized executive committee. Further, under no circumstances shall the Company cause or permit the aggregate offering amount of Placement Shares sold pursuant to this Agreement to exceed the Maximum Amount.

6. Representations and Warranties of the Company. The Company represents and warrants to, and agrees with the Agent that as of the date of this Agreement and as of each Applicable Time (as defined below):

(a) Registration Statement and Prospectus. The Company and the transactions contemplated by this Agreement meet the requirements for and comply with the applicable conditions set forth in Form S-3 (including General Instructions I.A and I.B) under the Securities Act as of the time the Registration Statement was filed and at the time the Company's most recent Annual Report on Form 10-K was filed with the Commission. The Registration Statement has been filed with the Commission and has been declared effective by the Commission under the Securities Act prior to the issuance of any Placement Notices by the Company. The Prospectus Supplement will name the Agent as the agent in the section entitled "Plan of Distribution." The Company has not received, and has no notice of, any order of the Commission preventing or suspending the use of the Registration Statement, or threatening or instituting proceedings for that purpose. The Registration Statement and the offer and sale of Placement Shares as contemplated hereby meet the requirements of Rule 415 under the Securities Act and comply in all material respects with said Rule. Any statutes, regulations, contracts or other documents that are required to be described in the Registration Statement or the Prospectus or that are required to be filed as exhibits to the Registration Statement have been so described or filed. Copies of the Registration Statement, the Prospectus, and any such amendments or supplements and all documents incorporated by reference therein that were filed with the Commission on or prior to the date of this Agreement have been delivered, or are available through EDGAR, to the Agent and its counsel. The Company has not distributed and, prior to the later to occur of each Settlement Date and completion of the distribution of the Placement Shares, will not distribute any offering material in

connection with the offering or sale of the Placement Shares other than the Registration Statement and the Prospectus and any Issuer Free Writing Prospectus (as defined below) to which the Agent has consented. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act and is currently listed on the Exchange under the trading symbol "PTE." The Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act, delisting the Common Stock from the Exchange, nor has the Company received any notification that the Commission or the Exchange is contemplating terminating such registration or listing. To the Company's knowledge, it is in compliance with all applicable listing requirements of the Exchange.

(b) No Misstatement or Omission. The Registration Statement, when it became or becomes effective, and the Prospectus, and any amendment or supplement thereto, on the date of such Prospectus or amendment or supplement, conformed and will conform in all material respects with the requirements of the Securities Act. At each Settlement Date, the Registration Statement and the Prospectus, as of such date, will conform in all material respects with the requirements of the Securities Act. The Registration Statement, when it became or becomes effective, did not, and will not, contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Prospectus and any amendment and supplement thereto, on the date thereof and at each Applicable Time, did not or will not include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. The documents incorporated by reference in the Prospectus or any Prospectus Supplement did not, and any further documents filed and incorporated by reference therein will not, when filed with the Commission, contain an untrue statement of a material fact or omit to state a material fact required to be stated in such document or necessary to make the statements in such document, in light of the circumstances under which they were made, not misleading. The foregoing shall not apply to statements in, or omissions from, any such document made in reliance upon, and in conformity with, information furnished to the Company by the Agent specifically for use in the preparation thereof.

(c) Market Capitalization. The Company is not a shell company (as defined in Rule 405 under the Securities Act) and has not been a shell company for at least 12 calendar months previously and if it has been a shell company at any time previously, has filed current Form 10 information (as defined in Instruction I.B.6 of Form S-3) with the Commission at least 12 calendar months previously reflecting its status as an entity that is not a shell company.

(d) Conformity with Securities Act and Exchange Act. The Registration Statement, the Prospectus, any Issuer Free Writing Prospectus or any amendment or supplement thereto, and the documents incorporated by reference in the Registration Statement, the Prospectus or any amendment or supplement thereto, when such documents were or are filed with the Commission under the Securities Act or the Exchange Act or became or become effective under the Securities Act, as the case may be, conformed or will conform in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable.

(e) Financial Information. The consolidated financial statements of the Company included or incorporated by reference in the Registration Statement and the Prospectus, together with the related notes and schedules, present fairly, in all material respects, the consolidated financial position of the Company and the Subsidiaries (as defined below) as of the dates indicated and the consolidated results of operations, cash flows and changes in stockholders' equity of the Company for the periods specified and have been prepared in compliance with the requirements of the Securities Act and Exchange Act and in conformity with GAAP (as defined below) applied on a consistent basis during the periods involved; there are no financial statements (historical or pro forma) that are required to be included or incorporated by reference in the Registration Statement or the Prospectus that are not included or incorporated by reference as required; the Company and the Subsidiaries (as defined below) do not have any material liabilities or obligations, direct or contingent (including any off-balance sheet obligations), not described in the Registration Statement (excluding the exhibits thereto) and the Prospectus; and all disclosures contained or incorporated by reference in the Registration Statement and the Prospectus regarding "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission) comply with Regulation G of the Exchange Act and Item 10 of Regulation S-K under the Securities Act, to the extent applicable. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement and the Prospectus fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.

(f) Conformity with EDGAR Filing. The Prospectus delivered to the Agent for use in connection with the sale of the Placement Shares pursuant to this Agreement will be identical to the versions of the Prospectus created to be transmitted to the Commission for filing via EDGAR, except to the extent permitted by Regulation S-T.

(g) Organization. The Company and each of its Subsidiaries are duly organized, validly existing as a corporation or limited liability company and in good standing under the laws of their respective jurisdictions of organization. The Company and each of its Subsidiaries are duly licensed or qualified as a foreign corporation for transaction of business and in good standing under the laws of each other jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such license or qualification, and have all corporate power and authority necessary to own or hold their respective properties and to conduct their respective businesses as described in the Registration Statement and the Prospectus, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, have a material adverse effect on or affecting the assets, business, operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity or results of operations of the Company and the Subsidiaries taken as a whole, or prevent or materially interfere with consummation of the transactions contemplated hereby (a "**Material Adverse Effect**").

(h) Subsidiaries. The subsidiaries set forth onSchedule 4 are the Company's only subsidiaries (any such subsidiaries that are significant subsidiaries, as such term is defined in Rule 1-02 of Regulation S-X promulgated by the Commission, the "**Subsidiaries**"). Except as set forth in the Registration Statement and the Prospectus, the Company owns, directly or indirectly, all of the equity interests of the Subsidiaries free and clear of any lien, charge, security interest, encumbrance, right of first refusal or other restriction, and all the equity interests of the Subsidiaries are validly issued and are fully paid, nonassessable and free of preemptive and similar rights. No Subsidiary is currently prohibited, directly or indirectly, from paying any dividends to the Company, from making any other distribution on such Subsidiary's capital stock, from repaying to the Company any loans or advances to such Subsidiary from the Company or from transferring any of such Subsidiary's property or assets to the Company or any other Subsidiary of the Company.

(i) No Violation or Default. Neither the Company nor any of its Subsidiaries is (i) in violation of its charter or by-laws or similar organizational documents; (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its Subsidiaries is a party or by which the Company or any of its Subsidiaries is bound or to which any of the property or assets of the Company or any of its Subsidiaries are subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any Governmental Authority, except, in the case of each of clauses (ii) and (iii) above, for any such violation or default that would not, individually or in the aggregate, have a Material Adverse Effect. To the Company's knowledge, no other party under any material contract or other agreement to which it or any of its Subsidiaries is a party is in default in any respect thereunder where such default would have a Material Adverse Effect.

(j) No Material Adverse Change. Subsequent to the respective dates as of which information is given in the Registration Statement, the Prospectus and the Free Writing Prospectuses, if any (including any document deemed incorporated by reference therein), there has not been (i) any Material Adverse Effect or the occurrence of any development that would reasonably be expected to have a Material Adverse Effect, (ii) any transaction which is material to the Company and the Subsidiaries taken as a whole, (iii) any obligation or liability, direct or contingent (including any off-balance sheet obligations), incurred by the Company or any Subsidiary, which is material to the Company and the Subsidiaries taken as a whole, (iv) any material change in the capital stock or outstanding long-term indebtedness of the Company or any of its Subsidiaries or (v) any dividend or distribution of any kind declared, paid or made on the capital stock of the Company or any Subsidiary, other than in each case above in the ordinary course

of business or as otherwise disclosed in the Registration Statement or Prospectus (including any document deemed incorporated by reference therein).

(k) Capitalization. The issued and outstanding shares of capital stock of the Company have been validly issued, are fully paid and nonassessable and, other than as disclosed in the Registration Statement or the Prospectus, are not subject to any preemptive rights, rights of first refusal or similar rights. The Company has an authorized, issued and outstanding capitalization as set forth in the Registration Statement and the Prospectus as of the dates referred to therein (other than the grant of additional options under the Company's existing stock option plans, or changes in the number of outstanding shares of Common Stock of the Company due to the issuance of shares upon the exercise or conversion of securities exercisable for, or convertible into, Common Stock outstanding on the date hereof) and such authorized capital stock conforms to the description thereof set forth in the Registration Statement and the Prospectus. The description of the securities of the Company in the Registration Statement and the Prospectus is complete and accurate in all material respects. Except as disclosed in or contemplated by the Registration Statement or the Prospectus, as of the date referred to therein, the Company does not have outstanding any options to purchase, or any rights or warrants to subscribe for, or any securities or obligations convertible into, or exchangeable for, or any contracts or commitments to issue or sell, any shares of capital stock or other securities.

(l) Authorization; Enforceability. The Company has full legal right, power and authority to enter into this Agreement and to perform the transactions contemplated hereby. This Agreement has been duly authorized, executed and delivered by the Company and is a legal, valid and binding agreement of the Company enforceable in accordance with its terms, except to the extent that enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general equitable principles.

(m) Authorization of Placement Shares. The Placement Shares, when issued and delivered pursuant to the terms approved by the board of directors of the Company or a duly authorized committee thereof, or a duly authorized executive committee, against payment therefor as provided herein, will be duly and validly authorized and issued and fully paid and nonassessable, free and clear of any pledge, lien, encumbrance, security interest or other claim, including any statutory or contractual preemptive rights, resale rights, rights of first refusal or other similar rights, and will be registered pursuant to Section 12 of the Exchange Act. The Placement Shares, when issued, will conform to the description thereof set forth in or incorporated into the Prospectus.

(n) No Consents Required. No consent, approval, authorization, order, registration or qualification of or with any Governmental Authority is required for the execution, delivery and performance by the Company of this Agreement, the issuance and sale by the Company of the Placement Shares, except for such consents, approvals, authorizations, orders and registrations or qualifications as may be required under applicable state securities laws or by the by-laws and rules of the Financial Industry Regulatory Authority ("**FINRA**") or the Exchange in connection with the sale of the Placement Shares by the Agent.

(o) No Preferential Rights. Except as set forth in the Registration Statement and the Prospectus, (i) no person, as such term is defined in Rule 1-02 of Regulation S-X promulgated under the Securities Act (each, a "**Person**"), has the right, contractual or otherwise, to cause the Company to issue or sell to such Person any Common Stock or shares of any other capital stock or other securities of the Company, (ii) no Person has any preemptive rights, resale rights, rights of first refusal, rights of co-sale, or any other rights (whether pursuant to a "poison pill" provision or otherwise) to purchase any Common Stock or shares of any other capital stock or other securities of the Company, (iii) no Person has the right to act as an underwriter or as a financial advisor to the Company in connection with the offer and sale of the Common Stock, and (iv) no Person has the right, contractual or otherwise, to require the Company to register under the Securities Act any Common Stock or shares of any other capital stock or other securities of the Company, or to include any such shares or other securities in the Registration Statement or the offering contemplated thereby, whether as a result of the filing or effectiveness of the Registration Statement or the sale of the Placement Shares as contemplated thereby or otherwise.

(p) Independent Public Accounting Firm. EisnerAmper LLP (the "**Accountant**"), whose report on the consolidated financial statements of the Company is filed with the Commission as part of the Company's most recent Annual Report on Form 10-K filed with the Commission and incorporated by reference into the Registration Statement and the Prospectus, are and, during the periods covered by their report, were an independent registered public accounting firm within the meaning of the Securities Act and the Public Company Accounting Oversight Board (United States). To the Company's knowledge, the Accountant is not in violation of the auditor independence requirements of the Sarbanes-Oxley Act of 2002 (the "**Sarbanes-Oxley Act**") with respect to the Company.

(q) Enforceability of Agreements. All agreements between the Company and third parties expressly referenced in the Prospectus are legal, valid and binding obligations of the Company enforceable in accordance with their respective terms, except to the extent that (i) enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general equitable principles and (ii) the indemnification provisions of certain agreements may be limited by federal or state securities laws or public policy considerations in respect thereof.

(r) No Litigation. Except as set forth in the Registration Statement or the Prospectus, there are no actions, suits or proceedings by or before any Governmental Authority pending, nor, to the Company's knowledge, any audits or investigations by or before any Governmental Authority, to which the Company or a Subsidiary is a party or to which any property of the Company or any of its Subsidiaries is the subject that, individually or in the aggregate, would have a Material Adverse Effect and, to the Company's knowledge, no such actions, suits, proceedings, audits or investigations are threatened or contemplated by any Governmental Authority or threatened by others; and (i) there are no current or pending audits, investigations, actions, suits or proceedings by or before any Governmental Authority that are required under the Securities Act to be described in the Prospectus that are not so described; and (ii) there are no statutes, regulations, contracts or other documents that are required under the Securities Act to be described in the Registration Statement or the Prospectus or to be filed as exhibits to the Registration Statement that are not so described or filed as required.

(s) Consents and Permits. The Company and its Subsidiaries have made all filings, applications and submissions required by, possesses and is operating in compliance with, all approvals, licenses, certificates, certifications, clearances, consents, grants, exemptions, marks, notifications, orders, permits and other authorizations issued by, the appropriate federal, state or foreign Governmental Authority (including, without limitation, the United States Food and Drug Administration (the " **FDA**"), the United States Drug Enforcement Administration or any other foreign, federal, state, provincial, court or local government or regulatory authorities including self-regulatory organizations engaged in the regulation of human cells, tissues, and cellular and tissue-based products regulated under Section 361 of the United States Public Health Service Act ("**361 HCT/Ps**")) necessary for the ownership or lease of their respective properties or to conduct its businesses as described in the Registration Statement and the Prospectus (collectively, "**Permits**"), except for such Permits the failure of which to possess, obtain or make the same would not have a Material Adverse Effect; the Company and its Subsidiaries are in compliance with the terms and conditions of all such Permits, except where the failure to be in compliance would not have a Material Adverse Effect; all of the Permits are valid and in full force and effect, except where any invalidity, individually or in the aggregate, would not have a Material Adverse Effect; and neither the Company nor any of its Subsidiaries has received any written notice relating to the limitation, revocation, cancellation, suspension, modification or non-renewal of any such Permit which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would have a Material Adverse Effect, or has any reason to believe that any such license, certificate, permit or authorization will not be renewed in the ordinary course. To the extent required by applicable laws and regulations of the FDA, the Company or the applicable Subsidiary has submitted to the FDA an Investigational New Drug Application or amendment or supplement thereto for each clinical trial it has conducted or sponsored or is conducting or sponsoring; all such submissions were in material compliance with applicable laws and rules and regulations when submitted and no material deficiencies have been asserted by the FDA with respect to any such submissions. The Company and each Subsidiary possess such valid and current certificates, authorizations or permits issued by the appropriate state, federal or foreign regulatory agencies or bodies necessary to conduct their respective businesses, and neither the Company nor any Subsidiary has received, or has any reason to believe that it will receive, any notice of proceedings relating to the revocation or modification of, or non-compliance with, any such certificate, authorization or permit which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would have a Material Adverse Effect.

(t) Regulatory Filings. None of the Company or any of its Subsidiaries has failed to file with the applicable Governmental Authority (including, without limitation, the FDA, or any foreign, federal, state, provincial or local Governmental Authority performing functions similar to those performed by the FDA) any required filing, declaration, listing, registration, report or submission, except for such failures that, individually or in the aggregate, would not have a Material Adverse Effect; except as disclosed in the Registration Statement and the Prospectus, all such filings, declarations, listings, registrations, reports or submissions were in compliance with applicable laws when filed and no deficiencies have been asserted by any applicable regulatory authority with respect to any such filings, declarations, listings, registrations, reports or submissions, except for any deficiencies that, individually or in the aggregate, would not have a Material Adverse Effect. The Company has operated and currently is, in all material respects, in compliance with the United States Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and all applicable rules, guidance regarding the exercise of enforcement discretion related to 361 HCT/Ps, and regulations of the FDA and other federal, state, local and foreign Governmental Authority exercising comparable authority, except where the failure to be in compliance would not have a Material Adverse Effect. The Company has no knowledge of any studies, tests or trials not described in the Registration Statement and Prospectus the results of which reasonably call into question in any material respect the results of the studies, tests and trials described in the Registration Statement and the Prospectus.

(u) Intellectual Property. Except as disclosed in the Registration Statement and the Prospectus, the Company and its Subsidiaries own, possess, license or have other rights to use all foreign and domestic patents, patent applications, trade and service marks, trade and service mark registrations, trade names, copyrights, licenses, inventions, trade secrets, technology, Internet domain names, know-how and other intellectual property (collectively, the "**Intellectual Property**"), necessary for the conduct of their respective businesses as now conducted except to the extent that the failure to own, possess, license or otherwise hold adequate rights to use such Intellectual Property would not, individually or in the aggregate, have a Material Adverse Effect. Except as disclosed in the Registration Statement and the Prospectus, (i) there are no rights of third parties to any such Intellectual Property owned by the Company and its Subsidiaries; (ii) to the Company's knowledge, there is no infringement by third parties of any such Intellectual Property; (iii) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the Company's and its Subsidiaries' rights in or to any such Intellectual Property, and the Company is unaware of any facts which could form a reasonable basis for any such action, suit, proceeding or claim; (iv) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property; (v) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others that the Company and its Subsidiaries infringe or otherwise violate any patent, trademark, copyright, trade secret or other proprietary rights of others; (vi) to the Company's knowledge, there is no third-party U.S. patent or published U.S. patent application which contains claims for which an Interference Proceeding (as defined in 35 U.S.C. § 135) has been commenced against any patent or patent application described in the Prospectus as being owned by or licensed to the Company; and (vii) the Company and its Subsidiaries have complied with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company or such Subsidiary, and all such agreements are in full force and effect, except, in the case of any of clauses (i)-(vii) above, for any such infringement by third parties or any such pending or threatened suit, action, proceeding or claim as would not, individually or in the aggregate, have a Material Adverse Effect.

(v) Clinical Studies. The preclinical studies and tests and clinical trials described in the Registration Statement and the Prospectus were, and, if still pending, are being conducted in all material respects in accordance with the experimental protocols, procedures and controls pursuant to, where applicable, accepted professional and scientific standards for products or product candidates comparable to those being developed by the Company; the descriptions of such studies, tests and trials, and the results thereof, contained in the Registration Statement and the Prospectus are accurate and complete in all material respects; the Company is not aware of any tests, studies or trials not described in the Registration Statement and the Prospectus, the results of which reasonably call into question the results of the tests, studies and trials described in the Registration Statement and the Prospectus; and the Company has not received any written notice or correspondence from the FDA or any foreign, state or local Governmental Authority exercising comparable authority or any institutional review board or comparable authority requiring the termination, suspension, clinical hold or material modification of any tests, studies or trials.

(w) No Material Defaults. Neither the Company nor any of the Subsidiaries has defaulted on any installment on indebtedness for borrowed money or on any rental on one or more long-term leases, which defaults, individually or in the aggregate, would have a Material Adverse Effect. The Company has not filed a report pursuant to Section 13(a) or 15(d) of the Exchange Act since the filing of its last Annual Report on Form 10-K, indicating that it (i) has failed to pay any dividend or sinking fund installment on preferred stock or (ii) has defaulted on any installment on indebtedness for borrowed money or on any rental on one or more long-term leases, which defaults, individually or in the aggregate, would have a Material Adverse Effect.

(x) Certain Market Activities. Neither the Company, nor any of its subsidiaries, has taken, directly or indirectly, any action designed to, or that has constituted or might reasonably be expected to cause or result in, under the Exchange Act or otherwise, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Placement Shares.

(y) Broker/Dealer Relationships. Neither the Company nor any of the Subsidiaries (i) is required to register as a "broker" or "dealer" in accordance with the provisions of the Exchange Act or (ii) directly or indirectly through one or more intermediaries, controls or is a "person associated with a member" or "associated person of a member" (within the meaning set forth in the FINRA Manual).

(z) No Reliance. The Company has not relied upon the Agent or legal counsel for the Agent for any legal, tax or accounting advice in connection with the offering and sale of the Placement Shares.

(aa) Taxes. The Company and each of its Subsidiaries have filed all federal, state, local and foreign tax returns which have been required to be filed and paid all taxes shown thereon through the date hereof, to the extent that such taxes have become due and are not being contested in good faith, except where the failure to so file or pay would not have a Material Adverse Effect. No tax deficiency has been determined adversely to the Company or any of its Subsidiaries which has had, or would have, individually or in the aggregate, a Material Adverse Effect. The Company has no knowledge of any federal, state or other governmental tax deficiency, penalty or assessment which has been or might be asserted or threatened against it which would have a Material Adverse Effect.

(bb) Title to Real and Personal Property. The Company and its Subsidiaries have good and marketable title in fee simple to all items of real property owned by them, good and valid title to all personal property described in the Registration Statement or Prospectus as being owned by them that are material to the businesses of the Company or such Subsidiary, in each case free and clear of all liens, encumbrances and claims, except those matters that (i) do not materially interfere with the use made and proposed to be made of such property by the Company and any of its Subsidiaries or (ii) would not, individually or in the aggregate, have a Material Adverse Effect. Any real or personal property described in the Registration Statement or the Prospectus as being leased by the Company and any of its Subsidiaries is held by them under valid, existing and enforceable leases, except those that (A) do not materially interfere with the use made or proposed to be made of such property by the Company or any of its Subsidiaries or (B) would not, individually or in the aggregate, have a Material Adverse Effect. Each of the properties of the Company and its Subsidiaries complies with all applicable codes, laws and regulations (including, without limitation, building and zoning codes, laws and regulations and laws relating to access to such properties), except for such failures to comply that would not, individually or in the aggregate, reasonably be expected to interfere in any material respect with the use made and proposed to be made of such property by the Company and its Subsidiaries or otherwise have a Material Adverse Effect. None of the Company or its subsidiaries has received from any Governmental Authority any notice of any condemnation of, or zoning change affecting, the properties of the Company and its Subsidiaries, and the Company knows of no such condemnation or zoning change which is threatened, except for such that would not reasonably be expected to interfere in any material respect with the use made and proposed to be made of such property by the Company and its Subsidiaries or otherwise have a Material Adverse Effect, individually or in the aggregate.

(cc) Environmental Laws. The Company and its Subsidiaries (i) are in compliance with any and all applicable federal, state, local and foreign laws, rules, regulations, decisions and orders relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants (collectively, "**Environmental Laws**"); (ii) have received and are in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses as described in the Registration Statement and the Prospectus; and (iii) have not received notice of any actual or potential liability for the investigation or remediation of any disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants, except, in the case of any of clauses (i), (ii) or (iii) above, for any such failure to comply or failure to receive required permits, licenses, other approvals or liability as would not, individually or in the aggregate, have a Material Adverse Effect.

(dd) Periodic Review of Costs of Environmental Compliance. In the ordinary course of its business, the Company conducts a periodic review of the effect of Environmental Laws on the business, operations and properties of the Company and its subsidiaries, in the course of which it identifies and evaluates associated costs and liabilities (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties). No facts or circumstances have come to the Company's attention in connection with any such reviews that could result in costs or liabilities that would, individually or in the aggregate, have a Material Adverse Effect.

(ee) Disclosure Controls. The Company and each of its Subsidiaries maintain systems of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company's internal control over financial reporting is effective and the Company is not aware of any material weaknesses in its internal control over financial reporting (in each case, other than as set forth in the Registration Statement or Prospectus). Since the date of the latest audited financial statements of the Company included in the Prospectus, there has been no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting (other than as set forth in the Registration Statement or Prospectus). The Company has established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 and 15d-15) for the Company and designed such disclosure controls and procedures to ensure that material information relating to the Company and each of its Subsidiaries is made known to the certifying officers by others within those entities, particularly during the period in which the Company's Annual Report on Form 10-K or Quarterly Report on Form 10-Q, as the case may be, is being prepared. The Company's certifying officers have evaluated the effectiveness of the Company's disclosure controls and procedures as of the last day of the period covered by the Form 10-K for the fiscal year most recently ended (such date, the **"Evaluation Date**"). The Company presented in its Form 10-K for the fiscal year most recently ended the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date and the disclosure controls and procedures are effective as of the Evaluation Date. Since the Evaluation Date, there have been no significant changes in the Company's internal controls (as such term is defined in Item 307(b) of Regulation S-K under the Securities Act) or, to the Company's knowledge, in other factors that could significantly affect the Company's internal controls.

(ff) Sarbanes-Oxley. There is and has been no failure on the part of the Company or any of the Company's directors or officers, in their capacities as such, to comply in all material respects with any applicable provisions of the Sarbanes-Oxley Act and the rules and regulations promulgated thereunder. Each of the principal executive officer and the principal financial officer of the Company (or each former principal executive officer of the Company and each former principal financial officer of the Company as applicable) has made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act with respect to all reports, schedules, forms, statements and other documents required to be filed by it or furnished by it to the Commission. For purposes of the preceding sentence, "principal executive officer" and "principal financial officer" shall have the meanings given to such terms in the Sarbanes-Oxley Act.

(gg) Finder's Fees. Neither the Company nor any of the Subsidiaries has incurred any liability for any finder's fees, brokerage commissions or similar payments in connection with the transactions herein contemplated, except as may otherwise exist with respect to the Agent pursuant to this Agreement.

(hh) Labor Disputes. No labor disturbance by or dispute with employees of the Company or any of its Subsidiaries exists or, to the knowledge of the Company, is threatened which would have a Material Adverse Effect.

(ii) Investment Company Act. Neither the Company nor any of the Subsidiaries is or, after giving effect to the offering and sale of the Placement Shares, will be required to register as an "investment company" or an entity "controlled" by an "investment company," as such terms are defined in the Investment Company Act of 1940, as amended (the "**Investment Company Act**").

(jj) Operations. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions to which the Company or its Subsidiaries are subject, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Authority (collectively, the "**Money Laundering Laws**"); and no action, suit or proceeding by or before any Governmental Authority involving the Company or any of its Subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(kk) Off-Balance Sheet Arrangements. There are no transactions, arrangements and other relationships between and/or among the Company, and/or any of its affiliates and any unconsolidated entity, including, but not limited to, any structural finance, special purpose or limited purpose entity (each, an "**Off-Balance Sheet Transaction**") that would affect materially the Company's liquidity or the availability of or requirements for its capital resources, including those Off-Balance Sheet Transactions described in the Commission's Statement about Management's Discussion and Analysis of Financial Conditions and Results of Operations (Release Nos. 33-8056; 34-45321; FR-61), required to be described in the Prospectus which have not been described as required.

(ll) ERISA. To the knowledge of the Company, each material employee benefit plan, within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended ("**ERISA**"), that is maintained, administered or contributed to by the Company or any of its affiliates for employees or former employees of the Company and any of its Subsidiaries has been maintained in material compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including but not limited to ERISA and the Internal Revenue Code of 1986, as amended (the "**Code**"); no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred which would result in a material liability to the Company with respect to any such plan excluding transactions effected pursuant to a statutory or administrative exemption; and for each such plan that is subject to the funding rules of Section 412 of the Code or Section 302 of ERISA, no "accumulated funding deficiency" as defined in Section 412 of the Code has been incurred, whether or not waived, and the fair market value of the assets of each such plan (excluding for these purposes accrued but unpaid contributions) exceeds the present value of all benefits accrued under such plan determined using reasonable actuarial assumptions.

(mm) Underwriter Agreements. The Company is not a party to any agreement with an agent or underwriter for any other "at the market" or continuous equity transaction.

(nn) Forward-Looking Statements. Each financial or operational projection or other "forward-looking statement" (as defined by Section 27A of the Securities Act or Section 21E of the Exchange Act) contained in the Registration Statement or the Prospectus (i) was so included by the Company in good faith and with reasonable basis

after due consideration by the Company of the underlying assumptions, estimates and other applicable facts and circumstances and (ii) is accompanied by meaningful cautionary statements identifying those factors that could cause actual results to differ materially from those in such forward-looking statement. No such statement was made with the knowledge of an executive officer or director of the Company that is was false or misleading.

(oo) Agent Purchases. The Company acknowledges and agrees that Agent has informed the Company that the Agent may, to the extent permitted under the Securities Act and the Exchange Act, purchase and sell Common Stock for its own account while this Agreement is in effect, *provided*, that (i) no such purchase or sales shall take place while a Placement Notice is in effect (except to the extent the Agent may engage in sales of Placement Shares purchased or deemed purchased from the Company as a "riskless principal" or in a similar capacity) and (ii) the Company shall not be deemed to have authorized or consented to any such purchases or sales by the Agent.

(pp) Margin Rules. Neither the issuance, sale and delivery of the Placement Shares nor the application of the proceeds thereof by the Company as described in the Registration Statement and the Prospectus will violate Regulation T, U or X of the Board of Governors of the Federal Reserve System or any other regulation of such Board of Governors.

(qq) Insurance. The Company and each of its Subsidiaries carry, or are covered by, insurance in such amounts and covering such risks as the Company and each of its Subsidiaries reasonably believe are adequate for the conduct of their properties and as is customary for companies engaged in similar businesses in similar industries.

(rr) Compliance with Anti-Corruption Laws. (i) None of the Company or its subsidiaries or affiliates, or any director, officer, or employee thereof, or, to the Company's knowledge, any agent or representative of the Company or of any of its subsidiaries or affiliates, has taken or will take any action in furtherance of an offer, payment, promise to pay, or authorization or approval of the payment, giving or receipt of money, property, gifts or anything else of value, directly or indirectly, to any government official (including any officer or employee of a government or government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office) in order to influence official action, or to any person in violation of any applicable anti-corruption laws; (ii) the Company and its subsidiaries and affiliates have conducted their businesses in compliance with applicable anti-corruption laws and have instituted and maintained and will continue to maintain policies and procedures reasonably designed to promote and achieve compliance with such laws and with the representations and warranties contained herein; and (iii) neither the Company nor its subsidiaries will use, directly or indirectly, the proceeds of the offering in furtherance of an offer, payment, promise to pay, or authorization of the payment or giving of money, or anything else of value, to any person in violation of any applicable anti-corruption laws.

(ss) Compliance with Anti-Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in material compliance with all applicable financial recordkeeping and reporting requirements, including those of the Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), and the applicable anti-money laundering statutes of jurisdictions where the Company and its subsidiaries conduct business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "**Anti-Money Laundering Laws**"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the best knowledge of the Company, threatened.

(tt) Status Under the Securities Act. The Company was not and is not an ineligible issuer as defined in Rule 405 under the Securities Act at the times specified in Rules 164 and 433 under the Securities Act in connection with the offering of the Placement Shares.

(uu) No Misstatement or Omission in an Issuer Free Writing Prospectus. Each Issuer Free Writing Prospectus, as of its issue date and as of each Applicable Time, did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement or the Prospectus, including any incorporated document deemed to be a part thereof that has not been superseded or modified. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with written information furnished to the Company by the Agent specifically for use therein.

(vv) No Conflicts. Neither the execution of this Agreement, nor the issuance, offering or sale of the Placement Shares, nor the consummation of any of the transactions contemplated herein and therein, nor the compliance by the Company with the terms and provisions hereof and thereof will conflict with, or will result in a breach of, any of the terms and provisions of, or has constituted or will constitute a default under, or has resulted in or will result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to the terms of any contract or other agreement to which the Company may be bound or to which any of the property or assets of the Company is subject, except (i) such conflicts, breaches or defaults as may have been waived and (ii) such conflicts, breaches and defaults that would not have a Material Adverse Effect; nor will such action result (x) in any violation of the provisions of the organizational or governing documents of the Company, or (y) in any violation of the provisions of any statute or any order, rule or regulation applicable to the Company or of any Governmental Authority having jurisdiction over the Company.

(ww) Sanctions. (i) None of the Company, any of its subsidiaries, or any director, officer, or employee thereof, or, to the Company's knowledge, any agent, affiliate or representative of the Company or any of its subsidiaries, is an individual or entity ("**Person**") that is, or is owned or controlled by one or more Persons that are:

(A) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control ("**OFAC**"), the United Nations Security Council ("**UNSC**"), the European Union ("**EU**"), Her Majesty's Treasury ("**HMT**"), or other relevant sanctions authority (collectively, "**Sanctions**"), or

(B) located, organized or resident in a country or territory that is the subject of Sanctions (including, without limitation, Crimea, Cuba, Iran, North Korea, Sudan and Syria).

(ii) The Company will not, directly or indirectly, use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other Person:

(A) to fund or facilitate any activities or business of or with any Person or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions; or

(B) in any other manner that will result in a violation of Sanctions by any Person (including any Person participating in the offering, whether as underwriter, advisor, investor or otherwise).

(iii) The Company and its subsidiaries have not knowingly engaged in, are not now knowingly engaged in, and will not engage in, any dealings or transactions with any Person, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

(xx) Compliance with Laws. Each of the Company and its Subsidiaries: (A) is and at all times has been in compliance with all statutes, rules, or regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by the Company or its Subsidiaries related to 361 HCT/Ps ("**Applicable Laws**"), except as would not, individually or in the aggregate, have a Material Adverse Effect; (B) except as disclosed in the Registration Statement or the Prospectus, has not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the FDA or any other Governmental Authority alleging or asserting noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws ("**Authorizations**"); (C) possesses all material Authorizations and such Authorizations are valid and in full force and effect and are not in material violation of any term of any such Authorizations; (D) except as disclosed in the Registration Statement or the Prospectus, has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Authority or third party alleging that any product operation or activity is in violation of any Applicable Laws or Authorizations and has no knowledge that any such Governmental Authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (E) has not received notice that any Governmental Authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations or exceptions from such Authorizations that may be in effect with respect to stated policies of enforcement discretion for 361 HCT/Ps, and has no knowledge that any such Governmental Authority is considering such action; (F) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct on the date filed (or were corrected or supplemented by a subsequent submission); and (G) has not, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post sale warning, "dear healthcare provider" letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to the Company's knowledge, no third party has initiated, conducted or intends to initiate any such notice or action.

(yy) Statistical and Market-Related Data. All statistical, demographic and market-related data included in the Registration Statement or the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate or represent the Company's good faith estimates that are made on the basis of data derived from such sources.

(zz) Stock Exchange Listing. The Placement Shares are registered pursuant to Section 12(b) or 12(g) of the Exchange Act and are listed on the Exchange, and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Placement Shares under the Exchange Act or delisting the Placement Shares from the Exchange, nor has the Company received any notification that the Commission or the Exchange is contemplating terminating such registration or listing. To the Company's knowledge, it is in compliance with all applicable listing requirements for the listing of the Placement Shares on the Exchange.

(aaa) Related-Party Transactions. There are no business relationships or related-party transactions involving the Company or any of its subsidiaries or any other person required to be described in the Registration Statement or the Prospectus that have not been described as required thereunder.

(bbb) FINRA Matters. All of the information provided to the Agent or to counsel for the Agent by the Company or its officers and directors, and to the Company's knowledge, its counsel and the holders of any securities (debt or equity) or options to acquire any securities of the Company in connection with this Agreement is true, complete, correct and compliant with FINRA's rules and any letters, filings or other supplemental information provided to FINRA by the Company and its officers and directors and, to the Company's knowledge, its counsel and the holders of any securities (debt or equity) or options to acquire any securities of the Company in connection with this Agreement pursuant to FINRA's rules is true, complete and correct.

(ccc) No Rights to Purchase Preferred Stock. The issuance and sale of the Placement Shares as contemplated hereby will not cause any holder of any shares of capital stock, securities convertible into or exchangeable or exercisable for capital stock or options, warrants or other rights to purchase capital stock or any other securities of the Company to have any right to acquire any shares of preferred stock of the Company.

(ddd) No Contract Terminations. Except as set forth in the Registration Statement and the Prospectus, neither the Company nor any of its subsidiaries has sent or received any communication regarding termination of, or intent not to renew, any of the contracts or agreements referred to or described in the Registration Statement or the Prospectus (other than the Company's employment agreements), and no such termination or non-renewal has been threatened by the Company or any of its subsidiaries or, to the Company's knowledge, any other party to any such contract or agreement, which threat of termination or non-renewal has not been rescinded as of the date hereof.

(eee) Dividend Restrictions. No subsidiary of the Company is prohibited or restricted, directly or indirectly, from paying dividends to the Company, or from making any other distribution with respect to such subsidiary's equity securities or from repaying to the Company or any other subsidiary of the Company any amounts that may from time to time become due under any loans or advances to such subsidiary from the Company or from transferring any property or assets to the Company or to any other subsidiary.

(fff) IT Systems and Data. (i)(x) There has been no security breach or other compromise of or relating to any of the Company's or any of its subsidiaries' information technology and computer systems, networks, hardware, software, data (including the data of their respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of them), equipment or technology (collectively, "**IT Systems and Data**") that would, individually or in the aggregate, have a Material Adverse Effect and (y) neither the Company nor any of its subsidiaries has been notified of, and has no knowledge of any event or condition that would reasonably be expected to result in, any security breach or other compromise to its IT Systems and Data; (ii) the Company and each of its subsidiaries is presently in compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification, except as would not, in the case of this clause (ii), individually or in the aggregate, be reasonably expected to have a Material Adverse Effect; and (iii) the Company and its subsidiaries have implemented backup and disaster recovery technology consistent with industry standards and practices.

Any certificate signed by an officer of the Company and delivered to the Agent or to counsel for the Agent pursuant to or in connection with this Agreement shall be deemed to be a representation and warranty by the Company, as applicable, to the Agent as to the matters set forth therein.

The Company has a reasonable basis for making each of the representations set forth in this Section 6. The Company acknowledges that the Agent and, for purposes of the opinions to be delivered pursuant to Section 7 hereof, counsel to the Company and counsel to the Agent, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

7. Covenants of the Company. The Company covenants and agrees with the Agent that:

(a) Registration Statement Amendments. After the date of this Agreement and during any period in which a Prospectus relating to any Placement Shares is required to be delivered by the Agent under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act or similar rule), (i) the Company will notify the Agent promptly of the time when any subsequent amendment to the Registration Statement, other than documents incorporated by reference, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus or for additional information, (ii) the Company will prepare and file with the Commission, promptly upon the Agent's request, any amendments or supplements to the Registration Statement or Prospectus that, in the Agent's reasonable opinion, may be necessary or advisable in connection with the distribution of the Placement Shares by the Agent (*provided*, *however*, that the failure of the Agent to make such request shall not

relieve the Company of any obligation or liability hereunder, or affect the Agent's right to rely on the representations and warranties made by the Company in this Agreement and *provided*, *further*, that the only remedy the Agent shall have with respect to the failure to make such filing shall be to cease making sales under this Agreement until such amendment or supplement is filed); (iii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus relating to the Placement Shares or a security convertible into the Placement Shares unless a copy thereof has been submitted to the Agent within a reasonable period of time before the filing and the Agent has not reasonably objected thereto in writing within two (2) Business Days (*provided*, *however*, that the failure of the Agent to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect the Agent's right to rely on the representations and warranties made by the Company in this Agreement, and the Company has no obligation to provide the Agent any advance copy of such filing or to provide the Agent an opportunity to object to such filing if such filing does not name the Agent and does not reference the transactions contemplated hereby; *provided*, *further*, that the only remedy the Agent shall have with respect to the failure by the Company to obtain such consent shall be to cease making sales under this Agreement) and the Company will furnish to the Agent at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; and (iv) the Company will cause each amendment or supplement to the Prospectus to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act or, in the case of any document to be incorporated therein by reference, to be filed with the Commission as required pursuant to the Exchange Act, within the time period prescribed (the determination to file or not file any amendment or supplement with the Commission under this Section 7(a), based on the Company's reasonable opinion or reasonable objections, shall be made exclusively by the Company).

(b) Notice of Commission Stop Orders. The Company will advise the Agent, promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, of the suspension of the qualification of the Placement Shares for offering or sale in any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose; and it will promptly use its commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued. The Company will advise the Agent promptly after it receives any request by the Commission for any amendments to the Registration Statement or any amendment or supplements to the Prospectus or any Issuer Free Writing Prospectus or for additional information related to the offering of the Placement Shares or for additional information related to the Registration Statement, the Prospectus or any Issuer Free Writing Prospectus; *provided*, *however*, that the Company may delay any such amendment or supplement if, in the reasonable judgment of the Company, it is in the best interests of the Company to do so.

(c) Delivery of Prospectus; Subsequent Changes. During any period in which a Prospectus relating to the Placement Shares is required to be delivered by the Agent under the Securities Act with respect to the offer and sale of the Placement Shares (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act or similar rule), the Company will comply in all material respects with all requirements imposed upon it by the Securities Act, as from time to time in force, and to file on or before their respective due dates all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If the Company has omitted any information from the Registration Statement pursuant to Rule 430B under the Securities Act, it will use its best efforts to comply with the provisions of and make all requisite filings with the Commission pursuant to said Rule 430B and to notify the Agent promptly of all such filings. If during such period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify the Agent to suspend the offering of Placement Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance.

(d) Listing of Placement Shares. On or prior to the date of the first Placement Notice, the Company will use its reasonable best efforts to cause the Placement Shares to be listed on the Exchange.

(e) Delivery of Registration Statement and Prospectus. The Company will furnish to the Agent and its counsel (at the expense of the Company) copies of the Registration Statement, the Prospectus (including all Incorporated Documents) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during any period in which a Prospectus relating to the Placement Shares is required to be delivered under the Securities Act (including all documents filed with the Commission during such period that are deemed to be incorporated by reference therein), in each case as soon as reasonably practicable and in such quantities as the Agent may from time to time reasonably request and, at the Agent's request, will also furnish copies of the Prospectus to each exchange or market on which sales of the Placement Shares may be made; *provided*, *however*, that the Company shall not be required to furnish any document (other than the Prospectus) to the Agent to the extent such document is available on EDGAR.

(f) Earning Statement. The Company will make generally available to its security holders as soon as practicable, but in any event not later than 15 months after the end of the Company's current fiscal quarter, an earning statement covering a 12-month period that satisfies the provisions of Section 11(a) and Rule 158 of the Securities Act.

(g) Use of Proceeds. The Company will use the Net Proceeds as described in the Prospectus in the section entitled "Use of Proceeds."

(h) Notice of Other Sales. Without the prior written consent of the Agent, the Company will not, directly or indirectly, offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Stock (other than the Placement Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire, Common Stock during the period beginning on the third (3^{rd}) Trading Day immediately prior to the date on which any Placement Notice is delivered to the Agent hereunder and ending on the third (3^{rd}) Trading Day immediately following the final Settlement Date with respect to Placement Shares sold pursuant to such Placement Notice (or, if the Placement Notice has been terminated or suspended prior to the sale of all Placement Shares covered by a Placement Notice, the date of such suspension or termination); and will not directly or indirectly in any other "at the market" or continuous equity transaction offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Stock (other than the Placement Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire, Common Stock prior to the sixtieth (60^{th}) day immediately following the termination of this Agreement; *provided*, *however*, that such restrictions will not be required in connection with the Company's issuance or sale of (i) Common Stock, options to purchase Common Stock or Common Stock issuable upon the exercise of options, restricted stock awards, restricted stock units or other equity awards settled in Common Stock issued pursuant to any employee or director equity compensation plan, stock ownership plan or dividend reinvestment plan (but not Common Stock subject to a waiver to exceed plan limits in its dividend reinvestment plan) of the Company whether now in effect or hereafter implemented, (ii) Common Stock issuable upon conversion of securities or the exercise of warrants, options or other rights in effect or outstanding, and disclosed in filings by the Company available on EDGAR or otherwise in writing to the Agent and (iii) Common Stock or securities convertible into or exchangeable for shares of Common Stock as consideration for mergers, acquisitions, other business combinations or strategic alliances occurring after the date of this Agreement which are not issued for capital raising purposes.

(i) Change of Circumstances. The Company will, at any time during the pendency of a Placement Notice, advise the Agent promptly after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect in any material respect any opinion, certificate, letter or other document required to be provided to the Agent pursuant to this Agreement.

(j) Due Diligence Cooperation. The Company will cooperate with any reasonable due diligence review conducted by the Agent or its representatives in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during regular business hours and at the Company's principal offices, as the Agent may reasonably request.

(k) Required Filings Relating to Placement of Placement Shares. The Company agrees that on such dates as the Securities Act shall require, the Company will (i) file a prospectus supplement with the Commission under the applicable paragraph of Rule 424(b) under the Securities Act, which prospectus supplement will set forth, within the relevant period, the amount of Placement Shares sold through the Agent, the Net Proceeds to the Company and the compensation payable by the Company to the Agent with respect to such Placement Shares, and (ii) deliver such number of copies of each such prospectus supplement to each exchange or market on which such sales were effected as may be required by the rules or regulations of such exchange or market.

(l) Representation Dates; Certificate. During the term of this Agreement, (1) on or prior to the date of the first Placement Notice and (2) thereafter, each time the Company:

(i) files the Prospectus relating to the Placement Shares or amends or supplements (other than a prospectus supplement relating solely to an offering of securities other than the Placement Shares) the Registration Statement or the Prospectus relating to the Placement Shares by means of a post-effective amendment, sticker, or supplement but not by means of incorporation of documents by reference into the Registration Statement or the Prospectus relating to the Placement Shares;

(ii) files an annual report on Form 10-K under the Exchange Act (including any Form 10-K/A containing amended financial information or a material amendment to the previously filed Form 10-K);

(iii) files its quarterly reports on Form 10-Q under the Exchange Act; or

(iv) files a current report on Form 8-K containing amended financial information (other than information "furnished" pursuant to Items 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to the reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) under the Exchange Act (each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a "**Representation Date**");

the Company shall furnish the Agent (but in the case of clause (iv) above only if the Agent reasonably determines that the information contained in such Form 8-K is material) with a certificate dated the Representation Date, in the form attached hereto as Schedule 7(l), modified, as necessary, to relate to the Registration Statement and the Prospectus as amended or supplemented. The requirement to provide a certificate under this Section 7(l) shall be automatically waived for any Representation Date occurring (1) at a time a Suspension is in effect, which waiver shall continue until the earlier to occur of the date the Company delivers instructions for the sale of Placement Shares hereunder (which for such calendar quarter shall be considered a Representation Date) and the next occurring Representation Date and (2) at a time when the Sales Agent is not in possession of a Placement Notice, which waiver shall continue until the date the Company delivers a Placement Notice. Notwithstanding the foregoing, if the Company subsequently decides to sell Placement Shares following a Representation Date when a Suspension was in effect and did not provide the Agent with a certificate under this Section 7(l), then before the Company delivers the Placement Notice or the Agent sells any Placement Shares pursuant to such instructions, the Company shall provide the Agent with a certificate in conformity with this Section 7(l) dated as of the date that the Placement Notice is delivered.

(m) Opinions of Company Counsel. (1) On or prior to the date of the first Placement Notice and (2) thereafter, within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 7(l) for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause to be furnished to the Agent the opinion and negative assurance letter of each of King & Spalding LLP, counsel for the Company, or other counsel satisfactory to the Agent, and the opinion of the Chief Legal Officer of the Company, dated as of such date, in form and substance reasonably satisfactory to the Agent and its counsel, substantially similar to the forms previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; *provided*, *however*, the Company shall be required to furnish to the Agent no more than one opinion hereunder per calendar quarter; *provided*, *further*, that in lieu of such opinions for subsequent Representation Dates, counsel may furnish the Agent with a letter (a "**Reliance Letter**") to the effect that the Agent may rely on a prior opinion delivered under this Section 7(m) to the same extent as if it were dated the date of such letter (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of the date of the Reliance Letter).

(n) Opinion of Intellectual Property Counsel. (1) On or prior to the date of the first Placement Notice and (2) within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 7(l) for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause to be furnished to the Agent a written opinion of Crowell & Moring LLP, counsel for the Company with respect to intellectual property matters, dated as of such date, in form and substance reasonably satisfactory to the Agent and its counsel.

(o) Comfort Letter. (1) On or prior to the date of the first Placement Notice and (2) within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 7(l) for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause its independent registered public accounting firm to furnish the Agent letters (the "**Comfort Letters**"), dated the date the Comfort Letter is delivered, which shall meet the requirements set forth in this Section 7(o); *provided*, that if requested by the Agent, the Company shall cause a Comfort Letter to be furnished to the Agent within ten (10) Trading Days of the date of occurrence of any material transaction or event, including the restatement of the Company's financial statements. The Comfort Letter from the Company's independent registered public accounting firm shall be in a form and substance satisfactory to the Agent, (i) confirming that they are an independent registered public accounting firm within the meaning of the Securities Act and the PCAOB, (ii) stating, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants' "comfort letters" to underwriters in connection with registered public offerings (the first such letter, the "**Initial Comfort Letter**") and (iii) updating the Initial Comfort Letter with any information that would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter.

(p) Market Activities. The Company will not, directly or indirectly, (i) take any action designed to cause or result in, or that constitutes or would reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of Common Stock or (ii) sell, bid for, or purchase Common Stock in violation of Regulation M, or pay anyone any compensation for soliciting purchases of the Placement Shares other than the Agent.

(q) Investment Company Act. The Company will conduct its affairs in such a manner so as to reasonably ensure that neither it nor any of its Subsidiaries will be or become, at any time prior to the termination of this Agreement, required to register as an "investment company," as such term is defined in the Investment Company Act.

(r) No Offer to Sell. Other than an Issuer Free Writing Prospectus approved in advance by the Company and the Agent in its capacity as agent hereunder, neither the Agent nor the Company (including its agents and representatives, other than the Agent in its capacity as such) will make, use, prepare, authorize, approve or refer to any written communication (as defined in Rule 405 under the Securities Act), required to be filed with the Commission, that constitutes an offer to sell or solicitation of an offer to buy Placement Shares hereunder.

(s) Blue Sky and Other Qualifications. The Company will use its commercially reasonable efforts, in cooperation with the Agent, to qualify the Placement Shares for offering and sale, or to obtain an exemption for the Placement Shares to be offered and sold, under the applicable securities laws of such states and other jurisdictions

(domestic or foreign) as the Agent may designate and to maintain such qualifications and exemptions in effect for so long as required for the distribution of the Placement Shares (but in no event for less than one year from the date of this Agreement); *provided*, *however*, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject. In each jurisdiction in which the Placement Shares have been so qualified or exempt, the Company will file such statements and reports as may be required by the laws of such jurisdiction to continue such qualification or exemption, as the case may be, in effect for so long as required for the distribution of the Placement Shares (but in no event for less than one year from the date of this Agreement).

(t) Sarbanes-Oxley Act. The Company and the Subsidiaries will maintain and keep accurate books and records reflecting their assets and maintain internal accounting controls in a manner 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 and including 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 Company, (ii) provide reasonable assurance that transactions are recorded as necessary to permit the preparation of the Company's consolidated financial statements in accordance with generally accepted accounting principles, (iii) that receipts and expenditures of the Company are being made only in accordance with management's and the Company's directors' authorization, and (iv) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on its financial statements. The Company and the Subsidiaries will maintain such controls and other procedures, including, without limitation, those required by Sections 302 and 906 of the Sarbanes-Oxley Act, and the applicable regulations thereunder that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms, including, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure and to ensure that material information relating to the Company or the Subsidiaries is made known to them by others within those entities, particularly during the period in which such periodic reports are being prepared.

(u) Secretary's Certificate; Further Documentation. On or prior to the date of the first Placement Notice, the Company shall deliver to the Agent a certificate of the Secretary of the Company and attested to by an executive officer of the Company, dated as of such date, certifying as to (i) the Restated Certificate of Incorporation of the Company, (ii) the Restated Bylaws of the Company, (iii) the resolutions of the Board of Directors of the Company authorizing the execution, delivery and performance of this Agreement and the issuance of the Placement Shares and (iv) the incumbency of the officers duly authorized to execute this Agreement and the other documents contemplated by this Agreement. Within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate pursuant to Section 7(l) for which no waiver is applicable, the Company shall have furnished to the Agent such further information, certificates and documents as the Agent may reasonably request.

8. Payment of Expenses. The Company will pay all expenses incident to the performance of its obligations under this Agreement, including without limitation (i) the preparation and filing of the Registration Statement, including any fees required by the Commission, and the printing or electronic delivery of the Prospectus as originally filed and of each amendment and supplement thereto, in such number as the Agent shall deem necessary, (ii) the printing and delivery to the Agent of this Agreement and such other documents as may be required in connection with the offering, purchase, sale, issuance or delivery of the Placement Shares, (iii) the preparation, issuance and delivery of the certificates, if any, for the Placement Shares to the Agent, including any stock or other transfer taxes and any capital duties, stamp duties or other duties or taxes payable upon the sale, issuance or delivery of the Placement Shares to the Agent, (iv) the fees and disbursements of the counsel, accountants and other advisors to the Company, (v) the fees and expenses of counsel to the Agent in an amount not to exceed $50,000 in connection with the execution of this Agreement, (vi) the qualification or exemption of the Placement Shares under state securities laws in accordance with the provisions of Section 7(s) hereof, including filing fees, but excluding fees of the Agent's counsel, (vii) the printing and delivery to the Agent of copies of any Permitted Issuer Free Writing Prospectus and the Prospectus and any amendments or supplements thereto in such number as the Agent shall deem necessary, (viii) the preparation, printing and delivery to the Agent of copies of any blue sky survey, (ix) the fees and expenses of the transfer agent and registrar for the Common Stock, (x) the filing and other fees incident to any review by FINRA of the terms of the sale of the Placement Shares including the fees of the Agent's counsel (subject to the cap, set forth in clause (v) above), and (xi) the fees and expenses incurred in connection with the listing of the Placement Shares on the Exchange.

9. Conditions to the Agent's Obligations. The obligations of the Agent hereunder with respect to a Placement will be subject to the continuing accuracy and completeness of the representations and warranties made by the Company herein, to the due performance by the Company of its obligations hereunder, to the completion by the Agent of a due diligence review satisfactory to it in its reasonable judgment, and to the continuing satisfaction (or waiver by the Agent in its sole discretion) of the following additional conditions:

(a) Registration Statement Effective. The Registration Statement shall have become effective and shall be available for the (i) resale of all Placement Shares issued to the Agent and not yet sold by the Agent and (ii) sale of all Placement Shares contemplated to be issued by any Placement Notice.

(b) No Material Notices. None of the following events shall have occurred and be continuing: (i) receipt by the Company of any request for additional information from the Commission during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Placement Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) the occurrence of any event that makes any material statement made in the Registration Statement or the Prospectus or any material document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, the Prospectus or documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, that in the case of the Prospectus, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(c) No Misstatement or Material Omission. The Agent shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in the Agent's reasonable opinion is material, or omits to state a fact that in the Agent's reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(d) Material Changes. Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any material adverse change in the authorized capital stock of the Company or any Material Adverse Effect or any development that would reasonably be expected to cause a Material Adverse Effect, or a downgrading in or withdrawal of the rating assigned to any of the Company's securities (other than asset backed securities) by any "nationally recognized statistical rating organization," as such term is defined in Section 3(a)(62) of the Exchange Act, that it has under surveillance or review its rating of any of the Company's securities (other than asset backed securities), the effect of which, in the case of any such action by such nationally recognized statistical rating organization described above, in the reasonable judgment of the Agent (without relieving the Company of any obligation or liability it may otherwise have), is so material as to make it impracticable or inadvisable to proceed with the offering of the Placement Shares on the terms and in the manner contemplated in the Prospectus.

(e) Legal Opinions. The Agent shall have received the opinions of counsel required to be delivered pursuant to Sections 7(m) and 7(n) on or before the date

on which such delivery of such opinions is required pursuant to Sections 7(m) and 7(n).

(f) Comfort Letter. The Agent shall have received the Comfort Letter required to be delivered pursuant to Section 7(o) on or before the date on which such delivery of such Comfort Letter is required pursuant to Section 7(o).

(g) Representation Certificate. The Agent shall have received the certificate required to be delivered pursuant to Section 7(l) on or before the date on which delivery of such certificate is required pursuant to Section 7(l).

(h) No Suspension. Trading in the Common Stock shall not have been suspended on the Exchange and the Common Stock shall not have been delisted from the Exchange.

(i) Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section 7(l), the Company shall have furnished to the Agent such appropriate further information, opinions, certificates, letters and other documents as the Agent may reasonably request. All such opinions, certificates, letters and other documents will be in compliance with the provisions hereof.

(j) Securities Act Filings Made. All filings with the Commission with respect to the Placement Shares required by Rule 424 under the Securities Act to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424.

(k) Approval for Listing. The Placement Shares shall either have been (i) approved for listing on the Exchange, subject only to notice of issuance, or (ii) the Company shall have filed an application for listing of the Placement Shares on the Exchange at, or prior to, the issuance of any Placement Notice and the Exchange shall have reviewed such application and not provided any objections thereto.

(l) FINRA. If applicable, FINRA shall have raised no objection to the terms of this offering and the amount of compensation allowable or payable to the Agent as described in the Prospectus.

(m) No Termination Event. There shall not have occurred any event that would permit the Agent to terminate this Agreement pursuant to Section 12(a).

10. Indemnification and Contribution.

(a) Company Indemnification. The Company agrees to indemnify and hold harmless the Agent, its affiliates and their respective partners, members, directors, officers, employees and agents and each person, if any, who controls the Agent within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act as follows:

(i) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, joint or several, arising out of or based upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto), or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading, or arising out of any untrue statement or alleged untrue statement of a material fact included in any related Issuer Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading;

(ii) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, joint or several, to the extent of the aggregate amount paid in settlement of any litigation, or any investigation or proceeding by any Governmental Authority, commenced or threatened, or of any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission; *provided* that (subject to Section 10(d) below) any such settlement is effected with the written consent of the Company, which consent shall not unreasonably be delayed or withheld; and

(iii) against any and all expense whatsoever, as incurred (including the fees and disbursements of counsel), reasonably incurred in investigating, preparing or defending against any litigation, or any investigation or proceeding by any Governmental Authority, commenced or threatened, or any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission (whether or not a party), to the extent that any such expense is not paid under (i) or (ii) above,

provided, *however*, that this indemnity agreement shall not apply to any loss, liability, claim, damage or expense to the extent arising out of any untrue statement or omission or alleged untrue statement or omission made solely in reliance upon and in conformity with the Agent Information (as defined below).

(b) Agent Indemnification. Agent agrees to indemnify and hold harmless the Company and its directors and each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all loss, liability, claim, damage and expense described in the indemnity contained in Section 10(a), as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendments thereto), the Prospectus (or any amendment or supplement thereto) or any Issuer Free Writing Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with information relating to the Agent and furnished to the Company in writing by the Agent expressly for use therein. The Company hereby acknowledges that the only information that the Agent has furnished to the Company expressly for use in the Registration Statement, the Prospectus or any Issuer Free Writing Prospectus (or any amendment or supplement thereto) are the statements set forth in the seventh paragraph under the caption "Plan of Distribution" in the Prospectus (the "**Agent Information**").

(c) Procedure. Any party that proposes to assert the right to be indemnified under this Section 10 will, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 10, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party will not relieve the indemnifying party from (i) any liability that it might have to any indemnified party otherwise than under this Section 10 and (ii) any liability that it may have to any indemnified party under the foregoing provision of this Section 10 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (1) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (2) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (3) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (4) the indemnifying party has not in fact employed counsel to assume the defense of such action or counsel reasonably satisfactory to the indemnified party, in each case, within a reasonable time

after receiving notice of the commencement of the action; in each of which cases the reasonable fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm (plus local counsel) admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly as they are incurred. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent. No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 10 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent (1) includes an express and unconditional release of each indemnified party, in form and substance reasonably satisfactory to such indemnified party, from all liability arising out of such litigation, investigation, proceeding or claim and (2) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d) Settlement Without Consent if Failure to Reimburse. If an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for reasonable fees and expenses of counsel, such indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by Section 10(a)(ii) effected without its written consent if (1) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request, (2) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into and (3) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

(e) Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 10 is applicable in accordance with its terms but for any reason is held to be unavailable or insufficient from the Company or the Agent, the Company and the Agent will contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted) to which the Company and the Agent may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and the Agent on the other hand. The relative benefits received by the Company on the one hand and the Agent on the other hand shall be deemed to be in the same proportion as the total net proceeds from the sale of the Placement Shares (before deducting expenses) received by the Company bear to the total compensation (before deducting expenses) received by the Agent from the sale of Placement Shares on behalf of the Company. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and the Agent, on the other hand, with respect to the statements or omission that resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or the Agent, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Agent agree that it would not be just and equitable if contributions pursuant to this Section 10(e) were to be determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense, or damage, or action in respect thereof, referred to above in this Section 10(e) shall be deemed to include, for the purpose of this Section 10(e), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim to the extent consistent with Section 10(c) hereof. Notwithstanding the foregoing provisions of this Section 10(e), the Agent shall not be required to contribute any amount in excess of the commissions received by it under this Agreement and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 10(e), any person who controls a party to this Agreement within the meaning of the Securities Act, and any officers, directors, partners, employees or agents of the Agent, will have the same rights to contribution as that party, and each director of the Company and each officer of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 10(e), will notify any such party or parties from whom contribution may be sought, but the omission to so notify will not relieve that party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 10(e) except to the extent that the failure to so notify such other party materially prejudiced the substantive rights or defenses of the party from whom contribution is sought. Except for a settlement entered into pursuant to the last sentence of Section 10(c) hereof, no party will be liable for contribution with respect to any action or claim settled without its written consent if such consent is required pursuant to Section 10(c) hereof.

11. Representations and Agreements to Survive Delivery. The indemnity and contribution agreements contained in Section 10 of this Agreement and all representations and warranties of the Company herein or in certificates delivered pursuant hereto shall survive, as of their respective dates, regardless of (i) any investigation made by or on behalf of the Agent, any controlling persons, or the Company (or any of their respective officers, directors, employees or controlling persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

12. Termination.

(a) The Agent may terminate this Agreement, by notice to the Company, as hereinafter specified at any time (1) if there has been, since the time of execution of this Agreement or since the date as of which information is given in the Prospectus, any change, or any development or event involving a prospective change, in the condition, financial or otherwise, or in the business, properties, earnings, results of operations or prospects of the Company and its Subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business, which individually or in the aggregate, in the sole judgment of the Agent is material and adverse and makes it impractical or inadvisable to market the Placement Shares or to enforce contracts for the sale of the Placement Shares, (2) if there has occurred any material adverse change in the financial markets in the United States or the international financial markets, any outbreak of hostilities or escalation thereof or other calamity or crisis or any change or development involving a prospective change in national or international political, financial or economic conditions, in each case the effect of which is such as to make it, in the judgment of the Agent, impracticable or inadvisable to market the Placement Shares or to enforce contracts for the sale of the Placement Shares, (3) if trading in the Common Stock has been suspended or limited by the Commission or the Exchange, or if trading generally on the Exchange has been suspended or limited, or minimum prices for trading have been fixed on the Exchange, (4) if any suspension of trading of any securities of the Company on any exchange or in the over-the-counter market shall have occurred and be continuing, (5) if a major disruption of securities settlements or clearance services in the United States shall have occurred and be continuing, or (6) if a banking moratorium has been declared by either U.S. Federal or New York authorities. Any such termination shall be without liability of any party to any other party except that the provisions of Section 8 (Payment of Expenses), Section 10 (Indemnification and Contribution), Section 11 (Representations and Agreements to Survive Delivery), Section 17 (Governing Law and Time; Waiver of Jury Trial) and Section 18 (Consent to Jurisdiction) hereof shall remain in full force and effect notwithstanding such termination. If the Agent elects to terminate this Agreement as provided in this Section 12(a), the Agent shall provide the required notice as specified in Section 13 (Notices).

(b) The Company shall have the right, by giving three (3) days' notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 8, Section 10, Section 11, Section 17 and Section 18 hereof shall remain in full force and effect notwithstanding such termination.

(c) The Agent shall have the right, by giving three (3) days' notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 8, Section 10, Section 11, Section 17 and Section 18 hereof shall remain in full force and effect notwithstanding such termination.

(d) Unless earlier terminated pursuant to this Section 12, this Agreement shall automatically terminate upon the issuance and sale of all of the Placement Shares on the terms and subject to the conditions set forth herein except that the provisions of Section 8, Section 10, Section 11, Section 17 and Section 18 hereof shall remain in full force and effect notwithstanding such termination.

(e) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 12(a), (b), (c) or (d) above or otherwise by mutual agreement of the parties; *provided*, *however*, that any such termination by mutual agreement shall in all cases be deemed to provide that Section 8, Section 10, Section 11, Section 17 and Section 18 shall remain in full force and effect.

(f) Any termination of this Agreement shall be effective on the date specified in such notice of termination; *provided*, *however*, that such termination shall not be effective until the close of business on the date of receipt of such notice by the Agent or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Shares, such Placement Shares shall settle in accordance with the provisions of this Agreement.

13. Notices. All notices or other communications required or permitted to be given by any party to any other party pursuant to the terms of this Agreement shall be in writing, unless otherwise specified, and if sent to the Agent, shall be delivered to:

Cantor Fitzgerald & Co.
499 Park Avenue
New York, NY 10022
Attention: Capital Markets
Facsimile: (212) 307-3730

and:

Cantor Fitzgerald & Co.
499 Park Avenue
New York, NY 10022
Attention: General Counsel
Facsimile: (212) 829-4708

with a copy to:

Covington & Burling LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018-1405
Attention: Brian K. Rosenzweig

and if to the Company, shall be delivered to:

PolarityTE, Inc.
1960 S. 4250 West
Salt Lake City, UT 84104
Attention: Cameron Hoyler, General Counsel

with a copy to:

King & Spalding LLP
601 California Avenue #100
Palo Alto, CA 94304
Attention: Laura Bushnell

Each party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally or by verifiable facsimile transmission (with an original to follow) on or before 4:30 p.m., New York City time, on a Business Day or, if such day is not a Business Day, on the next succeeding Business Day, (ii) by Electronic Notice as set forth in the next paragraph, (iii) on the next Business Day after timely delivery to a nationally-recognized overnight courier or (iv) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid). For purposes of this Agreement, "**Business Day**" shall mean any day on which the Exchange and commercial banks in the City of New York are open for business.

An electronic communication ("**Electronic Notice**") shall be deemed written notice for purposes of this Section 13 if sent to the electronic mail address specified by the receiving party under separate cover. Electronic Notice shall be deemed received at the time the party sending Electronic Notice receives verification of receipt by the receiving party. Any party receiving Electronic Notice may request and shall be entitled to receive the notice on paper, in a nonelectronic form (" **Nonelectronic Notice**") which shall be sent to the requesting party within ten (10) days of receipt of the written request for Nonelectronic Notice.

14. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and the Agent and their respective successors and the parties referred to in Section 10 hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party; *provided*, *however*, that the Agent may assign its rights and obligations hereunder to an affiliate thereof without obtaining the Company's consent, so long as such affiliate is a registered broker-dealer and the Agent provides advanced notice of such assignment to the Company.

15. Adjustments for Stock Splits. The parties acknowledge and agree that all share-related numbers contained in this Agreement shall be adjusted to take into account any stock split, stock dividend or similar event effected with respect to the Placement Shares.

16. Entire Agreement; Amendment; Severability; Waiver. This Agreement (including all schedules and exhibits attached hereto and Placement Notices issued pursuant hereto) constitutes the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with

regard to the subject matter hereof. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and the Agent. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement. No implied waiver by a party shall arise in the absence of a waiver in writing signed by such party. No failure or delay in exercising any right, power, or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any right, power, or privilege hereunder.

17. **GOVERNING LAW AND TIME; WAIVER OF JURY TRIAL. THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAWS. SPECIFIED TIMES OF DAY REFER TO NEW YORK CITY TIME. EACH PARTY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.**

18. **CONSENT TO JURISDICTION. EACH PARTY HEREBY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF THE STATE AND FEDERAL COURTS SITTING IN THE CITY OF NEW YORK, BOROUGH OF MANHATTAN, FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION WITH ANY TRANSACTION CONTEMPLATED HEREBY, AND HEREBY IRREVOCABLY WAIVES, AND AGREES NOT TO ASSERT IN ANY SUIT, ACTION OR PROCEEDING, ANY CLAIM THAT IT IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF ANY SUCH COURT, THAT SUCH SUIT, ACTION OR PROCEEDING IS BROUGHT IN AN INCONVENIENT FORUM OR THAT THE VENUE OF SUCH SUIT, ACTION OR PROCEEDING IS IMPROPER. EACH PARTY HEREBY IRREVOCABLY WAIVES PERSONAL SERVICE OF PROCESS AND CONSENTS TO PROCESS BEING SERVED IN ANY SUCH SUIT, ACTION OR PROCEEDING BY MAILING A COPY THEREOF (CERTIFIED OR REGISTERED MAIL, RETURN RECEIPT REQUESTED) TO SUCH PARTY AT THE ADDRESS IN EFFECT FOR NOTICES TO IT UNDER THIS AGREEMENT AND AGREES THAT SUCH SERVICE SHALL CONSTITUTE GOOD AND SUFFICIENT SERVICE OF PROCESS AND NOTICE THEREOF. NOTHING CONTAINED HEREIN SHALL BE DEEMED TO LIMIT IN ANY WAY ANY RIGHT TO SERVE PROCESS IN ANY MANNER PERMITTED BY LAW.**

19. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed Agreement by one party to the other may be made by facsimile or electronic transmission.

20. Construction. The section and exhibit headings herein are for convenience only and shall not affect the construction hereof. References herein to any law, statute, ordinance, code, regulation, rule or other requirement of any Governmental Authority shall be deemed to refer to such law, statute, ordinance, code, regulation, rule or other requirement of any Governmental Authority as amended, reenacted, supplemented or superseded in whole or in part and in effect from time to time and also to all rules and regulations promulgated thereunder.

21. Permitted Free Writing Prospectuses. The Company represents, warrants and agrees that, unless it obtains the prior written consent of the Agent, which consent shall not be unreasonably withheld, condition or delayed, and the Agent represents, warrants and agrees that, unless it obtains the prior written consent of the Company, it has not made and will not make any offer relating to the Placement Shares that would constitute an Issuer Free Writing Prospectus, or that would otherwise constitute a "free writing prospectus," as defined in Rule 405, required to be filed with the Commission. Any such free writing prospectus consented to by the Agent or by the Company, as the case may be, is hereinafter referred to as a "Permitted Free Writing Prospectus." The Company represents and warrants that it has treated and agrees that it will treat each Permitted Free Writing Prospectus as an "issuer free writing prospectus," as defined in Rule 433, and has complied and will comply with the requirements of Rule 433 applicable to any Permitted Free Writing Prospectus, including timely filing with the Commission where required, legending and record keeping. For the purposes of clarity, the parties hereto agree that all free writing prospectuses, if any, listed in Exhibit 21 hereto are Permitted Free Writing Prospectuses.

22. Absence of Fiduciary Relationship. The Company acknowledges and agrees that:

(a) the Agent is acting solely as agent in connection with the public offering of the Placement Shares and in connection with each transaction contemplated by this Agreement and the process leading to such transactions, and no fiduciary or advisory relationship between the Company or any of its respective affiliates, stockholders (or other equity holders), creditors or employees or any other party, on the one hand, and the Agent, on the other hand, has been or will be created in respect of any of the transactions contemplated by this Agreement, irrespective of whether or not the Agent has advised or is advising the Company on other matters, and the Agent has no obligation to the Company with respect to the transactions contemplated by this Agreement except the obligations expressly set forth in this Agreement;

(b) it is capable of evaluating and understanding, and understands and accepts, the terms, risks and conditions of the transactions contemplated by this Agreement;

(c) neither the Agent nor its affiliates have provided any legal, accounting, regulatory or tax advice with respect to the transactions contemplated by this Agreement and it has consulted its own legal, accounting, regulatory and tax advisors to the extent it has deemed appropriate;

(d) it is aware that the Agent and its affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and the Agent and its affiliates have no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship or otherwise; and

(e) it waives, to the fullest extent permitted by law, any claims it may have against the Agent or its affiliates for breach of fiduciary duty or alleged breach of fiduciary duty in connection with the sale of Placement Shares under this Agreement and agrees that the Agent and its affiliates shall not have any liability (whether direct or indirect, in contract, tort or otherwise) to it in respect of such a fiduciary duty claim or to any person asserting a fiduciary duty claim on its behalf or in right of it or the Company, employees or creditors of Company.

23. Definitions. As used in this Agreement, the following terms have the respective meanings set forth below:

"**Applicable Time**" means (i) each Representation Date and (ii) the time of each sale of any Placement Shares pursuant to this Agreement.

"**Governmental Authority**" means (i) any federal, provincial, state, local, municipal, national or international government or governmental authority, regulatory or administrative agency, governmental commission, department, board, bureau, agency or instrumentality, court, tribunal, arbitrator or arbitral body (public or private); (ii) any self-regulatory organization; or (iii) any political subdivision of any of the foregoing.

"**Issuer Free Writing Prospectus**" means any "issuer free writing prospectus," as defined in Rule 433, relating to the Placement Shares that (1) is required to be filed

with the Commission by the Company, (2) is a "road show" that is a "written communication" within the meaning of Rule 433(d)(8)(i) whether or not required to be filed with the Commission, or (3) is exempt from filing pursuant to Rule 433(d)(5)(i) because it contains a description of the Placement Shares or of the offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g) under the Securities Act Regulations.

"**knowledge**" means, as it pertains to the Company, the actual knowledge of the officers and directors of the Company, together with the knowledge which they would have had if they had conducted a reasonable inquiry of the relevant persons into the relevant subject matter.

"**Rule 164**," "**Rule 172**," "**Rule 405**," "**Rule 415**," "**Rule 424**," "**Rule 424(b)**," "**Rule 430B**," and "**Rule 433**" refer to such rules under the Securities Act Regulations.

All references in this Agreement to financial statements and schedules and other information that is "contained," "included" or "stated" in the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information that is incorporated by reference in the Registration Statement or the Prospectus, as the case may be.

All references in this Agreement to the Registration Statement, the Prospectus or any amendment or supplement to any of the foregoing shall be deemed to include the copy filed with the Commission pursuant to EDGAR; all references in this Agreement to any Issuer Free Writing Prospectus (other than any Issuer Free Writing Prospectuses that, pursuant to Rule 433, are not required to be filed with the Commission) shall be deemed to include the copy thereof filed with the Commission pursuant to EDGAR; and all references in this Agreement to "supplements" to the Prospectus shall include, without limitation, any supplements, "wrappers" or similar materials prepared in connection with any offering, sale or private placement of any Placement Shares by the Agent outside of the United States.

[***Signature Page Follows***]

If the foregoing correctly sets forth the understanding between the Company and the Agent, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between the Company and the Agent.

Very truly yours,

POLARITYTE, INC.

By: */s/ David Seaburg*
Name: David Seaburg
Title: Chief Executive Officer

ACCEPTED as of the date first-above written:

CANTOR FITZGERALD & CO.

By: */s/ Sage Kelly*
Name: Sage Kelly
Title: Senior Managing Director, Head of Investment Banking

SCHEDULE 1

Form of Placement Notice

From: PolarityTE, Inc.

To: Cantor Fitzgerald & Co.
Attention: [●]

Subject: Placement Notice

Date: [●], 20[●]

Ladies and Gentlemen:

Pursuant to the terms and subject to the conditions contained in the Sales Agreement between PolarityTE, Inc., a Delaware corporation (the "**Company**"), and Cantor Fitzgerald & Co. ("**Agent**"), dated March 30, 2021, the Company hereby requests that the Agent sell up to [●] of the Company's common stock, par value $0.001 per share, at a minimum market price of $[●] per share, during the time period beginning [month, day, time] and ending [month, day, time].

SCHEDULE 2

Compensation

The Company shall pay to the Agent in cash, upon each sale of Placement Shares pursuant to this Agreement, an amount equal to 4.0% of the aggregate gross proceeds from each sale of Placement Shares.

In the event the total amount paid to the Agent under the foregoing paragraph is not at least $400,000 as of March 30, 2022, the Company will pay to the Agent the

difference between $400,000 and the total amount of commissions paid to the Agent as of that date and the amount so paid shall be credited against payments due to the Agent under the foregoing paragraph after March 30, 2022. In the event the Agent terminates this Agreement prior to March 30, 2022 pursuant to Section 12(c) of this Agreement, the obligation of the Company to make any payment to the Agent under this paragraph shall automatically become void and unenforceable and the Company shall have no liability to the Agent in respect thereof. In the event the Company terminates this Agreement prior to March 30, 2022 pursuant to Section 12(b) of this Agreement, the Company shall make payment of the amount provided for in this paragraph within three (3) Business Days of the date of termination.

SCHEDULE 3

Notice Parties

The Company

Jacob Patterson, Chief Financial Officer (jacobpatterson@polarityte.com)

Cameron Hoyler, General Counsel (cameronhoyler@polarityte.com)

The Agent

Sameer Vasudev (svasudev@cantor.com)

Matthew Crawford (matthew.crawford@cantor.com)

With copies to:

CFControlledEquityOffering@cantor.com

SCHEDULE 4

Subsidiaries

Incorporated by reference to Exhibit 21.1 of the Company's most recently filed Form 10-K.

SCHEDULE 7(L)

Form of Representation Date Certificate Pursuant to Section 7(l)

The undersigned, the duly qualified and elected [●], of PolarityTE, Inc., a Delaware corporation (the "Company"), does hereby certify in such capacity and on behalf of the Company, pursuant to Section 7(l) of the Sales Agreement, dated March 30, 2021 (the "Sales Agreement"), between the Company and Cantor Fitzgerald & Co., that to the best of the knowledge of the undersigned:

(i) The representations and warranties of the Company in Section 6 of the Sales Agreement (A) to the extent such representations and warranties are subject to qualifications and exceptions contained therein relating to materiality or Material Adverse Effect, are true and correct on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date, and (B) to the extent such representations and warranties are not subject to any qualifications or exceptions, are true and correct in all material respects as of the date hereof as if made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct in all material respects as of such date; *provided*, *however*, that such representations and warranties also shall be qualified by the disclosure included or incorporated by reference in the Registration Statement and Prospectus; and

(ii) The Company has complied in all material respects with all agreements and satisfied in all material respects all conditions on its part to be performed or satisfied pursuant to the Sales Agreement at or prior to the date hereof.

Capitalized terms used herein without definition shall have the meanings given to such terms in the Sales Agreement.

POLARITYTE, INC.

By: _____
Name: _____
Title: _____

Date: [●]

Exhibit 21

Permitted Free Writing Prospectus

None.

Exhibit 4.13

Description of Capital Stock

The following description of our common stock and preferred stock, together with the additional information we include in any applicable prospectus supplements, 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, and by applicable law. We have filed copies of our certificate of incorporation and bylaws with the SEC. 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. As of March 15, 2021, we had 80,255,426 shares of common stock outstanding and no shares of preferred stock outstanding.

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.

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 5.1

KING & SPALDING

King & Spalding LLP
601 South California Avenue
Suite 100
Palo Alto, CA 94304
Tel: +1 650 422 6700
www.kslaw.com

March 30, 2021

PolarityTE, Inc.
1960 S. 4250 West
Salt Lake City, Utah, 84104

Ladies and Gentlemen:

We have acted as counsel to PolarityTE, Inc., a Delaware corporation (the "Company"), in connection with the issuance and sale of up to $50,000,000 in aggregate offering price of shares (the "Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), pursuant to the Company's Registration Statement on Form S-3 (File No. 333-229584) (the "Registration Statement"), a base prospectus and related prospectus supplement, dated March 30, 2021 (the "Prospectus Supplement"), and that certain Sales Agreement, dated March 30, 2021 (the "Sales Agreement"), between the Company and Cantor Fitzgerald & Co.

In so acting, we have examined and relied upon the accuracy of original, certified, conformed or photographic copies of such records, agreements, certificates and other documents as we have deemed necessary or appropriate to enable us to render the opinions set forth below. In all such examinations, we have assumed the genuineness of signatures on original documents and the conformity to such original documents of all documents submitted to us as certified, conformed or photographic copies and, as to certificates of public officials, we have assumed the same to have been properly given and to be accurate. As to matters of fact material to this opinion, we have relied, without independent verification, upon statements and representations of representatives of the Company and public officials.

Based upon the foregoing, and subject to the additional assumptions, qualifications and limitations set forth below, upon the completion of all Corporate Proceedings (as defined below) relating to the Shares, when the Shares have been issued and delivered, and payment therefor in an amount not less than the par value of thereof made, in accordance with the Corporate Proceedings and the terms of the Sales Agreement, we are of the opinion that the Shares will be validly issued, fully paid and non-assessable. In rending the foregoing opinion, we have assumed that (i) upon issuance of any Shares, the total number of shares of Common Stock issued and outstanding will not exceed the total number of shares of Common Stock that the Company is then authorized to issue under its certificate of incorporation and (ii) the terms on which any Shares are sold will be authorized and approved by the board of directors of the Company, or one or more committees thereof established prior to the issuance thereof by the board of directors of the Company with authority to issue and sell the Shares pursuant to the Sales Agreement (the "Corporate Proceedings").

This opinion is limited in all respects to the federal laws of the United States of America and the Delaware General Corporation Law, and no opinion is expressed with respect to the laws of any other jurisdiction or any effect that such laws may have on the opinions expressed herein. This opinion is limited to the matters stated herein, and no opinion is implied or may be inferred beyond the matters expressly stated herein.

This opinion is given as of the date hereof, and we assume no obligation to advise you after the date hereof of facts or circumstances that come to our attention or changes in law that occur, which could affect the opinions contained herein. This opinion is being rendered for the benefit of the Company in connection with the matters addressed herein.

We consent to the filing of this opinion as Exhibit 5.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2020 filed on March 30, 2021 to be incorporated by reference into the Registration Statement and to the reference to us under the caption "Legal Matters" in the Prospectus Supplement. In giving such consent, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act of 1933, as amended.

Very truly yours,

/s/ King & Spalding LLP

Exhibit 10.8

POLARITYTE, INC.
CHANGE IN CONTROL COMPENSATION PLAN

ARTICLE I - INTRODUCTION

Section 1.1 Background. The Board of Directors of PolarityTE, Inc. (the "Company"), has considered the effect a Change in Control of the Company may have on certain Executives of the Company. The Board has determined that it is in the best interests of the Company and its shareholders to assure that the Company will have the continued dedication of its Executives, notwithstanding the possibility, threat or occurrence of a Change in Control of the Company. The Board believes it is imperative to diminish the inevitable distraction of its Executives by virtue of the personal uncertainties and risks, including personal financial risks, created by a pending or threatened Change in Control of the Company.

Section 1.2 Purpose. This Plan is designed to encourage the Executives' full attention and dedication to the Company currently and in the event of any threatened or pending Change in Control transaction and, notwithstanding the outcome of any such proposed transaction, to assure fair treatment of such Executives in the event of a Change in Control of the Company.

ARTICLE II - ESTABLISHMENT OF THE POLICY

Section 2.1 Applicability of Plan. The benefits provided by this Plan shall be available to all Executives who, at or after the Effective Date, meet the eligibility requirements of Article IV hereof.

Section 2.2 Contractual Right to Benefits. Subject to the provisions of Article VIII hereof, this Plan establishes and vests in each Participant a contractual right to the benefits to which he or she is entitled hereunder, enforceable by the Participant against the Company on the terms and subject to the conditions hereof.

ARTICLE III - DEFINITIONS AND CONSTRUCTION

Section 3.1 Definitions. The following terms shall have the following meanings when used in this Plan with initial capital letters:

(a) "Base Pay" of a Participant means the Participant's annual base salary from the Company as in effect on the Termination Date; provided, however, that any reductions in Base Pay following the date of the Change in Control will not be considered when determining Base Pay hereunder.

(b) "Board" means the Board of Directors of the Company.

(c) "Change in Control" of the Company shall be deemed to have occurred if the events set forth in any one of the following paragraphs shall have occurred:

(i) The acquisition by any Person of Beneficial Ownership of fifty percent (50%) or more of either (A) the then-outstanding shares of common stock of the Company (the "Outstanding Company Common Stock"), or (B) the combined voting power of the then-outstanding voting securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (i), the following acquisitions shall not constitute a Change in Control: (aa) any acquisition directly from the Company, (bb) any acquisition by the Company, (cc) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company, or (dd) any acquisition by any corporation pursuant to a transaction that complies with clauses (A), (B), and (C) of subsection (iv) of this Section 3.1(c); or

(ii) The acquisition by any Person other than the Grandfathered Person of Beneficial Ownership of thirty percent (30%) or more of either (A) the adjusted then-outstanding shares of common stock of the Company (the "Adjusted Outstanding Company Common Stock"), or (B) the combined voting power of the adjusted then-outstanding voting securities of the Company entitled to vote generally in the election of directors (the "Adjusted Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (i), the following acquisitions shall not constitute a Change in Control: (aa) any acquisition directly from the Company, (bb) any acquisition by the Company, (cc) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any corporation controlled by the Company, or (dd) any acquisition by any corporation pursuant to a transaction that complies with clauses (A), (B), and (C) of subsection (iv) of this Section 3.1(c); or

(iii) Individuals who, as of the Effective Date, constitute the Board (the "Incumbent Board") cease for any reason to constitute at least a majority of the Board; provided, however, that any individual becoming a member of the Board subsequent to the Effective Date whose election, or nomination for election by the Company's shareholders, was approved by a vote of at least a majority of the members of the Board then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of members of the Board or other actual or threatened solicitation of proxies or consents by or on behalf of a Person other than the Board; or

(iv) Consummation of a reorganization, merger or consolidation of the Company or sale or other disposition of all or substantially all of the assets of the Company or the acquisition by the Company of assets or stock of another entity (a "Business Combination"), in each case, unless, following such Business Combination, (A) all or substantially all of the individuals and entities who were the Beneficial Owners, respectively, of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than eighty percent (80%) of, respectively, the then-outstanding shares of common stock and the combined voting power of the then-outstanding voting securities entitled to vote generally in the election of directors, as the case may be, of the corporation resulting from such Business Combination (including a corporation which as a result of such transaction owns the Company or all or substantially all of the Company's assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership, immediately prior to such Business Combination of the Outstanding Company Common Stock and Outstanding Company Voting Securities, as the case may be, (B) no Person (excluding any corporation resulting from such Business Combination or any employee benefit plan (or related trust) of the Company or such corporation resulting from such Business Combination) beneficially owns, directly or indirectly, fifty percent (50%) or more of, respectively, the then-outstanding shares of common stock of the corporation resulting from such Business Combination, 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 Business Combination, and (C) at least a majority of the members of the board of directors of the corporation resulting from such Business Combination were members of the Incumbent Board at the time of the execution of the initial agreement, or of the action of the Board, providing for such Business Combination.

For purposes of this Section 3.1(c), "Person" shall mean any individual, firm, corporation, partnership (general or limited), limited liability company, limited liability partnership, association, unincorporated organization, trust or other legal entity and also (y) any syndicate or group deemed to be a Person under Section 13(d)(3) of the Exchange Act and Rule 13d-5(b) thereunder and (z) any successor (by merger or otherwise) of any such firm, corporation, partnership (general or limited), limited liability

company, limited liability partnership, association, unincorporated organization, trust, or other group or entity.

(d) "Code" means the Internal Revenue Code of 1986, as amended.

(e) "Company" means PolarityTE, Inc., a Delaware corporation, and any successor thereto as provided in Section 7.1 hereof.

(f) "Effective Date" means August 6, 2019.

(g) "Exchange Act" means the Securities Exchange Act of 1934, as amended.

(h) "Executive" means any person who is the Company's Chief Executive Officer, President, Chief Operating Officer, Chief Financial Officer, Chief Scientific Officer, Chief Medical Officer Chief, Translational Medicine Officer, General Counsel, Chief Intellectual Property Officer, Chief Legal Officer, Senior Vice President of Operations, and Vice President of Commercial Strategy.

(i) "Good Reason" means, without the express written consent of the Participant:

(i) the assignment to the Participant of any duties inconsistent in any substantial respect with the Participant's position (including status, office or title), authority or responsibilities as in effect during the 120-day period immediately preceding the Change in Control, which assignment results in a substantial diminution in such position, authority or responsibilities or any other substantial adverse change in such position, authority or responsibilities, excluding an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Company as set forth below;

(ii) any failure by the Company to furnish the Participant with compensation (including Base Salary and Incentive Pay) and benefits at a level substantially equal to or exceeding those received by the Participant from the Company or any Subsidiary during the 120-day period preceding the Change in Control, other than (A) an insubstantial and inadvertent failure remedied by the Company as set forth below, (B) a reduction in the same type of compensation paid to Executives that is applied to substantially all of the Executives of the Company in approximately the same percentage of that type of compensation, or (C) a reduction or modification of any employee benefit program covering substantially all of the employees of the Company, which reduction or modification generally applies to all employees covered under such program; or

(iii) the Company requiring the Participant to be based or to perform services at any office or location that is in excess of 30 miles from the principal location of the Participant's work during the 120-day period immediately preceding the Change in Control, except for travel reasonably required in the performance of the Participant's responsibilities.

Before a termination by the Participant under this Section 3.1(i) will constitute termination for Good Reason, the Participant must give the Company a Notice of Termination within 30 calendar days of the occurrence of the event that constitutes Good Reason. Failure to provide such Notice of Termination within such 30-day period shall be conclusive proof that the Participant shall not have Good Reason to terminate employment.

For purposes of this Section 3.1(i), Good Reason shall exist only if the Company fails to remedy the event or events constituting Good Reason within 30 calendar days after receipt of the Notice of Termination from the Participant. If the Participant determines that Good Reason for termination exists and timely files a Notice of Termination, such determination shall be presumed to be true and the Company will have the burden of proving that Good Reason does not exist.

(j) "Grandfathered Person" shall mean Denver Lough, his spouse, lineal descendants and his Affiliates and Associates, and any trusts or other entities whose principal beneficiary is Denver Lough, his spouse, lineal descendants or his Affiliates and Associates.

(k) "Incentive Pay" means the target annual cash incentive award, if any, as notified to the Participant for the year in which the Termination Date occurs under the annual bonus, incentive or other payment of cash compensation in addition to Base Pay, made or to be made in regard to services rendered in any fiscal year or other annual measurement period pursuant to any bonus, incentive, performance, or similar agreement, policy, program or arrangement of the Company or any successor thereto.

(l) "Just Cause" means without the written consent of the Company, the Participant (i) participates in fraud or embezzlement, in each case related to the Company or its Subsidiaries, (ii) intentionally engages in other unlawful or criminal activity of a serious nature in connection with his or her duties as an Executive that causes or may reasonably be expected to cause substantial economic injury to or substantial injury to the reputation of the Company or its Subsidiaries, (iii) enters a guilty plea with respect to or is convicted of a felony that causes or may reasonably be expected to cause substantial economic injury to or substantial injury to the reputation of the Company or its Subsidiaries, (iv) commits any intentional and deliberate breach of his or her duties that, individually or in the aggregate, are material in relation to the Participant's overall duties and cause or are reasonably expected to cause substantial economic injury to or substantial injury to the reputation of the Company or its Subsidiaries, or (v) materially breaches any confidentiality or noncompete agreement entered into with the Company. The Company shall have the burden of proving that Just Cause exists. For purposes of this Plan, the Participant shall not be deemed to have been terminated for "Just Cause" hereunder unless (A) the Participant receives a Notice of Termination setting forth the grounds for the termination at least 30 calendar days prior to the specified Termination Date, (B) if requested by the Participant, the Participant (and/or the Participant's counsel or other representative) is granted a hearing before the Board, and (C) the Board determines, by resolution duly adopted by a majority of the members of the Board, that the Participant violated one or more of the provisions of the definition of "Just Cause" set forth above.

(m) "Notice of Termination" means (i) a written notice of termination by the Company to the Participant for Just Cause, or (ii) a written notice of termination for Good Reason by the Participant to the Company, in either case, setting forth in reasonable detail the specific reasons for termination and the facts and circumstances claimed to provide a basis for termination of employment under the provision indicated.

(n) "Participant" means an Executive who meets the eligibility requirements of Article IV hereof, other than an Executive who has entered into a separate agreement with the Company with terms that become operative upon the occurrence of a change in control of the Company as defined in the agreement with the Executive (other than a stock option or performance share award agreement or other form of equity award agreement or participation document entered into pursuant to a Company-sponsored plan that may incidentally refer to accelerated vesting or accelerated payment upon a change in control (as defined in such separate plan or document)).

(o) "Plan" means this Change in Control Compensation Plan.

(p) "Protection Period" means the period of time commencing on the date of the first occurrence of a Change in Control and continuing until the date that is six months following the date of the first occurrence of the Change in Control.

(q) "Severance Payment" means the payment of severance compensation as provided in Article V hereof.

(r) "Subsidiary" means any corporation or other legal entity a majority of the securities of which are owned by the Company or another Subsidiary of the Company.

(r) "Termination Date" means, (i) with respect to a termination by the Company for Just Cause, the date on which the Participant's employment is terminated as stated in the Notice of Termination, and (ii) with respect to a termination by the Participant for Good Reason, the date that is 30 calendar days following the Company's receipt of the Notice of Termination, modified to the extent necessary to be consistent with the requirements of Section 3.2(c) below.

Section 3.2 Status of Plan/Applicable Law.

(a) This Plan is classified as a "payroll practice" and is not a "plan" that is subject to the provisions of the Employee Retirement Income Security Act of 1974, as amended. The Plan will be interpreted and administered accordingly.

(b) This Plan shall in all respects be interpreted, enforced and governed in accordance with the laws of the state of Utah, without regard to principles of conflicts of laws.

(c) Payment of amounts, including any Severance Payments, under this Plan are intended to comply with an exception to or exclusion from the requirements of Code Section 409A to the maximum extent possible and, to the extent Code Section 409A is applicable to any payments or benefits, this Plan is intended to comply with the requirements of Code Section 409A. Notwithstanding any other provision of this Plan to the contrary, this Plan shall be interpreted, operated and administered in a manner consistent with such intentions. The payments or benefits to be made or provided under this Plan, including any Severance Payments, are intended to be exempt from the requirements of Code Section 409A because they are (i) non-taxable benefits, (ii) welfare benefits within the meaning of Treas. Reg. Sec. 1.409A-1(a)(5), (iii) short-term deferrals under Treas. Reg. Sec. 1.409A-1(b)(4), or (iv) payments under a separation pay plan within the meaning of Treas. Reg. Sec. 1.409A-1(b)(9). For purposes of Code Section 409A, each payment under this Plan shall be treated as a separate payment. Without limiting the generality of the foregoing, and notwithstanding any other provision of this Plan to the contrary, all references in this Plan to the termination of the Participant's employment or separation from service (including the date of such termination or separation or Termination Date) are intended to mean the Participant's "separation from service," within the meaning of Code Section 409A(a)(2)(A)(i). All reimbursements or in-kind benefits to be made under this Plan that constitute deferred compensation subject to Code Section 409A shall be made in accordance with the requirements of Treas. Reg. Sec. 1.409A-3(i)(1)(iv). If, at the time of Participant's termination of employment, Participant is a "specified employee" within the meaning of Code Section 409A, then any payment of an amount that is deferred compensation subject to Code Section 409A and payable on account of a separation from service shall be suspended and not made until the first business day following the end of the six month period following the Participant's termination of employment, or if earlier, upon the Participant's date of death.

Section 3.3 Severability. If a provision of this Plan shall be held illegal or invalid, the illegality or invalidity shall not affect the remaining parts of this Plan and this Plan shall be construed and enforced as if the illegal or invalid provision had not been included.

ARTICLE IV - ELIGIBILITY

Section 4.1 Participation. Each person who is an Executive on the Effective Date shall be a Participant on the Effective Date. Thereafter, each other person who becomes an Executive prior to both (a) a Change in Control, and (b) unless specifically provided for by the Board at the time a Participant is elected as an Executive, the date a notice of termination of the Plan is provided under Section 8.1(a), shall automatically become a Participant on the day on which such person becomes an Executive; provided, however, that if the person has not been employed by the Company on a continuous full-time basis during the period of 90 days prior to such day, he or she will not become a Participant until the day that 90 days of continuous full-time employment has been completed.

Section 4.2 Duration of Participation. A Participant shall cease to be a Participant and shall have no rights hereunder, without further action, when he or she ceases to be an Executive, unless such Participant is then entitled to payment of a Severance Payment as provided in Section 5.1 hereof. A Participant entitled to a Severance Payment shall remain a Participant in this Plan until the full amount of the Severance Payment has been paid to the Participant.

ARTICLE V - SEVERANCE PAYMENTS

Section 5.1 Right to Severance Payment.

(a) Subject to Subsection (c) hereof, a Participant shall be entitled to receive from the Company a Severance Payment in the amount provided in Section 5.2 hereof if there has been a Change in Control and if, after a Change in Control and within the Protection Period, (i) the Participant's employment by the Company shall be terminated by the Company without Just Cause, or (ii) the Participant shall terminate employment with the Company for Good Reason.

(b) Notwithstanding anything to the contrary contained in this Plan, any termination of employment of the Participant or removal of the Participant from the office or position in the Company that occurs prior to a Change in Control, but which the Participant reasonably demonstrates occurred at the request of a third party who had taken steps reasonably calculated to effect the Change in Control, shall be deemed to be a termination or removal of the Participant after a Change in Control for purposes of this Plan.

(c) Notwithstanding anything to the contrary contained in this Plan, a Participant shall not be entitled to receive any Severance Payment hereunder unless within 60 days of the Participant's termination (i) he or she has signed and returned to the Company a release substantially in the form attached to this Plan as Attachment A, and (ii) any applicable rescission period for such release has expired. The Company shall provide a form of release to the Participant not later than 5 days following the Participant's Termination Date.

Section 5.2 Amount of Severance Payment.

(a) Each Participant entitled to a Severance Payment under this Plan shall receive as such Severance Payment a lump sum cash payment in an amount equal to

(i) for any Participant who is designated as the Chief Operating Officer, President of Corporate Development, or Chief Financial Officer, the sum of (A) 1.5 multiplied by the greater of $400,000 or Base Pay, and (B) 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; and

(ii) for any other Participant, (A) 1.0 multiplied by the greater of $350,000 or Base Pay, and (B) 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;

provided, however, that the amount of such cash payment determined pursuant to this Section 5.2(a) shall be reduced by an amount equal to the aggregate amount of any other cash payments in the nature of severance payments paid or payable by the Company or any Subsidiary pursuant to any agreement, policy, program, arrangement or requirement of statutory or common law (other than this Plan or cash payments received in lieu of stock incentives) from the Company.

(b) The Participant shall not be required to mitigate damages or the amount of his or her Severance Payment by seeking other employment or otherwise, nor shall the amount of such payment be reduced by any compensation earned by the Participant as a result of employment after the termination of his or her employment by the Company.

Section 5.3 Time of Severance Payment The Severance Payment to which a Participant is entitled under Section 5.2(a) shall be paid to the Participant by the Company in cash and in full on the 60th day following the Participant's Termination Date. If a Participant should die before all amounts payable to him or her under this Plan have been paid, such unpaid amounts shall be paid to the personal representative of the Participant's estate.

Section 5.4 Liability for Payment. The Company shall be solely liable for and shall pay the Severance Payments (or cause the Severance Payments to be paid) to the Participant.

ARTICLE VI - OTHER RIGHTS AND BENEFITS NOT AFFECTED

Section 6.1 Other Benefits. Neither the provisions of this Plan nor the Severance Payment provided for hereunder shall reduce or increase any amounts otherwise payable, or in any other way affect a Participant's rights as an employee of the Company, whether existing now or hereafter, under any benefit, incentive, retirement, stock option, stock bonus, stock purchase or employment agreement, policy (other than this Plan), program or arrangement (collectively, the "Other Plans"), except to the extent specifically provided in such Other Plans. Notwithstanding the generality of the foregoing, each Participant is entitled to receive any Base Salary accrued but unpaid as of the Termination Date and any other bonus, incentive or other pay or employee benefits that are accrued but unpaid as of the Termination Date.

Section 6.2 Certain Limitations. This Plan does not constitute a contract of employment or impose on any Participant or the Company any obligation to retain any Participant as an employee or in any other capacity, to change or not change the status, terms or conditions of any Participant's employment, or to change or not change the Company's policies regarding termination of employment.

ARTICLE VII - SUCCESSORS SECTION

Section 7.1 Successors. Without limiting the obligations of any person or entity under applicable law, the Company shall require any successor or assignee, whether direct or indirect, by purchase, reorganization, merger, consolidation or otherwise, to all or substantially all the business or assets of the Company, expressly and unconditionally to assume and agree to perform the Company's obligations under this Plan, in the same manner and to the same extent that the Company would be required to perform if no such succession or assignment had taken place. In such event, the term "Company," as used in this Plan, shall mean the Company as hereinbefore defined and any successor assignee to the business or assets that by reason hereof becomes bound by the terms and provisions of this Plan.

ARTICLE VIII - DURATION, AMENDMENT AND TERMINATION

Section 8.1 Duration/Termination.

(a) This Plan will terminate as to all Participants: (i) if a Change in Control has not occurred, the date that is one year following the giving of notice to each Executive who is a Participant on the date of the notice that the Board has determined (by resolution adopted by a majority of the members of the Board) that the Plan will terminate; and (ii) if a Change in Control has occurred, the expiration of the Protection Period.

(b) Notwithstanding the foregoing, if a Change in Control occurs, this Plan shall continue in full force and effect, and shall not terminate or expire until after all Participants who were Participants on the date of the Change in Control who became entitled to a Severance Payment hereunder shall have received such payment in full.

Section 8.2 Amendment. Unless a Change in Control has previously occurred, this Plan may be amended in any respect by resolution duly adopted by the Board; provided, however, that no such amendment shall adversely affect the rights of a Participant under this Plan without the Participant's consent unless such amendment does not become effective until the date that is one year following the giving of notice to all Participants of the adoption of such amendment by the Board. If a Change in Control occurs, notwithstanding the foregoing, this Plan no longer shall be subject to amendment, change, substitution, deletion or revocation in any respect.

Section 8.3 Form of Amendment/Termination. The form of any proper amendment or termination of this Plan shall be a written instrument signed by a duly authorized officer or officers of the Company, certifying that the amendment or termination has been approved by the Board as provided in Sections 8.1 or 8.2 hereof. A proper amendment of this Plan automatically shall effectuate a corresponding amendment to all Participants' rights hereunder. A proper termination of this Plan automatically shall effectuate a termination of all Participants' rights and benefits hereunder without further action.

ARTICLE IX - MISCELLANEOUS SECTION

Section 9.1 Legal Fees and Expenses

(a) It is the intent of the Company that Participants not be required to incur any expenses associated with the enforcement of rights under this Plan because the cost and expense thereof would substantially detract from the benefits intended to be extended to Participants hereunder. Accordingly, if the Company has failed to comply with any of its obligations under this Plan or in the event that the Company or any other person takes any action to declare this Plan void or unenforceable, or institutes any litigation designed to deny, or to recover from, a Participant the benefits intended to be provided to the Participant hereunder, the Company irrevocably authorizes the Participant from time to time to retain counsel of his or her choice, at the expense of the Company, as hereafter provided, to represent the Participant in connection with the initiation or defense of any legal action, whether by or against the Company, in any jurisdiction. The Company shall pay or cause to be paid and shall be solely responsible for any and all reasonable attorneys' fees and expenses incurred by the Participant in enforcing his or her rights hereunder individually (but not as a representative of any class) as a result of the Company's failure to perform this Plan or any provision hereof or as a result of the Company or any person contesting the validity or enforceability of this Plan or any provision hereof.

(b) Notwithstanding any provision of the Plan to the contrary, all fees and expenses subject to payment or reimbursement pursuant to this Section 9.1 shall be paid not later than the last day of the calendar month following the calendar month in which the Participant incurs such fees or expenses. The Participant shall be solely responsible for timely providing to the Company sufficient proof of the fees and expenses to be paid or reimbursed pursuant to this Section.

Section 9.2 Withholding of Taxes. The Company may withhold from any amounts payable under this Plan all foreign, federal, state, or other taxes as the Company reasonably determines are required pursuant to any law or government regulation or ruling.

Section 9.3 Successors.

(a) This Plan shall inure to the benefit of and be enforceable by the Participant's personal or legal representatives, executors, administrators, successors, heirs, distributees and/or legatees.

(b) The rights under this Plan are personal in nature and neither the Company nor any Participant shall, without the consent of the other, assign or transfer any rights or

obligations hereunder except as expressly provided in Sections 5.3 and 7.1 hereof. Without limiting the generality of the foregoing, the Participant's right to receive a Severance Payment hereunder shall not be assignable or transferable, whether by pledge, creation of a security interest or otherwise, other than by a transfer by his or her will or by the laws of descent and distribution and, in the event of any attempted assignment or transfer contrary to this Section 9.3(b), the Company, shall have no liability to pay any amount so attempted to be assigned or transferred.

(c) The Company and each Participant recognize that each party will have no adequate remedy at law for breach by the other of any of the agreements contained herein and, in the event of any such breach, the Company, and each Participant hereby agree and consent that the other shall be entitled to a decree of specific performance, mandamus or other appropriate remedy to enforce performance of this Plan.

Section 9.4 Notices. For all purposes of this Plan, all communications, including without limitation notices, consents, requests or approvals provided for herein, shall be in writing and shall be deemed to have been duly given when delivered or five business days after having been mailed by registered or certified mail, return receipt requested, postage prepaid, addressed to the Company (to the attention of the General Counsel of the Company), at its principal executive office and to any Participant at his or her principal residence as shown in the relevant records of the Company, or to such other address as any party may have furnished to the other in writing and in accordance herewith, except that notices of change of address shall be effective only upon receipt.

Adopted by Resolution of the Board of Directors on August 6, 2019, as amended through November 5, 2020.

ATTACHMENT A

RELEASE

This Release (the "Release") is required to be delivered by _____ ("Executive") as a condition of Executive's receipt of severance and other benefits under the PolarityTE, Inc., Change in Control Compensation Plan (the "Plan").

1. Executive agrees that, in consideration of the severance and other benefits to which he/she is eligible under the terms of the Plan, Executive hereby releases and forever discharges the Company, as well as its affiliates and all of their respective directors, officers, employees, members, agents, and attorneys (the "**Released Parties**"), of and from any and all manner of actions and causes of action, suits, debts, claims, and demands whatsoever, in law or equity, known or unknown, asserted or unasserted, which he/she ever had, now has, or hereafter may have on account of his/her employment with the Company, the termination of his/her employment with the Company, and/or any other fact, matter, incident, claim, injury, event, circumstance, happening, occurrence, and/or thing of any kind or nature which arose or occurred prior to the date when he/she executes this Agreement, including, but not limited to, any and all claims for wrongful termination; breach of any implied or express employment contract; unpaid compensation of any kind; breach of any fiduciary duty and/or duty of loyalty; breach of any implied covenant of good faith and fair dealing; negligent or intentional infliction of emotional distress; defamation; fraud; unlawful discrimination, harassment; or retaliation based upon age, race, sex, gender, sexual orientation, marital status, religion, national origin, medical condition, disability, handicap, or otherwise; any and all claims arising under arising under Title VII of the Civil Rights Act of 1964, as amended ("**Title VII**"); the Utah Anti-Discrimination Act, as amended; the Equal Pay Act of 1963, as amended ("**EPA**"); the Americans with Disabilities Act of 1990, as amended ("**ADA**"); the Family and Medical Leave Act, as amended ("**FMLA**"); the Employee Retirement Income Security Act of 1974, as amended ("**ERISA**"); the Sarbanes-Oxley Act of 2002, as amended ("**SOX**"); the Worker Adjustment and Retraining Notification Act of 1988, as amended ("**WARN**"); and/or any other federal, state, or local law(s) or regulation(s); any and all claims for damages of any nature, including compensatory, general, special, or punitive; and any and all claims for costs, fees, or other expenses, including attorneys' fees, incurred in any of these matters. The Company also acknowledges that Executive does not release or waive any claims, and that he/she retains any rights he/she may have, to any vested 401(k) monies (if any) or benefits (if any), or any other benefit entitlement that is vested as of the Employment Termination Date pursuant to the terms of any Company-sponsored benefit plan governed by ERISA. Nothing contained herein shall release the Company from its obligations set forth in this Agreement. However, this general release and waiver of claims excludes, and the Executive does not waive, release, or discharge any right to file an administrative charge or complaint with, or testify, assist, or participate in an investigation, hearing, or proceeding conducted by, the Equal Employment Opportunity Commission or other similar federal or state administrative agencies, although the Executive waives any right to monetary relief related to any filed charge or administrative complaint. Executive is not waiving rights or claims that otherwise cannot be waived by applicable law, including without limitation claims: (a) that may arise after the date of this Release, (b) for indemnification and/or advanced expenses under applicable law, any directors and officers liability insurance, applicable certificate of incorporation or by-laws, (c) to enforce the Plan, (d) to exercise vested equity awards determined as of the date hereof, (e) to benefits that have accrued and are payable pursuant to the Company's employee benefit plans, including deferred compensation plans, (f) for unemployment insurance benefits; (g) for workers' compensation benefits related to any injury he/she sustained in the course of his/her duties for the Company, (h) to rights under the Consolidated Omnibus Reconciliation Act of 1985, as amended, ("COBRA"), and (i) to his/her rights, if any, under the Uniformed Services Employment and Reemployment Rights Act (USERRA) 38 U.S.C. § 4301, et seq.

[Without limiting the generality of Section 1, above, Executive acknowledges and agrees that he/she is waiving and releasing any rights he/she may have under the Age Discrimination in Employment Act of 1967, as amended (the "**ADEA**") (29 U.S. Code §621 et seq.), and that this waiver and release is knowing and voluntary. Executive and the Company agree that this waiver and release does not apply to any rights or claims that may arise under the ADEA after Executive has executed this Agreement. Nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this Agreement under the ADEA, nor does it impose any condition precedent, penalties or costs for doing so, unless specifically authorized by federal law. Executive acknowledges that the consideration given for this Agreement is in addition to anything of value to which he/she was already entitled. The Company advises Executive in this Agreement to consult with an attorney prior to executing this Agreement. Executive understands that insofar as this Release relates to Executive's rights, if any, under the ADEA, it shall not become effective or enforceable until seven days after he/she signs it. Executive acknowledges that he/she has been advised to consult with an attorney if he/she chooses before signing this Release. Executive understands that he/she has the right to revoke this Release, insofar as it extends to Executive's claims, if any, under the ADEA, by written notice of such to the Company within seven (7) calendar days following his/her signing this Release. Any such revocation must be in writing and hand-delivered to the Company or, if sent by mail, postmarked within the applicable revocation period, sent by certified mail, return receipt requested, and addressed to: PolarityTE, Inc., Attention: General Counsel, 123 N. Wright Brothers Drive, Salt Lake City, Utah, 84106.][1]

2. Executive agrees not to sue any Releasee or participate in any lawsuit against a Releasee concerning any claim released under Section 1 above, or to challenge the enforceability of this Release or the release given thereby. This covenant not to sue does not apply to any claim that Executive did not knowingly and voluntarily sign this Release as required by the ADEA and the Older Workers Benefit Protection Act.

3. Notwithstanding the above, Executive is not waiving and is not being required to waive any right that cannot be waived under law, including the right to file an administrative charge or participate in an administrative investigation or proceeding; provided, however, that Executive hereby waives all right to any monetary recovery should any foreign, federal, state or other administrative agency pursue any claims on Executive's behalf arising out of or related to employment with and/or termination of employment with any of the Releasees.

4. Executive and the Company each agree to treat this Release as confidential and will not discuss or disclose, the terms of this Release, other than his/her immediate family members, attorneys and financial advisors, or as required by law.

[1] Retain this section if ADEA applicable to Executive.

5. Executive has been advised that this Release shall be executed by him/her no earlier than Executive's termination date and no later than forty-five (45) days after Executive's Termination Date.

6. Executive expressly acknowledges and understands that this Release is not an admission of liability under any statute or otherwise by Company, and it does not admit any violation of Executive's legal rights.

7. The parties agree that this Release shall be binding upon and inure to the benefit of Executive's assigns, heirs, executors and administrators as well as all Releasees.

8. This Release shall in all respects be interpreted, enforced and governed in accordance with the laws of the state of Utah, without regard to principles of conflicts of laws, and furthermore, any dispute regarding this Release shall be subject to the exclusive jurisdiction of any court of competent jurisdiction located in Salt Lake County, Utah.

9. The language of all parts of this Release shall in all cases be construed as a whole, according to its fair meaning, and not strictly for or against any of the parties. In the event that one or more provisions of this Release shall for any reason be held to be illegal or unenforceable, this Release shall be revised only to the extent necessary to make the Release or such provision(s) legal and enforceable.

EXECUTIVE

_____

Print Name: _____

Date _____

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 (No. 333-229584) and Form S-8 (Nos. 333-251795, 333-237189, 333-227721, 333-225264, and 333-211959) of our report dated March 30, 2021, on our audits of the consolidated financial statements as of December 31, 2020 and 2019 and for each of the years then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 30, 2021.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Iselin, NJ
March 30, 2021

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 financial 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 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 control over financial reporting which 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 control over financial reporting.

Date: March 30, 2021

/s/ David Seaburg
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Jacob Patterson, 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 financial 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 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 control over financial reporting which 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 control over financial reporting.

Date: March 30, 2021

/s/ Jacob Patterson
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, 2020 (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 30, 2021

/s/ David Seaburg
David Seaburg
Chief Executive Officer

/s/ Jacob Patterson
Jacob Patterson
Chief Financial Officer