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, 2021

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. 001-32404

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, 2021, was $80,190,567.

The outstanding number of shares of common stock as of March 25, 2022, was 89,498,691.

Documents incorporated by reference: Portions of the registrant's definitive proxy statement for the Special Meeting of Stockholders called for May 12, 2022 (2022 Proxy Statement) are incorporated into Part III hereof. The 2022 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, 2021.

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

Forward-looking Statements

This Annual Report on Form 10-K contains forward-looking statements. Risks and uncertainties are inherent in forward-looking statements. Furthermore, such statements may be based on assumptions that fail to materialize or prove incorrect. Consequently, our business development, operations, and results could differ materially from those expressed in forward-looking statements made in this Annual Report. We make such forward-looking statements pursuant to the safe harbor provisions 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:

(A) the timing or success of obtaining regulatory licenses or approvals for initiating clinical trials or marketing our products;
(B) the initiation, timing, progress, and results of our pre-clinical studies or clinical trials;
(C) sufficiency of our working capital to fund our operations in the near and long term, which raises doubt about our ability to continue as a going concern;
(D) infrastructure required to support operations in future periods, including the expected costs thereof;
(E) estimates associated with revenue recognition, asset impairments, and cash flows;
(F) variance in our estimates of future operating costs;
(G) future vesting and forfeitures of compensatory equity awards;
(H) the effectiveness of our disclosure controls and our internal control over financial reporting;
(I) the impact of new accounting pronouncements;
(J) size and growth of our target markets; and
(K) 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 delivery of our services;
- the ability to meet demand for our services;
- the ability to deliver our 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; and
- unauthorized access to confidential information and data on our information technology systems and security and data breaches.

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. Our first regenerative tissue product is SkinTE. On July 23, 2021, we submitted an investigational new drug application ("IND") for SkinTE to the U.S. Food and Drug Administration (the "FDA") through our subsidiary, PolarityTE MD, Inc. ("PTE-MD"), as the first step in the regulatory process for obtaining licensure for SkinTE under Section 351 of the Public Health Service Act. The FDA subsequently issued clinical hold correspondence to us identifying certain issues that needed to be addressed before the IND could be approved. We provided responses to the FDA, and on January 14, 2022, the FDA notified us that the clinical hold had been removed. The IND approval enables us to commence the first of two expected pivotal studies needed to support a biologics license application ("BLA") seeking a chronic cutaneous ulcer indication for SkinTE. Our first planned pivotal study under our IND is a multi-center, randomized controlled trial evaluating SkinTE in the treatment of diabetic foot ulcers classified as Grade 2 in the Wagner classification system ("Wagner 2 DFUs") entitled "Closure Obtained with Vascularized Epithelial Regeneration for DFUs with SkinTE," or "COVER DFUs Trial." We plan to enroll up to 100 patients at up to 20 sites in the U.S. in the COVER DFUs Trial, which will compare treatment with SkinTE plus the standard-of-care to the standard-of-care alone. The primary endpoint is the incidence of DFUs closed at 24 weeks. Secondary endpoints include percent area reduction ("PAR") at 4, 8, 12, 16, and 24 weeks, improved quality of life, and new onset of infection of the DFU being evaluated. As we pursue the first study, we plan to engage in discussions with the FDA regarding the design and implementation of the second pivotal study.

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 IBEX, we also offer preclinical research services to unrelated third parties on a contract basis.

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 defense 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 1/100th 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 tunneling, 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 future clinical trials conducted under our 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

Under the SkinTE IND

Our IND for SkinTE was opened in January 2022. Our first planned pivotal study under our IND is a multi-center, randomized controlled trial evaluating SkinTE in the treatment of diabetic foot ulcers classified as Grade 2 in the Wagner classification system (“Wagner 2 DFUs”) entitled “Closure Obtained with Vascularized Epithelial Regeneration for DFUs with SkinTE,” or “COVER DFUs Trial.” We plan to enroll up to 100 patients at up to 20 sites in the U.S. in the COVER DFUs Trial, which will compare treatment with SkinTE plus the standard-of-care to the standard-of-care alone. The primary endpoint is the incidence of DFUs closed at 24 weeks. Secondary endpoints include percent area reduction (“PAR”) at 4, 8, 12, 16, and 24 weeks, improved quality of life, and new onset of infection of the DFU being evaluated. As we pursue the first study, we plan to engage in discussions with the FDA regarding the design and implementation of the second pivotal study.

On June 25, 2021, we entered into a statement of work with a contract research organization to provide services for the clinical trial described in the IND at a cost of approximately $6.5 million consisting of $3.1 million of service fees and $3.4 million of estimated costs. The estimate increased $1.4 million from the $5.1 million estimated at September 30, 2021, due to additional costs expected for longer trial subject follow up (6 months versus 3 months) and a corresponding increase in trial subject visits. In July 2021 we prepaid 10% of the total cost recited in the original work order, or $0.5 million, which will be applied to payment of the final invoice under the work order. Over the approximately three-year term of the clinical trial the service provider shall submit to us for payment invoices on a monthly basis for units of work stated in the work order that are completed and billable expenses incurred.

Pre-IND

PolarityTE conducted several clinical trials before it filed its IND for SkinTE, which were conducted on a post-marketing basis with SkinTE as a 361 HCT/P. These clinical trials include the following:

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. A single adverse event at a SkinTE harvest site secondary to a dehiscence (technical error) occurred requiring secondary closure at the time of the patient's definitive grafting procedure. There were no other adverse events pertaining to the SkinTE applications in the trial.

Diabetic Foot Ulcer (DFU) Trials

DFUs are chronic wounds and represent one of the costliest, and medically significant, health related morbidities encountered during a patient's lifetime. The estimated annual U.S. 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:

(1) 10 of 11 (90.9%) DFUs healed within eight weeks of a single application of SkinTE
(2) Median time to closure was 25 days
(3) DFU sizes ranged from 1.0 to 21.7 cm2
(4) One patient was removed from the study at week three due to adverse events not related to the study or SkinTE procedure
(5) No SkinTE-related adverse reactions were observed

After that trial, we conducted a multicenter, randomized controlled trial evaluating SkinTE plus standard of care (SOC) versus SOC alone in treatment of diabetic foot ulcers [NCT03881254] (the "DFU RCT"). In July 2021, we announced final data from the DFU RCT. The size of the study was 100 patients who were evaluated across 13 sites, with 50 participants receiving SkinTE plus SOC and 50 receiving SOC alone. The primary endpoint was percentage of ulcers closed at 12 weeks. A secondary endpoint was percent area reduction (PAR) at 4, 6, 8, and 12 weeks.

The trial met the primary endpoint of wound closure at 12 weeks and secondary endpoint of Percent Area Reduction (PAR) assessed at 4, 6, 8, 10, and 12 weeks. Final analysis of the DFU RCT shows the following:

(1) Primary Endpoint: 70% (35/50) of participants receiving SkinTE plus SOC had wound closure at 12 weeks versus 34% (17/50) of participants receiving SOC alone (p=0.00032)
(2) Secondary Endpoint: Percent Area Reduction (PAR) assessed at 4, 6, 8, 10, and 12 weeks was significantly greater for the SkinTE plus SOC treatment group vs SOC alone (p=0.009)
(3) 90% (45/50) of SkinTE plus SOC treated participants received a single application of SkinTE
(4) Treatment with SkinTE plus SOC increased the odds of wound closure by 5.37 times versus SOC alone (p=0.001)

Mean (SD) values for PAR at weeks 4, 6, 8, 10, and 12 by treatment group

Week	SkinTE	SOC
4	74.0 (27.63)	22.0 (149.92)
6	82.9 (26.35)	21.2 (160.60)
8	80.7 (35.16)	26.8 (147.42)
10	79.7 (54.07)	45.6 (114.18)
12	84.3 (39.46)	50.5 (92.24)

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 PolarityTE 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 (12.2cm2), 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; and
- No SkinTE-related adverse reactions were observed

We started a multicenter, randomized controlled trial evaluating SkinTE versus standard of care in treatment of VLU [NCT03881267] ("the "VLU-RCT"), but decided in the first quarter of 2021 to suspend that trial after 29 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. In February 2022, we announced final data from the VLU RCT. The 29 patients who were evaluated across 10 sites, with 14 participants receiving SkinTE plus SOC and 15 receiving SOC alone. The primary endpoint was percentage of ulcers closed at 12 weeks. A secondary endpoint was percent area reduction (PAR) at 4, 6, 8, and 12 weeks.

The trial met the primary endpoint of wound closure at 12 weeks and secondary endpoint of Percent Area Reduction (PAR) assessed at 4, 6, 8, 10, and 12 weeks. Final analysis of the VLU RCT shows the following:

(1) Primary Endpoint: 71% (10/14) of participants receiving SkinTE plus SOC had wound closure at 12 weeks versus 33% (5/15) of participants receiving SOC alone (p=0.046)
(2) Secondary Endpoint: Percent Area Reduction (PAR) assessed at 4, 6, 8, 10, and 12 weeks was significantly greater for the SkinTE plus SOC treatment group vs SOC alone (p=0.000035)
(3) 93% (13/14) of SkinTE plus SOC treated participants received a single application of SkinTE

Mean (SD) values for PAR at weeks 4, 6, 8, 10, and 12 by treatment group

Week	SkinTE	SOC
4	61.7 (53.13)	19.7 (77.03)
6	70.1 (52.43)	21.4 (96.36)
8	79.1 (51.97)	33.5 (89.10)
10	82.0 (50.81)	42.8 (68.60)
12	82.6 (50.52)	65.4 (43.98)

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 result in hospitalization.

Our Plan for Advancing SkinTE

Our IND for SkinTE was accepted by the FDA in January 2022, and this enables us to commence the first of two expected pivotal studies needed to support a BLA for a chronic cutaneous ulcer indication for SkinTE. We expect to begin enrolling subjects in the COVER DFUs Trial in the second quarter of 2022. We also expect to engage with the FDA during 2022 regarding the design of the second pivotal study we plan to conduct under our open IND.

Products subject to BLA requirements must be licensed under the Public Health Service Act to be marketed. In order to be licensed, 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 chemistry, manufacturing, and controls (CMC) and other manufacturing information, and the applicant must pass an FDA pre-license inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with the FDA's current good manufacturing practices ("cGMP") requirements. Satisfaction of FDA licensure requirements typically takes several years, and the actual time required may vary substantially based on the type, complexity, and novelty of the product. PolarityTE cannot be certain that any BLA approvals for its products will be granted on a timely basis, or at all.

The steps for obtaining FDA approval of a BLA to market a 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, packaged, labelled, tested, or held 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;
- satisfactory completion of inspections of clinical trial sites to verify the accuracy and reliability of data that has been submitted to FDA; and
- FDA approval of the BLA including agreement on post-marketing requirements or 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. Even though our IND for SkinTE is open, the FDA can request additional information and testing pertaining to the product and the procedures for manufacturing and delivering the product.

Our preliminary experience indicates that SkinTE may benefit patients with immediately life-threatening conditions and other serious diseases or conditions. In 2009, the FDA implemented new regulations related to Expanded Access Investigational New Drug Applications ("Expanded Access INDs"), which are often colloquially referred to as "compassionate use," and pertain to the use of an investigational drug or biologic when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition, rather than to obtain the kind of information about the drug that is generally derived from clinical trials. The FDA has proposed several processes for obtaining Expanded Access INDs, which we will evaluate for potential implementation now that the IND for SkinTE is open. Under FDA regulations the amount that may be charged for SkinTE used under an Expanded Access IND must be authorized by the FDA and, if authorized at all, may be limited to our direct costs of manufacture. We believe, however, that an Expanded Access IND may enable us to provide SkinTE to providers treating persons with life-threatening or serious diseases and conditions, and thereby maintain existing, and develop new, relationships with physicians in the wound care industry.

Potential Product Enhancements or Additions

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.

SkinTE Cryo

SkinTE Cryo allows PolarityTE to offer multiple deployments from one original harvest through a cryopreservation process. 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.

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 Tissue Regeneration 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 we intend to apply our business and financial resources to the SkinTE IND and BLA and development work on SkinTE POC, and we have at this time put on hold further work on other product development.

Manufacturing

PolarityTE maintains at its facility in Salt Lake City, Utah, manufacturing processes and quality systems that allow it 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. PolarityTE validated its manufacturing process as being aseptic. All SkinTE is manufactured within an ISO 5 isolator located within an ISO 7 cleanroom. PolarityTE's processes are designed and validated to prevent the spread of communicable disease, and to prevent cross-contamination between samples, and its quality systems comply with current Good Tissue Practices ("cGTP") under 21 C.F.R. Part 1271.

PolarityTE is modifying its manufacturing practices and facility so that it complies with cGMP under requirements of the Federal Food, Drug and Cosmetic Act, as well as 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 PolarityTE's strategy of ensuring timely delivery of its products, it has avoided relying on any third-party supplier as a sole source vendor for any element of its production process. PolarityTE has identified alternate suppliers and, where appropriate, supply alternatives for any sourcing need.

Intellectual Property

As we advance our technologies, 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 issued on February 23, 2021; U.S. Patent No. 11,000,629 issued on May 11, 2021; U.S. Patent No. 11,266,765 issued on March 8, 2022; and U.S. Application No. 17/326,734 filed on May 21, 2021. Each of U.S. Patent Nos. 10,926,001; 11,000,629; and 11,266,765 have 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 provide preclinical research services to third parties. In 2021 all of IBEX' business activity was providing services to third parties. The business consists of a preclinical research facility that complies with Good Laboratory Practices and is USDA registered, and includes a 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. In March 2022, we reached a non-binding understanding with an unrelated third party that contemplates the sale of IBEX and the real property used in the operation of IBEX. The potential sale is subject to a number of contingencies. Even though the proposed sale may not materialize, we are exploring our options with respect to IBEX, which is likely to result in some other disposition or winding up of the business in 2022.

Historically, Arches offered 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. 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 2020 and 2021, Arches had equipment and staff capable of performing polymerase chain reaction testing for COVID-19. Arches had the opportunity to use its 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 it began providing COVID-19 testing services on May 27, 2020.

Arches' primary customer for testing services was an organization controlling multiple long-term care and laboratory facilities in New York State and surrounding areas. Beginning in April 2021 there was a significant loss of COVID-19 testing revenues due to the loss of Arches' major testing customer in the first quarter of 2021. Subsequent efforts to find new business to replace the lost testing business were not successful and we made the decision to cease COVID-19 testing in August 2021.

Government Regulation

FDA and Marketing Approval

In the U.S., the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Public Health Service Act, and various federal regulations. These FDA-regulated products are also subject to state and local statutes and regulations, as well as applicable laws or regulations in foreign countries. The FDA, and comparable regulatory agencies in state and local jurisdictions and in foreign countries, impose substantial requirements on the research, development, testing, manufacture, quality control, labeling, packaging, storage, distribution, record-keeping, approval, post-approval monitoring, advertising, promotion, marketing, sampling, and import and export of FDA-regulated products. Failure to comply with the applicable requirements at any time during the development process, approval process, or after approval may subject an applicant to administrative or judicial sanctions, suspension of development or marketing, or non-approval of product candidates. These sanctions could include a clinical hold on clinical trials, FDA's refusal to approve pending applications or related supplements, withdrawal of or restrictions on an existing approval or licensure, untitled or warning letters, product recalls, product seizures, import detentions or export restrictions, total or partial suspension of production or distribution, injunctions, fines, restitution, disgorgement, civil penalties, or criminal prosecution. Such actions by government agencies could also require us to expend a large number of resources to respond to the actions. Any agency or judicial enforcement action could have a material adverse effect on us. We are not sure whether legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of any such changes may be on the marketing approvals or licensures, or the prospects thereof, for our products.

IND and Clinical Trials of Drug and Biological Products

Prior to commencing a human clinical trial of a drug or biological product, an IND application, which contains the results of preclinical studies and relevant clinical studies or other human experience along with other information, such as information about product chemistry, manufacturing, and controls and a proposed protocol, must be submitted to the FDA. An IND is a request for authorization from the FDA to administer an investigational drug or biological product to humans. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA within the 30-day time period raises concerns or questions about the conduct of the clinical trial. In such a case, the IND sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin. A separate submission to the existing IND must be made for each successive clinical trial to be conducted during development of the drug or biologic.

An independent Institutional Review Board ("IRB") must review and approve the investigational plan for the trial before it commences at each site. Informed written consent must be obtained from each trial subject.

Human clinical trials for drug and biological products typically are conducted in sequential phases that may overlap:

- Phase 1 - the investigational drug/biologic is given initially to healthy human subjects with the target disease or condition in order to determine metabolism and pharmacologic actions of the drug in humans, side effects and, if possible, to gain early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational drug/biologic's pharmacokinetics and pharmacologic effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.
- Phase 2 - clinical trials are conducted to evaluate the effectiveness of the drug/biologic for a particular indication or in a limited number of trial subjects in the target population to identify possible adverse effects and safety risks, to determine the efficacy of the drug/biologic for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 - clinical trials are conducted in an expanded trial subject population to further evaluate dosage, effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug/biologic, and to provide an adequate basis for product labeling and approval by the FDA. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug or biologic in an expanded trial subject population at multiple clinical trial sites.

All clinical trials must be conducted in accordance with FDA regulations, including good clinical practice ("GCP") requirements, which are intended to protect the rights, safety, and well-being of trial participants, define the roles of clinical trial sponsors, investigators, administrators, and monitors, and ensure clinical trial data integrity and reliability. Regulatory authorities, including the FDA, an IRB, a data safety monitoring board, or the sponsor, may suspend or terminate a clinical trial at any time on various grounds, including, among other reasons, a finding that the participants are being exposed to an unacceptable health risk or that the clinical trial is not being conducted in accordance with FDA requirements.

During the development of a new drug or biologic, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2 clinical trials, and before a New Drug Application ("NDA") or Biologics License Application ("BLA") is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the end-of-Phase 2 clinical trials meetings to discuss their Phase 2 clinical trials results and present their plans for the pivotal Phase 3 registration trial that they believe will support approval of the new drug/biologic.

Disclosure of Clinical Trial Information

Sponsors of certain clinical trials of FDA-regulated products, including drugs, biologics, and devices, are required to register and disclose certain clinical trial information on clinicaltrials.gov. Information related to the product, trial subject population, phase of investigation, study sites and investigators, and other aspects of the clinical trial, is made public as part of the registration. Sponsors also are obligated to disclose the results of their clinical trials, including the study protocol and statistical analysis plan, after completion. Disclosure of the clinical trial results can be delayed until the new product or new indication being studied has been approved, as long as approval occurs within a certain timeframe. Competitors may use this publicly available information to gain knowledge regarding our development programs.

The BLA Approval Process

SkinTE is an autologous product, meaning it is derived from the cells and tissues of the individual to be treated with the product. Based on the FDA's feedback to the Company, SkinTE will not be marketed in the U.S. until it is licensed by the FDA through the BLA approval process. The process required by the FDA to obtain licensure generally involves the following:

- completion of non-clinical laboratory tests, animal studies and formulation studies conducted according to good laboratory practice or other applicable regulations;
- submission of an IND application;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity, and potency of the proposed biologic for its intended use or uses conducted in accordance with GCP;
- submission to the FDA of a BLA after completion of all pivotal clinical trials;
- FDA pre-license inspection of manufacturing facilities and audit of clinical trial sites; and
- FDA approval of a BLA.

The FDA has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in- depth review. The FDA has agreed to certain performance goals in the review of BLAs. Most applications for standard review BLA products are reviewed within ten months of submission, and most applications for priority review BLA products are reviewed within six months of submission. The review process may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. Even if such additional information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval.

The FDA may also refer applications for novel BLA products or products that present difficult questions of safety, purity, or potency, to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. The FDA may also inspect preclinical study sites to verify compliance with Good Laboratory Practice ("GLP") requirements prior to approval. Additionally, the FDA will inspect the facility or the facilities at which the BLA product is manufactured. The FDA will not approve the BLA unless compliance with cGMP requirements is satisfactory, and the BLA contains data that provide substantial evidence that the product is safe, pure, and potent for the indication studied.

After the FDA evaluates the BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter outlines the deficiencies in the submission and may require substantial additional testing, including additional large-scale clinical testing or other information in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

The cost of preparing and submitting a BLA is substantial. Furthermore, each BLA submission requires a user fee payment (approximately $3.1 million in fiscal year 2022), unless a waiver or exemption applies. Waiver of the fee may be sought on several grounds, including that the applicant is a small business submitting its first human drug application to the FDA for review, but there is no assurance we will qualify or receive a waiver if and when we file a BLA in the future. The manufacturer or sponsor of an approved BLA is also subject to annual establishment fees.

An approval letter authorizes commercial marketing and distribution of the licensed product with specific prescribing information for specific indications. As a condition of BLA approval, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety, purity, and potency and may impose other conditions, including post-market studies, labeling restrictions, or other risk evaluation and mitigation strategies, which can materially affect the product's potential market and profitability. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained, or problems or safety issues are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, device components, or manufacturing processes or facilities, require submission and FDA approval of a new BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs.

Biosimilar Exclusivity

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) creates an abbreviated approval pathway for biosimilar products. A biosimilar is a biological product that is highly similar to, and has no clinically meaningful differences from, an existing FDA-licensed reference product. Biosimilarity must be shown through analytical studies, animal studies, and at least one clinical study, absent a waiver. A biosimilar product may be deemed interchangeable with a prior licensed product if it is biosimilar and meets additional requirements under the BPCIA, including that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Where permitted by state law, an interchangeable product may be substituted for the reference product without the involvement of the prescriber.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar may be submitted for four years from the date of licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product may obtain exclusivity against a finding of interchangeability for other biosimilars for the same condition or use for the lesser of (i) one year after the first commercial marketing of the first interchangeable biosimilar; (ii) eighteen months after the first interchangeable biosimilar is approved if there is no patent challenge; (iii) eighteen months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant; or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the 42-month period.

Post-Marketing Requirements for FDA Regulated Products

Following licensure of a new product, the company and the licensed products are subject to continuing regulation by the FDA, state, and foreign regulatory authorities including, among other things, monitoring and record-keeping activities, reporting adverse experiences to the applicable regulatory authorities, providing regulatory authorities with updated safety and efficacy information, manufacturing products in accordance with cGMP requirements, product sampling, and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising and restrictions on promoting products for uses or in patient populations that are not consistent with the product's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet, including social media. Although physicians may prescribe products for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, who may or may not grant approval, or may engage in a lengthy review process.

The FDA, state, and foreign regulatory authorities have broad enforcement powers. Failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state, or foreign regulatory authorities, which may include the following:

- untitled letters or warning letters;
- fines, disgorgement, restitution, or civil penalties;
- injunctions (e.g., total or partial suspension of production) or consent decrees;
- product recalls, administrative detention, or seizure;
- customer notifications or repair, replacement, or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant requests for future product licenses or approvals or foreign regulatory approvals of new products, new intended uses, or modifications to existing products;
- withdrawals or suspensions of FDA product licenses or marketing approvals or foreign regulatory approvals, resulting in prohibitions on product sales;
- clinical holds on clinical trials;
- FDA refusal to review pending or new applications in the event of issues concerning the integrity or reliability of supporting data;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition, and results of operations. Such actions by government agencies could also require us to expend a large amount of managerial and financial resources to respond to the actions. Any agency or judicial enforcement action could have a material adverse effect on us.

In the U.S., after a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in registered facilities and in accordance with cGMP. We have a facility for the production of clinical and commercial quantities of SkinTE that is being modified to operate in accordance with cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct deviations from cGMP. For human cellular or tissue-based products like ours, cGMP also includes current good tissue practices to prevent the transmission of communicable diseases. These regulations also impose certain organizational, procedural, and documentation requirements with respect to manufacturing and quality assurance activities. Manufacturers and other entities involved in the manufacture and distribution of approved drugs, biologics, and medical devices are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP and other laws. Accordingly, as a manufacturer we must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

If in the future we elect to use a contract manufacturer, we will be responsible for the selection and monitoring of qualified firms and, in certain circumstances, suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that can interrupt the operation of any such firm or result in restrictions on product supply, including, among other things, recall or withdrawal of the product from the market.

Newly discovered or developed data on safety, purity, or potency may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures.

Reimbursement, Anti-Kickback and False Claims Laws, and Other Regulatory Matters

In the U.S., the research, manufacturing, distribution, sale, and promotion of drug and biological products are potentially subject to regulation by various federal, state, and local authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, state Attorneys General, and other state and local government agencies. For example, sales, marketing, and scientific/educational grant programs must comply when applicable with the federal Anti-Kickback Statute, the federal False Claims Act, the privacy regulations promulgated under HIPAA, and similar state laws. Pricing and rebate programs must comply with the Medicaid Drug Rebate Program requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that will provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive regulatory approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-government payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality, and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sale of SkinTE in the future. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's product could adversely affect the sale of our product. If third-party payors do not consider SkinTE to be cost-effective compared to other available therapies, they may not cover our product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our product on a profitable basis.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug and biologics pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for our product. Historically, products launched in the European Union do not follow price structures of the U.S. and generally tend to be priced significantly lower than in the U.S.

In the U.S. PolarityTE is subject to complex laws and regulations pertaining to healthcare "fraud and abuse," including, but not limited to, the federal Anti-Kickback Statute, the federal False Claims Act, and other state and federal laws and regulations. The federal Anti-Kickback Statute makes it illegal for any person, or a party acting on its behalf, to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, or other good or service for which payment in whole or in part may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the federal Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. Due to the breadth of these federal and state anti-kickback laws, the absence of guidance in the form of regulations or court decisions and the potential for additional legal or regulatory change in this area, it is possible that PolarityTE's future sales and marketing practices or its future relationships with medical professionals might be challenged under fraud and abuse laws, which could harm PolarityTE.

The federal False Claims Act prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs and biologics, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of estimated prices for SkinTE, the reporting of prices used to calculate Medicaid rebate information, and other information affecting federal, state, and third-party reimbursement for our product, and the sale and marketing of SkinTE, are subject to scrutiny under this law. Penalties for a federal False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between $11,181 and $22,363 for each separate false claim, the potential for exclusion from participation in federal healthcare programs. Although the federal False Claims Act is a civil statute, conduct resulting in a federal False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine. In addition, private individuals have the ability to bring actions under the federal False Claims Act and certain states have enacted laws modeled after the federal False Claims Act.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, as discussed below, a similar federal requirement requires manufacturers to track and report to the federal government certain payments made to physicians and teaching hospitals in the previous calendar year. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

The failure to comply with regulatory requirements exposes companies to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a company to enter into supply contracts, including government contracts.

Changes in regulations, statutes, or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing facility; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our product; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Patient Protection and Affordable Care Act

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the PPACA, was enacted, which includes measures that have or will significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the drug industry are the following:

- The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's covered outpatient drugs furnished to Medicaid patients. Effective in 2010, the PPACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs and biologic agents to 23.1% of the Average Manufacturer Price ("AMP") and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The PPACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by expanding the population potentially eligible for Medicaid drug benefits. The CMS have proposed to expand Medicaid rebate liability to the territories of the U.S. as well. In addition, the PPACA provides for the public availability of retail survey prices and certain weighted average AMPs under the Medicaid program. The implementation of this requirement by the CMS may also provide for the public availability of pharmacy acquisition of cost data, which could negatively impact our sales.
- In order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. The PPACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs when used for the orphan indication. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.
- The PPACA imposes a requirement on manufacturers of branded drugs and biologic agents to provide a 50% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (i.e., "donut hole").
- The PPACA imposes an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications.
- The PPACA requires pharmaceutical manufacturers to track certain financial arrangements with physicians and teaching hospitals, including any "transfer of value" made or distributed to such entities, as well as any investment interests held by physicians and their immediate family members. Manufacturers are required to track this information and were required to make their first reports in March 2014. The information reported is publicly available on a searchable website.
- As of 2010, a new Patient-Centered Outcomes Research Institute was established pursuant to the PPACA to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products.

There have been prior public announcements by members of the federal government regarding their plans to repeal and replace the PPACA and Medicare. For example, the Tax Cuts and Jobs Act of 2017 eliminated the individual mandate requiring most Americans (other than those who qualify for a hardship exemption) to carry a minimum level of health coverage, effective January 1, 2019. We are not sure whether additional legislative changes will be enacted and are unable to predict what impact changes in the law may have on the pricing and distribution of our product.

Employees

We have approximately 59 full-time employees and 10 part-time employees as of December 31, 2021, all of whom are in the U.S. 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.

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.

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.

We file annual, quarterly, and current reports, proxy statements, and other information with the SEC. Our SEC filings are available to the public at the SEC's website at *www.sec.gov*. We also maintain a website located at *www.polarityte.com*, where these SEC filings and other information about the Company can be accessed, free of charge, as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC.

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 will need additional funding to pursue the regulatory process for SkinTE and sustain our operations, and we may be unable to raise capital when needed, which would force us to delay, reduce, eliminate, or abandon our product development program.

We reported an operating loss of $33.7 million for the year ended December 31, 2021, and on that date we had had an accumulated deficit of $508.4 million. We believe our cash and cash equivalents at December 31, 2021, will fund our current business plan including related operating expenses and capital expenditure requirements through the end of the third calendar quarter of 2022. Accordingly, there is substantial doubt about our ability to continue as a going concern beyond that time unless we can raise additional capital from external sources.

We expect to incur significant operating costs in the near term as we pursue the regulatory process for SkinTE with the FDA, conduct clinical trials and studies, and pursue product research, all while operating our business and incurring continuing fixed costs related to the maintenance of our assets and business. We expect to incur significant losses in the future, and those losses could be more severe as a result of unforeseen expenses, difficulties, complications, delays, and other unknown events.

If adequate funds are not available for our business in the future, we may be required to delay, reduce the scope of, or eliminate the plans for obtaining regulatory licensure or approval for SkinTE or be unable to continue operations over a longer term, any of which would have a material adverse effect on our business, financial condition, and results of operation.

We discontinued sales of SkinTE and COVID-19 testing, and may make a disposition of IBEX, so we will be entirely dependent on capital obtained from outside sources to fund our operations.

We discontinued sales of SkinTE as a 361 HCT/P product at the end of May 2021 and discontinued COVID-19 testing through Arches in August 2021, and it is likely there will be some disposition of IBEX in 2022. As a result of these developments, in the near term we may not be engaged in any revenue generating activity that would contribute to defraying our operating costs, which will make us entirely dependent on capital obtained from external sources to fund our operations. The inability to obtain capital as needed to fund our operations could result in us curtailing or ceasing operations, which would have a material adverse effect on our business, financial condition, results of operation, and the value of an investment in us.

Our wholly owned subsidiary accepted a loan under the CARES Act pursuant to the Paycheck Protection Program ("PPP"), and the loan 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 "PTE-MD") entered into a promissory note offered by a bank (the "Lender") evidencing an unsecured loan in the amount of $3,576,145 made to PTE-MD under the PPP (the "Loan"). On October 15, 2020, PTE-MD applied to the Lender for forgiveness of the PPP Loan in its entirety (as provided for in the CARES Act) based on PTE-MD's use of the PPP Loan for payroll costs, rent, and utilities. On October 26, 2020, PTE-MD was advised that the Lender approved the application, and that the Lender was submitting the application to the Small Business Administration ("SBA") for a final decision. The SBA subsequently approved PTE-MD's application for forgiveness of the PPP Loan, and the principal and interest of $3,612,376 was fully paid by the SBA on June 12, 2021.

Pursuant to the requirements under the CARES Act, in connection with the PPP Loan PTE-MD certified that current economic uncertainty made the Loan request necessary to support the ongoing operations of PTE-MD. We believe that certification was made 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. In connection with PTE-MD's application for forgiveness of the PPP Loan, it provided information on the use of the PPP Loan proceeds for payroll costs, rent, and utilities, which are permitted uses to qualify for forgiveness of the loan.

Under the CARES Act, the SBA may review any PPP loan of any size at any time at its discretion. On September 17, 2021, PTE-MD received notice from the Lender that the SBA is continuing to review the PPP Loan. As part of this review, the SBA requested that PTE-MD provide documents that it is required to maintain but may not have been required to submit with its application for the PPP Loan. These documents included an affiliation worksheet showing the relationship between PolarityTE and PTE-MD and affiliated subsidiaries, documents showing the use of the PPP Loan proceeds, documents showing PTE-MD's calculation of the loan amount it requested in its loan application, its federal tax returns, and documents showing employee compensation information. PTE-MD submitted the documents to the SBA through the Lender on September 28, 2021.

There is no assurance the SBA will conclude PTE-MD properly applied for, and used the proceeds of, the PPP Loan. If there is any adverse finding in the SBA review or if PTE-MD were alleged, or determined, not to qualify for the Loan or alleged, or found, to have made false certifications in connection with the PPP Loan and its forgiveness, PTE-MD 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, PTE-MD 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 U.S. PTE-MD 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 PTE-MD 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, PTE-MD may face negative publicity, which could have a materially adverse impact on its business and operations and on PolarityTE's 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.

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

Our product is subject to extensive regulation by the FDA or comparable foreign regulatory authorities, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required licensures and approvals to commercialize our product.

The preclinical and clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing, and distribution of SkinTE is subject to extensive regulation by the FDA and other U.S. regulatory agencies, or comparable authorities in foreign markets. In the U.S., we are not permitted, directly or through others, to market our product until the FDA approves a BLA for SkinTE and licenses the product. Similar approval is required in foreign jurisdictions. The process of obtaining these approvals is uncertain, dependent on future clinical trial results, expensive, often takes many years, and can vary substantially based upon the type, complexity, and novelty of the product candidate involved. Approval policies or regulations may change and may be influenced by the results of other similar or competitive products, making it more difficult for us to achieve such approval in a timely manner or at all. Any guidance that may result from FDA advisory committee discussions may make it more difficult or expensive to develop and commercialize SkinTE. In addition, as a company, we have not previously filed a BLA with the FDA or filed a similar application with other foreign regulatory agencies. This lack of experience may impede our ability to obtain FDA or other foreign regulatory agency licensure or approval in a timely manner, if at all, for our product.

Despite the time and expense invested, regulatory approval is never guaranteed. The FDA or comparable foreign authorities can delay, limit, or deny approval or licensure of a product candidate for many reasons, including:

- a product candidate for a BLA may not be deemed safe, pure, and potent;
- agency officials of the FDA or comparable foreign regulatory authorities may not find the data from non-clinical or preclinical studies and clinical trials generated during development to be sufficient;
- the FDA or comparable foreign regulatory authorities may not approve manufacturing processes or may determine that the manufacturing facilities are not compliant with cGMP; or
- the FDA or a comparable foreign regulatory authority may change its approval policies or adopt new regulations.

Our inability to obtain these approvals would prevent us from commercializing our product.

The FDA regulatory approval process is lengthy and time-consuming, and PolarityTE could experience significant delays or other challenges in the clinical development and regulatory licensures or approval of its product.

We may experience delays or other challenges in commencing and completing clinical trials for SkinTE that would be necessary for product licensure or approval. We do not know whether planned clinical trials will begin on time, need to be redesigned, enroll trial subjects on time or in sufficient numbers, or be completed on schedule, if at all. Any of our future clinical trials may be delayed or precluded for a variety of reasons, including issues related to:

- the availability of financial resources for commencing and completing planned clinical trials;
- reaching agreement on acceptable terms with prospective contract research organizations (“CROs”) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining and maintaining approval of each reviewing institutional review board (“IRB”);
- obtaining and maintaining regulatory approval for clinical trials in each country;
- recruiting sufficient numbers of suitable trial subjects to participate in clinical trials;

- competing priorities at clinical trial sites or departures of study investigators or personnel;
- having trial subjects complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites;
- developing one or more new formulations or routes of administration; or
- manufacturing sufficient quantities of our product candidate for use in clinical trials.

Trial subject enrollment, a significant factor in the timing and success of clinical trials, is affected by many factors including the size and nature of the trial subject population, the proximity of trial subjects to clinical sites, the eligibility criteria for the clinical trial, the potential impact of COVID-19 or other pandemic, the design of the clinical trial, competing clinical trials and clinicians, and trial subjects' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any therapies that may be approved for the indications we are investigating. In addition, significant numbers of trial subjects who enroll in our clinical trials may drop out during the clinical trials for various reasons. We endeavor to account for dropout rates in our trials when determining expected clinical trial timelines, but we cannot assure you that our assumptions are correct, or that trials will not experience higher numbers of dropouts than anticipated, which would result in the delay of completion of such trials beyond our expected timelines, if at all.

We could encounter delays if physicians encounter unresolved ethical issues associated with enrolling trial subjects in clinical trials of our product candidate in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be delayed, suspended, or terminated by us, any reviewing IRB, the institutions in which such trial is conducted, the data monitoring committee for such trial, or by the FDA or other regulatory authorities due to a number of factors, including inadequate protocols or other information supporting an IND, failure to conduct the clinical trial in accordance with regulatory requirements, GCP, or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations, or administrative actions or lack of adequate funding to continue the clinical trial. Furthermore, many of the factors that cause, or lead to, a termination or delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory licensure or approval of a product. In connection with clinical trials, we face additional risks that:

- there may be slower than expected rates of trial subject recruitment and enrollment;
- trial subjects may fail to complete the clinical trials;
- there may be an inability or unwillingness of trial subjects or medical investigators to follow our clinical trial protocols;
- there may be an inability to monitor trial subjects adequately during or after treatment;
- conditions of trial subjects may deteriorate rapidly or unexpectedly, which may cause the trial subjects to become ineligible for a clinical trial or may prevent our product from demonstrating the regulatory standard of safety, purity, and potency;
- trial subjects may die or suffer other adverse effects for reasons that may or may not be related to our product being tested;
- we may not be able to sufficiently standardize certain of the tests and procedures that are part of our clinical trials because such tests and procedures are highly specialized and involve a high degree of expertise;
- the clinical trials may not be able to commence, or to proceed, because of problems with compliance with cGMP at the manufacturing facilities;
- a product candidate may not prove to be efficacious in all or some trial subject populations;
- the results of the clinical trials may not confirm the results of earlier trials;
- the results of the clinical trials may not meet the level of statistical significance required by the FDA or other regulatory agencies;
- there may be data discrepancies or documentation issues in the clinical trials that raise questions about data integrity or reliability; and
- a product candidate may not have a favorable risk/benefit assessment in the disease areas studied.

We cannot assure you that any future clinical trial for our product will be started or completed successfully, on schedule, or at all. If we experience suspension or termination of, or delays in the completion of, any clinical trial for our product, the commercial prospects for the product will be harmed, and our ability to generate product revenues will be delayed or diminished. In addition, any delays in initiating or completing our clinical trials will increase our costs, slow down our product development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, prospects, financial condition, and results of operations significantly.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve or license new products can be affected by a variety of factors, including (i) government budget and funding levels, as well as government shutdowns, (ii) the ability to hire and retain key personnel and accept the payment of user fees, and (iii) statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new products to be reviewed or licensed or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Additionally, over the last several years, the COVID-19 pandemic has caused unexpected increases in the FDA's workload and has degraded the timeliness of many agency activities, including pre-submission interactions, product reviews, and pre-license inspections.

Even if we obtain and maintain regulatory licensure or approval for our product in one jurisdiction, it may never obtain regulatory licensure or approval for the product in any other jurisdiction, which would limit our market opportunities and adversely affect our business.

Obtaining and maintaining regulatory licensure or approval for our product in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory licensure or approval in other jurisdictions. For example, even if the FDA grants marketing approval for SkinTE, comparable regulatory authorities in foreign countries must also approve the manufacturing, marketing, and promotion of the product in those countries. Approval procedures vary amongst jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our product in certain countries. In many countries outside the U.S., a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our product is also subject to approval. If we fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product will be harmed, which would adversely affect our business, prospects, financial condition, and results of operations.

Even if our product candidate receives regulatory licensure or approval, our product candidate may still face future development and regulatory difficulties.

If our product receives regulatory approval, the FDA or comparable foreign regulatory authorities may still impose significant restrictions on the indicated uses or marketing of the product or impose ongoing requirements for potentially costly post-approval studies and trials or other risk mitigation measures. In addition, regulatory agencies subject a product, its manufacturer, and the manufacturer's facilities to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, including adverse events of unanticipated nature, severity or frequency, or problems with the facility where the product is manufactured, stored, tested, or released, a regulatory agency may impose restrictions on that product or PolarityTE, including narrowing product indications, requiring labeled warnings, or requiring withdrawal of the product from the market. Our product candidate will also be subject to ongoing FDA or comparable foreign regulatory authorities' requirements for labeling, packaging, storage, advertising, promotion, record-keeping, import, export, clinical trial registration and results disclosure for post-market as well as pre-market trials, and submission of safety and other post-market information. If our product fails to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or other notices of possible violations;

- impose civil or criminal penalties or fines or seek disgorgement of revenue or profits;
- suspend or terminate any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us or our licensees;
- withdraw any regulatory licensures or approvals;
- impose restrictions on operations, including costly new manufacturing requirements, or shut down our manufacturing operations; or
- seize or detain product or require a product recall.

The FDA and comparable foreign authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses and other unlawful promotion.

The FDA and comparable foreign authorities strictly regulate the promotional claims that may be made about products, such as SkinTE, if licensed or approved. In particular, a product may not be promoted for uses that are not approved by the FDA or comparable foreign authorities as reflected in the product's approved labeling and may not be promoted with claims that are false, misleading, or inadequately substantiated. If we receive marketing approval for our product for its proposed indications, physicians may nevertheless use our product for their patients in a manner that is inconsistent with the approved label, if the physicians believe in their professional medical judgment that our product could be used in such manner.

However, if we are found to have promoted our product for any off-label uses, or with claims that are false, misleading, or not adequately substantiated, the federal government could levy civil, criminal, or administrative penalties, and seek to impose fines on us. Such enforcement has become more common in the industry. The FDA or comparable foreign authorities could also request that we enter into a consent decree or a corporate integrity agreement or seek a permanent injunction against us under which specified promotional conduct is monitored, changed, or curtailed. If we cannot successfully manage the promotion of our product, if licensed or approved, we could become subject to significant liability, which would materially adversely affect our business, financial condition, and results of operations.

PolarityTE, and any contract manufacturer it may engage in the future, are subject to significant regulation with respect to manufacturing PolarityTE's product. Even once cGMP compliance is initially achieved, the manufacturing facility on which PolarityTE relies may not continue to meet regulatory requirements.

Entities involved in the preparation of products subject to BLA approval for clinical trials or commercial sale, including us and any contract manufacturer we may engage in the future, are subject to extensive regulation. Products sold commercially after BLA approval or used in clinical trials must be manufactured in accordance with cGMP. cGMP laws and regulations govern manufacturing facilities, processes, and procedures and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes or facilities can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidate that may not be detectable in final product testing. We, or our contract manufacturers, must supply all necessary documentation on a timely basis in support of a BLA or a change in manufacturing site after a BLA is issued on a timely basis and must adhere to cGMP statutory requirements and regulations enforced by the FDA or comparable foreign authorities through their facilities inspection program. The facilities and quality systems of our facility where we will manufacture SkinTE must pass a pre-license inspection for compliance with the applicable statutory and regulatory requirements as a condition of regulatory licensure or approval of our product. In addition, the regulatory authorities may, at any time, with or without cause, audit, inspect, or conduct a remote review of records or information about a manufacturing facility involved with the preparation of our product or the associated quality systems for compliance with the statute or regulations applicable to the activities being conducted. If our facility does not pass a pre-license plant inspection, regulatory licensure or approval of our product may not be granted or may be substantially delayed until any deficiencies are corrected to the satisfaction of the regulatory authority, if ever. If we engage contract manufacturers in the future, we intend to oversee the contract manufacturers, but we cannot control the manufacturing process and will be completely dependent on our contract manufacturing partners for compliance with the regulatory requirements.

The regulatory authorities also may, at any time following approval of a product for sale, audit, inspect, or remotely review records regarding our facility or the manufacturing facilities of our third-party contractors. If any such inspection, audit, or review identifies a failure to comply with applicable statute or regulations or if a violation of our product specifications or applicable statute or regulations occurs independent of such an inspection, audit, or review, we or the relevant regulatory authority may require remedial measures that may be costly or time consuming for us or a third party to implement, and may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business, financial condition, and results of operations.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or comparable foreign authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a product candidate, withdrawal of an approval, or suspension of production. As a result, our business, financial condition, and results of operations may be materially and adversely affected.

Additionally, if supply from our facility or the facility of a future contract manufacturer is interrupted, an alternative manufacturer would need to be qualified through a BLA supplement, or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies or trials if a new manufacturer is relied upon for commercial production. Switching manufacturing facilities may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals, or commercialization of our product. Furthermore, if our facility or future contract manufacturers fail to meet production requirements and we is unable to secure one or more replacement manufacturing facilities capable of production at a substantially equivalent cost or at all, our clinical trials may be delayed, or we could lose potential revenue.

If we fail to obtain and sustain an adequate level of reimbursement for our product by third-party payors, potential future sales would be materially adversely affected.

There will be no viable commercial market for our product, if approved, without reimbursement from third-party payors. Reimbursement policies may be affected by future healthcare reform measures. We cannot be certain that reimbursement will be available for our product. Additionally, even if there is a viable commercial market, if the level of reimbursement is below our expectations, our anticipated revenue and gross margins will be adversely affected. Third-party payors, such as government or private healthcare insurers, carefully review and increasingly question and challenge the coverage of and the prices charged for drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan, and other factors. Reimbursement rates may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. There is a current trend in the U.S. healthcare industry toward cost containment.

Large public and private payors, managed care organizations, group purchasing organizations, and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge the prices charged for, medical products and services, and many third-party payors limit coverage of or reimbursement for newly approved healthcare products. In particular, third-party payors may limit the covered indications. Cost-control initiatives could decrease the price we might establish for products, which could result in product revenues being lower than anticipated. If we are unable to show a significant benefit relative to existing therapies, Medicare, Medicaid, and private payors may not be willing to provide reimbursement for our product, which would significantly reduce the likelihood of our product gaining market acceptance.

We expect that private insurers will consider the efficacy, cost-effectiveness, safety, and tolerability of our product in determining whether to approve reimbursement and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business, financial condition, and results of operations would be materially adversely affected if we do not receive approval for reimbursement of our product from private insurers on a timely or satisfactory basis. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Medicare Part D, which provides a pharmacy benefit to Medicare patients as discussed below, does not require participating prescription drug plans to cover all drugs within a class of products. Our business, financial condition, and results of operations could be materially adversely affected if Part D prescription drug plans were to limit access to, or deny or limit reimbursement of, our product.

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. In many countries, the product cannot be commercially launched until reimbursement is approved. In some foreign markets, prescription drug pricing remains subject to continuing governmental control even after initial approval is granted. The negotiation process in some countries can be very long. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products to other available therapies.

If the prices for our product are reduced or if governmental and other third-party payors do not provide adequate coverage and reimbursement of our product, our future revenue, cash flows, and prospects for profitability will suffer.

Current and future legislation may increase the difficulty and cost of commercializing our product and may affect the prices we may obtain if our product is approved for commercialization.

In the U.S. and some foreign jurisdictions, there have been a number of adopted and proposed legislative and regulatory changes regarding the healthcare system that could prevent or delay regulatory licensure or approval of our product, restrict or regulate post-marketing activities, and affect our ability to profitably sell our product.

In the U.S., the Medicare Modernization Act of 2003 ("MMA") changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could limit the coverage and reimbursement rate that we receive for our product. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

The Patient Protection and Affordable Care Act ("PPACA") was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms. The PPACA increased manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate amount for both branded and generic drugs and revised the definition of Average Manufacturer Price, which may also increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also expanded Medicaid drug rebates and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the rebates due on those drugs. The Centers for Medicare & Medicaid Services, which administer the Medicaid Drug Rebate Program, also proposed to expand Medicaid rebates to the utilization that occurs in the territories of the U.S., such as Puerto Rico and the Virgin Islands. Further, beginning in 2011, the PPACA imposed a significant annual fee on companies that manufacture or import branded prescription drug products and required manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole." Legislative and regulatory proposals have been introduced at both the state and federal level to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

There have been prior public announcements by members of the federal government regarding their plans to repeal and replace the PPACA and Medicare. For example, the Tax Cuts and Jobs Act of 2017 eliminated the individual mandate requiring most Americans (other than those who qualify for a hardship exemption) to carry a minimum level of health coverage, effective January 1, 2019. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing approval testing and other requirements.

We are subject to "fraud and abuse" and similar laws and regulations, and a failure to comply with such regulations or prevail in any adverse claim or proceeding related to noncompliance could harm our business, financial condition, and results of operations.

In the U.S., we are subject to various federal and state healthcare "fraud and abuse" laws, including anti-kickback laws, false claims laws, and other laws intended, among other things, to reduce fraud and abuse in federal and state healthcare programs. The federal Anti-Kickback Statute makes it illegal for any person, including a drug or biologics manufacturer, or a party acting on its behalf, to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug or biologic, or other good or service, for which payment in whole or in part may be made under a federal healthcare program, such as Medicare or Medicaid. Although we seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the federal Anti-Kickback Statute.

The federal False Claims Act prohibits anyone from, among other things, knowingly presenting or causing to be presented for payment to the government, including the federal healthcare programs, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Under the Health Insurance Portability and Accountability Act of 1996, we are prohibited from knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors, or knowingly and willfully falsifying, concealing or covering up a material fact, or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services to obtain money or property of any healthcare benefit program. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including penalties, fines, or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid, and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several states.

Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that as we pursue our business we may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If we are found in violation of one of these laws, we could be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from governmental funded federal or state healthcare programs, and the curtailment or restructuring of our operations. If this occurs, our business, financial condition, and results of operations may be materially adversely affected.

If we face allegations of noncompliance with the law and encounter sanctions, our reputation, revenues, and liquidity may suffer, and our product, if approved for commercialization, could be subject to restrictions or withdrawal from the market.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to generate revenues from our product, if approved. If regulatory sanctions are applied or if regulatory licensure or approval is not granted or is withdrawn, our business, financial condition, and results of operations will be adversely affected. Additionally, if we are unable to generate revenues from product sales, our potential for achieving profitability will be diminished and our need to raise capital to fund our operations will increase.

Risks Related to 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 three issued patents and one allowed patent application in the U.S. relating to our minimally polarized functional unit ("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 benefit. 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 benefit 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 U.S. 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 us 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 product, require us to obtain licenses from third parties, require us to develop non-infringing alternatives, or subject us to substantial monetary damages.

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, which could adversely affect our business and results of operations.

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

Intellectual property law outside the U.S. 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 U.S. 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 U.S. 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.

General Risks

We have one facility for the production of SkinTE for our clinical trials, so if this facility is destroyed or it experiences any manufacturing or laboratory difficulties, disruptions, or delays, this could adversely affect our ability to conduct our clinical trials.

Manufacturing of SkinTE takes place at our single U.S. facility. If regulatory, manufacturing, or other problems cause us to discontinue production operations at this facility, we would not be able to supply SkinTE for clinical trials, which would adversely impact our business. If this facility or the equipment in it is significantly damaged or destroyed by fire, flood, power loss, or similar events, we may not be able to replace our manufacturing capacity quickly or inexpensively, or 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. 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.

Our success depends on members of our senior management team and the loss of one or more key employees or an inability to attract and retain 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 certain members of senior management and other key personnel. Although we have entered into employment agreements with our executive officers, each of them may terminate 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. 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 we do. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees have or we have breached legal obligations, resulting in a diversion of our time and resources to disputes and litigation and, potentially, result in liability.

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 decline, it may harm our ability to recruit and retain highly skilled employees.

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.

The impact of COVID-19, including the impact of restrictions imposed to combat its spread, could result in businesses shutting down, additional work restrictions, and reduced capacity and access to healthcare facilities, in particular as new COVID-19 variants such as the Delta and Omicron and other new variants spread. Depending upon the length of COVID-19 surges and resulting work restrictions and limitations on healthcare facilities, our future clinical trials for SkinTE may be adversely affected by: (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 the clinical trials, 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 trials are to be conducted, which may result in unexpected costs or discontinuance of the clinical trials 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 trials; (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 or reliability of clinical trial data; (vii) risk that participants enrolled in our clinical trials will acquire COVID-19 while clinical trials are ongoing, which could impact the results of the clinical trials, including by increasing the number of observed adverse events; (viii) risk that clinical trial investigators or other site staff will acquire COVID-19 while the clinical trial is ongoing, which could impede the conduct or progress of the clinical trials; (ix) 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; (x) 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; (xi) and interruption or delays to our clinical trial activities.

We may not be able to enforce our patent or intellectual property rights against third parties, which could adversely affect the trading price for our common stock.

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. Unauthorized disclosure of our claims to our trade secrets could result in loss of those intellectual property rights. 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 that we have lost rights to our intellectual property or the results of these disputes are negative, it could have a substantial adverse effect on the price of our common stock.

In the event that we fail to satisfy any of the listing requirements of the Nasdaq Capital Market, our common stock may be delisted, which could affect our market price and liquidity.

Our common stock is listed on the Nasdaq Capital Market. For continued listing on the Nasdaq Capital Market, we will be required to comply with the continued listing requirements, including the minimum market capitalization standard, the minimum stockholders' equity requirement, the corporate governance requirements, and the minimum closing bid price requirement, among other requirements. On August 13, 2021, we received a deficiency letter from the staff of the Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market ("Nasdaq") notifying us that we did not meet the $1.00 per share minimum bid price requirement for continued inclusion on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days to regain compliance with the Minimum Bid Price Requirement, which ended February 9, 2022. On February 10, 2022, we received an additional notice from the Staff stating that, although we had not regained compliance with the Minimum Bid Price Rule by February 9, 2022, the Staff determined in accordance with Nasdaq Listing Rule 5810(c)(3)(A) that we are eligible for an additional 180 calendar days from the date of that notice, or until August 8, 2022, to regain compliance with the Minimum Bid Price Rule. To regain compliance, the bid price for the Company's common stock must close at $1.00 per share or more for a minimum of 10 consecutive business days.

To resolve the noncompliance, we may consider available options, including effecting a reverse stock split, which may not result in a permanent increase in the market price of our common stock and is dependent on many factors, including general economic, market, and industry conditions, the timing and results of our clinical trials, regulatory developments, and other factors detailed from time to time in the reports we file with the SEC. It is not uncommon for the market price of a company's shares to decline in the period following a reverse stock split. Furthermore, implementation of a reverse stock split requires approval of a majority of the outstanding voting power of our capital stock, and there is no assurance we can obtain that approval.

In the event that we fail to satisfy any of the listing requirements of the Nasdaq Capital Market our common stock may be delisted, and our current deficiency in meeting the Minimum Bid Price Requirement could result in our common stock being delisted in August 2022 if we are unable to resolve that deficiency. If our securities are delisted from trading on the Nasdaq Stock Market, and we are not able to list our securities on another exchange or to have them quoted on the Nasdaq Stock Market, our common stock could be quoted on the OTC Markets or on the Pink Open Market. As a result, we could face significant adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock," which would require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage;
- a decreased ability to obtain additional financing because we would be limited to seeking capital from investors willing to invest in securities not listed on a national exchange; and
- the inability to use short-form registration statements on Form S-3, including the registration statement on Form S-3 we filed in February 2022, to facilitate offerings of our securities.

We will need to issue additional equity securities in the future, which may result in dilution to existing investors and investors purchasing securities in this offering.

We expect to seek the additional capital necessary to fund our future operations through public or private equity offerings, debt financings, and collaborative and licensing arrangements. To the extent we raise additional capital by issuing equity securities, including in a debt financing where we issue convertible notes or notes with warrants and any shares of our common stock to be issued in a private placement, our stockholders may experience substantial dilution. We expect to sell additional equity securities from time to time in one or more transactions at prices and in a manner we determine. If we sell additional equity securities, existing stockholders may be materially diluted. In addition, new investors could gain rights superior to existing stockholders, such as liquidation and other preferences.

In addition, the exercise or conversion of outstanding options or warrants to purchase shares of capital stock may result in dilution to our stockholders upon any such exercise or conversion. As of March 25, 2022, we had a significant number of securities convertible into, or allowing the purchase of, our common stock, including 9,836,067 shares reserved for issuance upon conversion of our Series A Convertible Preferred Stock, 35,500,843 warrants to purchase shares of our common stock, 8,911,879 options and rights to acquire shares of our common stock that are outstanding under our equity incentive plans, and 4,097,401 shares of common stock reserved for future issuance under our equity incentive plans.

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 it 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 public trading price of our common stock, if any, will provide a return to investors.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

PolarityTE is party to a Commercial Lease Agreement with Adcomp LLC ("Adcomp") dated December 27, 2017 (the "Adcomp Lease"). The Adcomp Lease is for PolarityTE's principal business facility and property located at 1960 S 4250 W, Salt Lake City, Utah (the "Property"). The Adcomp Lease pertains to approximately 178,528 rentable square feet of warehouse, manufacturing, office, and lab space. The initial term of the Adcomp Lease is five years, expiring on November 30, 2022. PolarityTE 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% per annum thereafter. The current monthly base rent is $110,514. The initial lease rate on an extension of the lease is $113,830 per month with annual rent increases equal to 3% of the prior year's lease rate.

Under the original terms of the Adcomp Lease, we have an option to purchase the Property at a purchase price of $17.5 million, which is waived unless we exercise such option on or before March 27, 2022. On December 16, 2021, we gave written notice of its election to exercise the purchase option to Adcomp. Once that notice was given, the Adcomp Lease states the Company and Adcomp are required to negotiate the terms of a purchase agreement covering property diligence, conditions of closing, the timing of closing, and other customary matters for a sale and purchase of improved real estate. In addition, as required by the Adcomp Lease we made an earnest money deposit of $150,000 that may be refunded if closing conditions or contingencies running in our favor are not satisfied or Adcomp defaults in its obligations under the Adcomp Lease or the purchase agreement for the Property. On March 14, 2022, the Company and Adcomp entered into a purchase and sale on the terms described above that provides for a closing of the transaction on November 15, 2022 (the "Adcomp Agreement").

On October 25, 2021, we signed a Purchase and Sale Agreement, the terms of which were finalized on December 10, 2021, and subsequently amended by Amendment No. 1 thereto dated March 15, 2022 (the "BCG Agreement"), with BCG Acquisitions LLC ("BCG"). Under the BCG Agreement we agreed to sell the Property to BCG or its assigns after our purchase of the Property from Adcomp, if the parties could agree on the terms for BCG to demise the building located on the Property to establish a smaller space within the building for us to lease and agree on the terms of that lease (the "BCG Lease"). The BCG Lease and, therefore, the BCG Agreement, was finalized on December 10, 2021. On March 15, 2022, the parties agreed to amend the BCG Agreement to change the closing date of the transaction from March 2022 to November 2022.

Under the BCG Agreement the Company has agreed to sell the Property to BCG for $17.5 million, subject to the closing of our purchase of the Property from Adcomp. The BCG Agreement also provides for property diligence (which has been completed by BCG), conditions of closing, the timing of closing, and other customary matters for a sale and purchase of improved real estate. Under the BCG Agreement, BCG made an initial earnest money deposit totaling $200,000, which the parties subsequently agreed to reduce to $150,000, that will be refunded if we are unable to complete the purchase of the Property from Adcomp on a timely basis, closing conditions or contingencies running in favor of BCG are not satisfied, or we default in our obligations under the BCG Agreement for the Property. Under the BCG Lease, BCG will demise the building on the Property to create a space of approximately 62,500 square feet that the Company will lease for a term of 10 years with an option to extend for an additional 10 years. The parties may agree to increase the size of the space prior to commencement of the BCG Lease.

The closing of the transactions described above are subject to a number of risks and uncertainties including, but not limited to, the following: our completion of diligence and title review of the Property pursuant to the Adcomp Agreement; satisfaction of all closing conditions, including obtaining financing for the purchase, and closing on the purchase of the Property from Adcomp; and satisfaction of all closing conditions, including BCG obtaining financing for the purchase, and closing on the sale of the Property to BCG. Consequently, we may not be successful in closing the transactions described above. If the transactions fail for any reason we will continue to occupy the Property under an extension of the existing lease.

The foregoing description of the terms and conditions of the Adcomp Lease and the Purchase and Sale Agreement between us and BCG are not complete and are in all respects subject to the actual provisions of such agreements, copies of which are exhibits to this Annual Report.

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, IBEX.

Item 3. Legal Proceedings.

On September 24, 2021, a class action complaint alleging violations of the Federal securities laws was filed in the United States District Court, District of Utah, by Marc Richfield against the Company and certain officers of the Company, Case No. 2:21-cv-00561-BSJ. The Court subsequently appointed a Lead Plaintiff and ordered the Lead Plaintiff to file an amended Complaint by February 7, 2022, which was extended to February 21, 2022. The Lead Plaintiff filed an amended complaint on February 21, 2022, against the Company, two current officers of the Company, and three former officers of the Company (the "Complaint"). The Complaint alleges that during the period from January 30, 2018, through November 9, 2021, the defendants made or were responsible for, disseminating information to the public through reports filed with the Securities and Exchange Commission and other channels that contained material misstatements or omissions in violation of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, as amended, and Rule 10b-5 adopted thereunder. Specifically, the Complaint alleges that the defendants misrepresented or failed to disclose that: (i) the Company's product, SkinTE, was improperly registered as a 361 HCT/P under Section 361 of the Public Health Service Act and that, as a result, the Company's ability to commercialize SkinTE as a 361 HCT/P was not sustainable because it was inevitable SkinTE would need to be registered under Section 351 of the Public Health Service Act; (ii) the Company characterized itself as a commercial stage company when it knew sales of SkinTE as a 361 HCT/P were unsustainable and that, as a result, it would need to file an IND and become a development stage company; (iii) issues arising from an FDA inspection of the Company's facility in July 2018, were not resolved even though the Company stated they were resolved; and (iv) the IND for SkinTE was deficient with respect to certain chemistry, manufacturing, and control items, including items identified by the FDA in July 2018, and as a result it was unlikely that the FDA would approve the IND in the form it was originally filed. The Company believes the allegations in the Complaint are without merit, and intends to defend the litigation, vigorously. At this early stage of the proceedings, we are unable to make any prediction regarding the outcome of the litigation.

On October 25, 2021, a stockholder derivative complaint alleging violations of the Federal securities laws was filed in the United States District Court, District of Utah, by Steven Battams against the Company, each member of the Board of directors, and two officers of the Company, Case No. 2:21-cv-00632-DBB (the "Stockholder Derivative Complaint"). The Stockholder Derivative Complaint alleges that the defendants made, or were responsible for, disseminating information to the public through reports filed with the Securities and Exchange Commission and other channels that contained material misstatements or omissions in violation of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, as amended, and Rule 10b-5 adopted thereunder. Specifically, the Stockholder Derivative Complaint alleges that the defendants misrepresented or failed to disclose that: (i) the IND for the Company's product, SkinTE, filed with the FDA was deficient with respect to certain chemistry, manufacturing, and control items; (ii) as a result, it was unlikely that the FDA would approve the IND in its current form; (iii) accordingly, the Company had materially overstated the likelihood that the SkinTE IND would obtain FDA approval; and (iv) as a result, the public statements regarding the IND were materially false and misleading. The parties stipulated to a stay of the Stockholder Derivative Complaint until (1) the dismissal of the Complaint described above, (2) denial of a motion to dismiss the Complaint, or (3) notice is given that any party is withdrawing its consent to the stipulated stay of the Stockholder Derivative Complaint proceeding. At this early stage of the proceedings, we are unable to make any prediction regarding the outcome of the litigation.

In the ordinary course of business, we may become involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements, employment, regulatory compliance, and other matters. Except as described above, at December 31, 2021, 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." On August 13, 2021, we received a deficiency letter from the Staff of Nasdaq notifying us that we did not meet the $1.00 per share minimum bid price requirement for continued inclusion on the Nasdaq Capital Market pursuant to the Minimum Bid Price Requirement. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days to regain compliance with the Minimum Bid Price Requirement, which ended February 9, 2022. On February 10, 2022, we received an additional notice from the Staff stating that, although we had not regained compliance with the Minimum Bid Price Rule by February 9, 2022, the Staff determined in accordance with Nasdaq Listing Rule 5810(c)(3)(A) that we are eligible for an additional 180 calendar days from the date of that notice, or until August 8, 2022, to regain compliance with the Minimum Bid Price Rule. To regain compliance, the bid price for the Company's common stock must close at $1.00 per share or more for a minimum of 10 consecutive business days. To resolve the noncompliance, we may consider available options, including effecting a reverse stock split.

At March 25, 2022, there were approximately 98 holders of record of our common stock.

The following table provides information on our compensation plans at December 31, 2021, 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	5,677,802	$ 7.81	194,102
Equity compensation plans not approved by security holders (1)	95,000	$ 13.36	-
Total	5,772,802		194,102

(1) These plans are individual grants of stock options to three 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
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 three-month period ended December 31, 2021, 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.

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
October 1-31, 2021	78,846	$ 0.59	N/A	N/A
November 1-30, 2021	–	$ –	N/A	N/A
December 1-31, 2021	150,434	$ 0.41	N/A	N/A
Total	229,280	$ 0.47		

Item 6. [Reserved]

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 above in 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

PolarityTE is a clinical stage biotechnology company developing regenerative tissue products and biomaterials. PolarityTE also operates a pre-clinical research business. PolarityTE's 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.

Since the beginning of 2017, PolarityTE has incurred substantial operating losses and its operations have been financed primarily by public equity financings. The clinical trials for SkinTE and the regulatory process will likely result in an increase in PolarityTE's expenses. PolarityTE will continue to incur substantial operating losses as we pursue an IND and BLA, and PolarityTE expects to seek financing from external sources over the foreseeable future to fund its operations.

Regenerative Tissue Product

Our first regenerative tissue product is SkinTE. On July 23, 2021, we submitted an IND for SkinTE to the FDA through our subsidiary, PTE-MD, as the first step in the regulatory process for obtaining licensure for SkinTE under Section 351 of the Public Health Service Act. The FDA subsequently issued clinical hold correspondence to us identifying certain issues that needed to be addressed before the IND could be approved. We provided responses to the FDA, and on January 14, 2022, the FDA sent correspondence informing us that the clinical hold had been removed. The IND approval enables us to commence the first of two expected pivotal studies needed to support a BLA seeking a chronic cutaneous ulcer indication for SkinTE. The first planned pivotal study is the COVER DFUs Trial, which is a multi-center, randomized controlled trial evaluating SkinTE in the treatment of Wagner 2 DFUs. We plan to enroll up to 100 patients at up to 20 sites in the U.S. in the COVER DFUs Trial, which will compare treatment with SkinTE plus the standard-of-care to the standard-of-care alone. The primary endpoint is the incidence of DFUs closed at 24 weeks. Secondary endpoints include PAR at 4, 8, 12, 16, and 24 weeks, improved quality of life, and new onset of infection of the DFU being evaluated. As we pursue the first study, we plan to engage in discussions with the FDA regarding the design and implementation of the second pivotal study.

We expect to incur significant operating costs in the next three to four calendar years as we pursue the regulatory process for SkinTE with the FDA, conduct clinical trials and studies, and pursue product research, all while operating our business and incurring continuing fixed costs related to the maintenance of our assets and business. We expect to incur significant losses in the future, and those losses could be more severe as a result of unforeseen expenses, difficulties, complications, delays, and other unknown events. 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 licensure 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. At the beginning of May 2018, we acquired a preclinical research and veterinary sciences business to be used, in part, for preclinical studies on its regenerative tissue products, which we operate through our subsidiary IBEX. Through Arches and IBEX, we also offered research and laboratory testing services to unrelated third parties on a contract basis. As noted above, Arches offered COVID-19 testing from the end of May 2020 to August 2021, when it discontinued the service, and since then Arches has been engaged in supporting our IND and clinical trial effort and has not offered services to outside third parties. IBEX continues to offer pre-clinical research services to third parties, which generates positive cash flow to defray our operating expenses, but we do not believe this positive cash flow will be a significant contributor to defraying our costs associated with obtaining regulatory licensure or approval of SkinTE.

PPP Loan

As described above, PTE-MD entered into a promissory note evidencing an unsecured loan in the amount of $3,576,145 made to PTE-MD under the Paycheck Protection Program. On October 15, 2020, PTE-MD applied to the Lender for forgiveness of the PPP Loan in its entirety (as provided for in the CARES Act) based on PTE-MD's use of the PPP Loan for payroll costs, rent, and utilities. On October 26, 2020, PTE-MD was advised that the Lender approved the application, and that the Lender was submitting the application to the SBA for a final decision. The SBA subsequently approved PTE-MD's application for forgiveness of the PPP Loan, and the principal and interest of $3,612,376 was fully paid by the SBA on June 12, 2021.

On September 17, 2021, PTE-MD received notice from the Lender that the SBA is reviewing the PPP Loan. As part of this review, the SBA requested that PTE-MD provide documents that it is required to maintain but may not have been required to submit with its application for the PPP Loan. These documents included an affiliation worksheet showing the relationship between PolarityTE and PTE-MD and affiliated subsidiaries, documents showing the use of the PPP Loan proceeds, documents showing PTE-MD's calculation of the loan amount it requested in its loan application, our federal tax returns, and documents showing employee compensation information. PTE-MD submitted the documents to the SBA through the Lender on September 28, 2021, and there has been no further communication from the SBA since that date.

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 licensure of SkinTE under a BLA is highly uncertain and cannot be accurately predicted. We have engaged and will need to continue to engage 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.

Recent Developments

On March 16, 2022, we completed a registered direct offering of (i) 3,000.000435 shares of Series A Convertible Preferred Stock, par value $0.001 per share ("Series A"); (ii) 2,000.00029 shares of Series B Convertible Preferred Stock, par value $0.001 per share ("Series B," and together with the Series A, the "Preferred Stock"); and (iii) warrants to purchase up to 16,393,445 shares of common stock ("Common Warrants"). The shares of Preferred Stock have a stated value of $1,000 per share and are convertible, following the date of the issuance thereof, into an aggregate of 9,836,067 shares of our common stock upon the conversion of Series A and into an aggregate of 6,557,378 shares of our common stock upon the conversion of Series B, at a conversion price of $0.305 per share each. Each Common Warrant has an exercise price of $0.35 per share and will become exercisable six months after the original issuance date and will expire two years following the original issuance. We also issued to designees of the placement agent for the registered direct offering as part of the placement agent's compensation warrants to purchase up to 819,672 shares of common stock at an exercise price of $0.38125 per share. We expect to realize net proceeds of approximately $4,485,000 from the offering after deducting offering expenses. On March 17, 2022, the holder of the Series B converted the shares to 6,557,378 shares of our common stock.

The investor in this offering is a holder of warrants to purchase up to 9,090,901 shares of common stock at an exercise price of $1.20 per share issued on January 14, 2021, and warrants to purchase up to 8,016,033 shares of common stock at an exercise price of $1.20 per share issued on January 25, 2021 (collectively, the "Existing Warrants"). Concurrent with the offering, we entered into a Warrant Amendment Agreement (the "Warrant Amendment Agreement") with the investor pursuant to which, in consideration for the investor's purchase of $5 million of securities in the offering (the "Purchase Commitment"), we agreed to reduce the exercise price of the Existing Warrants to $0.35 per share, effective upon the consummation of the offering, and confirmation by the placement agent that the investor satisfied the Purchase Commitment. Pursuant to the Warrant Amendment Agreement, the Existing Warrants will not be exercisable at the adjusted price until the date that is six months after the consummation of this offering. Except for these amendments, no other changes have been made to the Existing Warrants. We are currently assessing the impact of the Existing Warrant exercise price reduction to our consolidated financial statements.

On March 30, 2021, we entered into a sales agreement ("Sales Agreement") with an investment banking firm to sell shares of 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 the investment banking firm would act as sales agent. By written notice given by us to the investment banking company on February 28, 2022, we exercised our right to terminate the Sales Agreement and the "at the market" equity offering program. As of the date of termination, no common stock had been sold under the Sales Agreement. Upon such termination we were obligated to make a one-time payment to the investment banking firm of $400,000.

Liquidity and Capital Resources

As of December 31, 2021, we had $19.4 million in cash and cash equivalents and working capital of approximately $17.7 million. As of December 31, 2020, we had $25.5 million in cash and cash equivalents, and working capital of approximately $22.7 million.

We believe cash and cash equivalents on our balance sheet will fund our business activities into the fourth calendar quarter of 2022. For the year ended December 31, 2021, cash used in operating activities was $22.6 million, or an average of $1.9 million per month, compared to $37.8 million of cash used in operating activities, or an average of $3.2 million per month, for the year ended December 31, 2020.

As noted above, we are focused primarily on the advancement of our IND and subsequent BLA to attain a license to manufacture and distribute SkinTE. To that end, in June 2021, we engaged a CRO to provide services for the COVER DFUs Trial at a cost of approximately $6.5 million consisting of $3.1 million of service fees and $3.4 million of estimated costs. In July 2021, we prepaid 10% of the total cost of the original work order, or $0.5 million, which will be applied to payment of the final invoice under the work order. Over the approximately three-year term of the DFU Trial the service provider will submit to us for payment invoices on a monthly basis for units of work stated in the work order that are completed and billable expenses incurred. Our expectation is that the second clinical trial will be similar to the COVER DFUs Trial with respect to size, length of time to complete, and cost. In the course of advancing our IND and subsequent BLA, we may propose additional clinical trials to advance our application or broaden the therapeutic indications of use 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, our most significant uses of cash to maintain our business going forward are expected to be compensation, costs of occupying, operating, and maintaining our facilities, and the costs associated with maintaining our status as a publicly traded company listed on Nasdaq.

For the year ended December 31, 2021, the gross profit on sales of SkinTE was $2.6 million, which partially contributed to covering our operating costs for the period. As discussed above in this Annual Report, we ceased our SkinTE sales activity at the end of May 2021, so SkinTE sales will not contribute to defraying our operating costs in 2022. To mitigate the effect of this lost revenue, we eliminated some staff and resources that supported the SkinTE commercial effort, but we did not see the benefit of these cost reductions until the fourth quarter of 2021 because of severance and other costs associated with winding down our SkinTE commercial activity. In 2022 our plan is to preserve the facilities, equipment, and staff we need to advance the COVER DFUs Trial and other work necessary for advancing the process for obtaining regulatory approval of SkinTE.

During 2021, we engaged in discussions with certain third parties regarding potential M&A and strategic initiatives. In the fourth quarter of 2021 we recognized $1.2 million one-time costs for professional services associated with such M&A and strategic initiatives and estimate we will recognize an additional $1.4 million of such costs in the first quarter of 2022.

As of the date of this Annual Report we do not expect that our cash and cash equivalents of $19.4 million as of December 31, 2021, would be sufficient to fund our current business plan including related operating expenses and capital expenditure requirements beyond the fourth calendar quarter of 2022. Accordingly, there is substantial doubt about our ability to continue as a going concern, as we do not believe that our cash and cash equivalents will be sufficient to fund our business plan for at least twelve months from the date of issuance of our annual financial statements. We plan to address this condition by raising additional capital to finance our operations. 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 we may not be successful in obtaining additional financing. Therefore, it is not considered probable, as defined in applicable accounting standards, that our plan to raise additional capital will alleviate the substantial doubt regarding our ability to continue as a going concern.

To enhance our ability to do future financings, on February 11, 2022, we filed a registration statement on Form S-3 to register sales of our securities after our current registration statement on Form S-3 expires with the filing of this Annual Report. Pursuant to General Instruction I.B.6 of Form S-3, after this Annual Report and the new Form S-3 registration statement is effective the aggregate market value of securities sold by us during the period of 12 calendar months immediately prior to, and including, the sale is limited to one-third of the aggregate market value of the voting and non-voting common equity held by our non-affiliates so long as the aggregate market value of our common stock held by non-affiliates is less than $75.0 million. In the event that subsequent to the effective date of the new Form S-3 registration statement the aggregate market value of our outstanding common stock held by non-affiliates equals or exceeds $75.0 million, then the one-third limitation on sales shall not apply to additional sales.

Our actual capital requirements will depend on many factors, including the cost and timing of advancing our IND and subsequent BLA for SkinTE, the cost and timing of clinical trials, the cost of establishing and maintaining our facilities in compliance with cGMP and cGTP (current good tissue practices) regulations, and the cost and timing of advancing our product development initiatives related to SkinTE. Our forecast of the period of time through which our financial resources will be adequate to support its operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

We will need to raise additional capital in the future to fund our effort to obtain FDA approval of SkinTE and maintain our operations. Any additional equity financing including financings involving convertible securities, if able to be obtained, may be highly dilutive, on unfavorable terms, or otherwise disadvantageous, to existing stockholders, and debt financing, if available, may involve restrictive covenants or require us to grant a security interest in our assets. If we elect to pursue collaborative arrangements, the terms of such arrangements may require us to relinquish rights to certain of our technologies, products, or marketing territories. Our failure to raise additional capital when needed, and on acceptable terms, would require us to reduce our operating expenses and would limit our ability to continue operations, any of which would have a material adverse effect on our business, financial condition, and results of operation.

Results of Operations

Changes in Polarity's Operations

There have been significant changes in our operations affecting Polarity's results of operations for the year ended December 31, 2021, compared to year ended December 31, 2020.

SkinTE was registered and listed with the FDA in August 2017 based on our determination that SkinTE should be 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, and while SkinTE was marketed it was used in complex wounds, such as diabetic foot ulcers penetrating to tendon, capsule, and bone classified, Stage 3 and 4 pressure injuries, and acute wounds. Following informal, voluntary discussions with 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, based on the FDA's preliminary assessment, SkinTE should be regulated under Section 351 of the Public Health Service Act. We re-evaluated our regulatory approach and determined it was prudent to submit an IND for SkinTE and an eventual BLA rather than engage in a protracted dispute with the FDA. Accordingly, we ceased commercial sales of SkinTE at the end of May 2021.

On July 23, 2021, we submitted an IND for SkinTE to the FDA through our subsidiary, PTE-MD, as the first step in the regulatory process for obtaining licensure for SkinTE under Section 351 of the Public Health Service Act. The FDA subsequently issued clinical hold correspondence to us identifying certain issues that needed to be addressed before the IND could be approved. We provided responses to the FDA, and on January 14, 2022, the FDA sent correspondence informing us that the clinical hold had been removed. The IND approval enables us to commence the first of two expected pivotal studies needed to support a BLA seeking a chronic cutaneous ulcer indication for SkinTE. We ceased selling SkinTE at the end of May 2021, when the period of enforcement discretion previously announced by the FDA with respect to its IND and premarket approval requirements for 361 HCT/Ps came to an end, and we do not expect to be able to commercialize SkinTE until our BLA is approved, which we believe will take at least three to four years.

Arches began offering COVID-19 testing services in May 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, which substantially added to our services net revenues in the last seven months of 2020 and first three months of 2021. When the New York nursing homes and pharmacies adopted on-site employee testing at the end of March 2021, our COVID-19 testing revenues declined substantially, and in August 2021, we decided to cease COVID-19 testing. Arches focused on supporting our IND and clinical trial efforts for the remainder of 2021, and we expect it will continue in that role in 2022 and not provide research services to third parties.

The COVID-19 pandemic had a significant adverse effect on the preclinical research services offered by IBEX in 2020, but there was a resurgence in that business in 2021. The increase in revenues from IBEX services helped to offset the loss of COVID-19 testing revenues in the last nine months of 2021. As a result, revenues from our services business were unchanged in 2021 compared to 2020 and we expect services revenues will be less in 2022 than 2021 since Arches will not be a contributor to services revenues in 2022.

In March 2022, the Company reached a non-binding understanding with an unrelated third party that contemplates the sale of IBEX and the real property used in the operation of IBEX. The potential sale is subject to a number of contingencies. Even though the proposed sale may not materialize, we are exploring our options with respect to IBEX, which is likely to result in curtailed operation of the business or some other disposition in 2022. Under the circumstance, we believe IBEX may not generate services revenues through the remainder of 2022 that would help defray our operating costs.

As a result of the foregoing developments, we made a number of changes to our operations that impacted our results of operations. These included reductions in its work force in 2021 and 2020, and reducing the services and infrastructure needed to support a larger work force and commercial sales effort.

Comparison of the years ended December 31, 2021, and December 31, 2020.

	For the Year Ended		Increase (Decrease)	
(in thousands)	**December 31, 2021**	**December 31, 2020**	**Amount**	**%**
Net revenues				
Products	$ 3,076	$ 3,730	$ (654)	(18)%
Services	6,328	6,396	(68)	(1)%
Total net revenues	9,404	10,126	(722)	(7)%
Cost of revenues				
Products	448	1,068	(620)	(58)%
Services	3,868	3,356	512	15%
Total cost of revenues	4,316	4,424	(108)	(2)%
Gross profit	5,088	5,702	(614)	(11)%
Operating costs and expenses				
Research and development	14,182	11,532	2,650	23%
General and administrative	20,476	27,557	(7,081)	(26)%
Sales and marketing	2,808	8,719	(5,911)	(68)%
Restructuring and other charges	678	3,834	(3,156)	(82)%
Impairment of goodwill and intangible assets	630	–	630	100%
Total operating costs and expenses	38,774	51,642	(12,868)	(25)%
Operating loss	(33,686)	(45,940)	12,254	(27)%
Other income (expense), net				
Gain on extinguishment of debt	3,612	–	3,612	100%
Change in fair value of common stock warrant liability	4,995	2,914	2,081	71%
Inducement loss on sale of liability classified warrants	(5,197)	–	(5,197)	(100)%
Interest (expense) income, net	(127)	(182)	55	(30)%
Other income, net	216	354	(138)	(39)%
Net loss	$ (30,187)	$ (42,854)	$ 12,667	(30)%

Net Revenues. Net revenues decreased $0.7 million, or 7%, for the year ended December 31, 2021, compared to year ended December 31, 2020.

Products net revenues of $3.1 million in 2021 were 18% less products net revenues in 2020 due to the cessation of commercial sales of SkinTE at the end of May 2021.

The mix of business activity generating services net revenues changed from a majority of service revenues generated by COVID-19 testing in 2020, to a majority of service revenues generated by pre-clinical research services in 2021. Service revenues generated by our pre-clinical research services business in the year ended December 31, 2021, were substantially higher than in 2020, as this business activity experienced a strong recovery from the poor results in 2020, which we believe was caused by the COVID-19 pandemic. Our COVID-19 testing services were a significant contributor to overall services revenues only in the first three months of 2021, which was offset by the increases from revenues from our pre-clinical research services business. As a result of these developments net revenues from services remained essentially unchanged in fiscal year 2021 compared to fiscal year 2020.

Cost of Revenues. The amount for cost of revenues remained essentially unchanged for the year ended December 31, 2021, compared to year ended December 31, 2020. There was a change, however, in the mix of cost of revenues amounts between products and services. Due to the cessation of SkinTE sales activity at the end of May 2021, products cost of revenues decreased by 58% from $1.1 million in 2020 to $0.4 million in 2021. This decrease was largely offset by an increase in services cost of revenues in the amount of $0.5 million. Services cost of revenues increased from $3.4 million in 2020 to $3.9 million in 2021 due to an increase in revenues and resulting cost of sales in our pre-clinical research services, which is a lower margin business than the COVID -19 testing services that was the major component of our services revenues in 2020.

Operating Costs and Expenses. Operating costs and expenses decreased $12.9 million, or 25%, for the year ended December 31, 2021, compared to the year ended December 31, 2020. The reduction in operating costs and expenses is attributable to reductions in general and administrative expenses, sales and marketing expenses, and restructuring and other charges that were partially offset by increases in research and development expenses.

Research and development expenses increased 23% for the year ended December 31, 2021, compared to the year ended December 31, 2020. The substantial increase in 2021 is primarily attributable to an increase in lab supply costs and consulting services for work on the CMC elements of our IND; re-allocation of costs for manufacturing supplies and compensation following the cessation of SkinTE sales from products cost of goods, general and administrative expenses, and sales and marketing expenses to research and development costs; the costs in our pre-IND clinical trials that we concluded during 2021; and, costs incurred in connection with the planning and initial payments required for the clinical trial we are about to begin under the IND for SkinTE.

We effectuated a reduction in force for our commercial operations in 2021. Consequently, there were reductions in cash compensation, stock compensation, consulting fees, and travel expense. As we reduced and then ended our commercial sales of SkinTE, we also reduced expenses related to a larger operation by terminating our lease for the Utah corporate office in September 2020 and ceasing operations at our manufacturing node in Georgia in the fourth quarter of 2020, from which we recognized the benefits in 2021. Furthermore, with the cessation of SkinTE sales we re-allocated manufacturing supplies and compensation from general and administrative expenses to research and development costs. These reductions were partially offset by executive and employee bonus compensation paid or accrued in 2021 at levels higher than bonus compensation paid or accrued in 2020 and professional fees incurred in connection with our pursuit of a strategic transaction that did not materialize. The cost cutting measures and re-allocation of costs described above are the primary causes of a 26% decrease in general and administrative expense period over period for the year ended December 31, 2021, compared to the year ended December 31, 2020.

When we reduced the commercial sales team and related commercial activities, we also took steps to reduce staff and consultants in sales and marketing. With the cessation of SkinTE sales several employees who supported sales and marketing moved into new roles in research and development, so their compensation was allocated to research and development. Consequently, there were significant reductions in cash compensation, stock compensation, consulting fees, and travel expense, which resulted in a 68% decrease in sales and marketing expense for the year ended December 31, 2021, compared to the year ended December 31, 2020.

We realized restructuring and other charges as a result of the transition to a clinical stage company, much of which were recognized in the year ended December 31, 2020. In connection with reducing our commercial sales activity in 2020 we incurred severance charges of $1.1 million. We abandoned operations at the manufacturing node in Augusta, Georgia, which resulted in the recognition of a charge in the amount of $1.2 million consisting of equipment, leasehold improvements, and a right of use asset. In 2020 we also decided to abandon equipment in addition to the development of a vivarium research facility at our Salt Lake City location resulting in a charge of $1.5 million. By contrast, during the 12-month period ended December 31, 2021, we recognized an impairment of property and equipment in the amount of $0.4 million and severance charges of $0.6 million, which were offset by a $0.3 million gain on the termination of Polarity's Augusta node lease. Consequently, there was an 82% decrease in restructuring and other charges for the year ended December 31, 2021, compared to the year ended December 31, 2020.

We recognized an impairment of goodwill and intangible assets pertaining to IBEX for $0.6 million based on management's judgment regarding the likelihood that IBEX will continue to be a meaningful contributor to the operations of the Company through the remainder of 2022.

Operating Loss and Net Loss. Operating loss decreased $12.3 million, or 27%, for the year ended December 31, 2021, compared to the year ended December 31, 2020. Net loss decreased $12.7 million, or 30%, for the year ended December 31, 2021, compared to the year ended December 31, 2020.

Warrants issued in connection with financings we completed in 2021 and 2020 are classified as liabilities and remeasured each period until settled, classified as equity or expiration. As a result of the periodic remeasurement, we recorded a gain for change in fair value of common stock warrant liability of $5.0 million for the year ended December 31, 2021, compared to a gain of $2.9 million for the year ended December 31, 2020. For additional information on the change in fair value of common stock warrant liability please see Note 12 to the Consolidated Financial Statements included in this report.

We issued common stock purchase warrants in January 2021, as an inducement to holders of warrants issued in December 2020 to exercise those December warrants. As a result, we recognized an inducement loss of $5.2 million. There was no similar action taken in 2020.

When the PPP Loan was forgiven in June 2021, we recognized a gain on extinguishment of debt in the amount of $3.6 million. This gain together with the positive change in fair value of common stock warrant liability was offset by the inducement loss of $5.2 million recognized in January 2021, which, primarily accounts for the difference of $3.5 million between our operating loss and net loss for the year ended December 31, 2021.

Critical Accounting Policies and Estimates

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. Our management 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 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. We measure all stock-based compensation to employees and non-employees using a fair value method. For stock options with graded vesting, we recognize 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 commensurate with the expected term of the option. The volatility factor is determined based on our 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 our common stock on the date of grant and amortized to compensation expense over the vesting period of, generally, six months to three years.

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, 2021, 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, 2021. 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, 2021.

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, 2021.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

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 2022 annual meeting of stockholders (our "2022 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 2022 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 2022 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 2022 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, 2022, in our 2022 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 2022 Proxy Statement, our 2022 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 2022 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. (incorporated by reference to Exhibit 1.1 to our Annual Report on Form 10-K filed on March 30, 2021)
3.1	Restated Certificate of Incorporation of PolarityTE, Inc. (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on October 1, 2021).
3.2	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on March 17, 2022).
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K filed on March 17, 2022).
3.4	PolarityTE, Inc., Amended and Restated Bylaws - September 28, 2021 (incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K filed on October 1, 2021).
4.1	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)
4.2	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)
4.3	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)
4.4	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)
4.5	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)
4.6	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)
4.7	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)
4.8	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)
4.9	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)
4.10	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)

4.11	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)
4.12	Form of Common Warrant – March 2022 (incorporated by reference to Exhibit 4.1 to our Form 8-K filed with the SEC on March 17, 2022)
4.13	Form of Placement Agent Warrant – January 2021 March 2022 (incorporated by reference to Exhibit 4.2 to our Form 8-K filed with the SEC on March 17, 2022)
#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	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)
#10.09	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)
#10.10	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)
#10.11	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)
#10.12	PolarityTE 2017 Equity Incentive Plan (incorporated by reference to Appendix A of our proxy statement filed with the SEC on February 24, 2017)
#10.13	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)
#10.14	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)
#10.15	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)
#10.16	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)
#10.17	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)
#10.18	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)
#10.19	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)
#10.20	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)
#10.21	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)
#10.22	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)
#10.23	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)
#10.24	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)
#10.25	Employment Agreement with Richard Hague dated August 18, 2021 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on August 24, 2021)
#10.26	Employment Agreement with Cameron Hoyler dated August 18, 2021 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the SEC on August 24, 2021)

#10.27	Employment Agreement with Jacob Patterson dated August 18, 2021 (incorporated by reference to Exhibit 10.3 to our Form 8-K filed with the SEC on August 24, 2021)
#10.28	Consulting Agreement with David Seaburg dated September 1, 2021 (incorporated by reference to Exhibit 10.4 to our Form 10-Q filed with the SEC on November 10, 2021)
10.29	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)
10.30	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)
10.31	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)
10.32	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)
10.33	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)
10.34	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)
10.35	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)
10.36	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)
10.37	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)
10.38	Purchase and Sale Agreement between PolarityTE, Inc., and BCG Acquisitions LLC (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the SEC on December 17, 2021)
10.39	Purchase and Sale Agreement between PolarityTE, Inc., and Adcomp LLC (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the SEC on March 15, 2022)
10.40	Amendment No. 1 to Purchase and Sale Agreement between PolarityTE, Inc., and BCG Acquisitions LLC (incorporated by reference to Exhibit 10.4 to our Form 8-K filed with the SEC on March 15, 2022)
10.41	Form of Securities Purchase Agreement dated March 15, 2022 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on March 17, 2022)
10.42	Form of Warrant Amendment Agreement dated March 15, 2022 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the SEC on March 17, 2022)
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
*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	Inline EXBRL Instance Document
*101.SCH	Inline XBRL Taxonomy Extension Schema Document
*101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
*101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
*101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
*101.PRE	Inline 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/ Richard Hague*
Chief Executive Officer
(Principal Executive Officer)

Date: March 30, 2022

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

Date: March 30, 2022

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, 2022
/s/ Jeffrey Dyer Jeffrey Dyer	Director	March 30, 2022
/s/ Chris Nolet Chris Nolet	Director	March 30, 2022
/s/ Willie C. Bogan Willie C. Bogan	Director	March 30, 2022
/s/ David Seaburg David Seaburg	Director	March 30, 2022

POLARITYTE, INC. AND SUBSIDIARIES

Consolidated Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
PolarityTE, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of PolarityTE, Inc. and Subsidiaries (the "Company") as of December 31, 2021 and 2020, and the related 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 financial position of the Company as of December 31, 2021 and 2020, and the 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.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has recurring losses and negative cash flows from operating activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 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 financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the 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.

Accounting for Liability Classified Common Stock Warrants

As discussed in Note 12 to the financial statements, the Company issued common stock warrants to purchasers of its common stock. The warrants are classified as a liability and are recorded at fair value in the Company's balance sheets with a value of $6,844,000 as of December 31, 2021. Management utilized the Monte Carlo Simulation model to estimate the fair value of each warrant on the date of issuance and at each interim and annual reporting date until settled or classified as equity. Estimates and assumptions impacting the fair value measurement include simulated future stock price amounts over the remaining life of the commitment, as well as estimated change of control considerations. This valuation technique involves a significant amount of estimation and judgement. In general, the assumptions used in calculating the fair value of the liability classified common stock warrants represent management's best estimate but the estimate involves inherent uncertainties and the application of significant management judgement.

We identified the accounting for liability classified common stock warrants 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. We also applied significant judgement in performing our audit procedures which involved the use of valuation professionals with specialized skill and knowledge to evaluate the audit evidence obtained from the audit procedures performed, in particular to evaluate the reasonableness of management's valuation technique, as well as certain inputs used within the model.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. We obtained an understanding and evaluated the design of controls relating to the Company's valuation and accounting for liability classified common stock warrants. Our procedures also included, among others, (i) use of a valuation specialist in 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.

/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 29, 2022

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

	December 31, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 19,375	$ 25,522
Accounts receivable, net	978	3,819
Inventory	–	883
Assets held for sale	441	–
Prepaid expenses and other current assets	1,595	992
Total current assets	22,389	31,216
Property and equipment, net	6,923	10,550
Operating lease right-of-use assets	1,146	2,452
Intangible assets, net	–	542
Goodwill	–	278
Other assets	720	472
TOTAL ASSETS	$ 31,178	$ 45,510
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 3,115	$ 4,148
Other current liabilities	1,520	2,106
Current portion of long-term note payable	–	2,059
Deferred revenue	74	168
Total current liabilities	4,709	8,481
Common stock warrant liability	6,844	5,975
Operating lease liabilities	43	1,476
Other long-term liabilities	338	723
Long-term notes payable	–	1,517
Total liabilities	11,934	18,172
Commitments and Contingencies (Note 16)		
STOCKHOLDERS' EQUITY		
Preferred stock – 25,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2021 and 2020	–	–
Common stock - $.001 par value; 250,000,000 shares authorized; 82,484,462 and 54,857,099 shares issued and outstanding at December 31, 2021 and 2020, respectively	82	55
Additional paid-in capital	527,560	505,494
Accumulated deficit	(508,398)	(478,211)
Total stockholders' equity	19,244	27,338
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 31,178	$ 45,510

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,	
	2021	**2020**
Net revenues		
Products	$ 3,076	$ 3,730
Services	6,328	6,396
Total net revenues	9,404	10,126
Cost of revenues		
Products	448	1,068
Services	3,868	3,356
Total costs of revenues	4,316	4,424
Gross profit	5,088	5,702
Operating costs and expenses		
Research and development	14,182	11,532
General and administrative	20,476	27,557
Sales and marketing	2,808	8,719
Restructuring and other charges	678	3,834
Impairment of goodwill and intangible assets	630	–
Total operating costs and expenses	38,774	51,642
Operating loss	(33,686)	(45,940)
Other income (expense), net		
Gain on extinguishment of debt	3,612	–
Change in fair value of common stock warrant liability	4,995	2,914
Inducement loss on sale of liability classified warrants	(5,197)	–
Interest (expense) income, net	(127)	(182)
Other income, net	216	354
Net loss	$ (30,187)	$ (42,854)
Net loss per share attributable to common stockholders		
Basic	$ (0.38)	$ (1.11)
Diluted	$ (0.38)	$ (1.16)
Weighted average shares outstanding		
Basic	80,014,014	38,779,316
Diluted	80,014,014	39,367,390

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,	
	2021	**2020**
Net loss	$ (30,187)	$ (42,854)
Other comprehensive income (loss):		
Unrealized gain on available-for-sale securities	–	**11**
Reclassification of realized gains included in net loss	–	(83)
Comprehensive loss	$ (30,187)	$ (42,926)

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)

	For the Year Ended December 31, 2021 and 2020					
	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Number	Amount	Capital	Income	Deficit	Equity
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	(117,987)	–	(155)	–	–	(155)
Forfeiture of restricted stock awards	(46,886)	–	–	–	–	–
Other comprehensive income	–	–	–	(72)	–	(72)
Net loss	–	–	–	–	(42,854)	(42,854)
Balance – December 31, 2020	54,857,099	55	505,494	–	(478,211)	27,338
Issuance of common stock and pre-funded warrants through underwritten offering, net of issuance costs of $114	6,670,000	7	1,248	–	–	1,255
Issuance of common stock upon exercise of warrants	10,713,543	10	6,661	–	–	6,671
Reclassification of warrant liability upon exercise	–	–	8,964	–	–	8,964
Issuance of common stock upon exercise of pre-funded warrants	7,658,953	8	–	–	–	8
Stock-based compensation expense	–	–	5,600	–	–	5,600
Stock option exercises	2,500	–	3	–	–	3
Purchase of ESPP shares	101,900	–	55	–	–	55
Vesting of restricted stock units	3,126,564	2	(2)	–	–	–
Shares withheld for tax withholding	(608,144)	–	(463)	–	–	(463)
Forfeiture of restricted stock awards	(37,953)	–	–	–	–	–
Net loss	–	–	–	–	(30,187)	(30,187)
Balance – December 31, 2021	82,484,462	$ 82	$ 527,560	$ –	$ (508,398)	$ 19,244

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,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (30,187)	$ (42,854)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	5,381	7,258
Depreciation and amortization	2,652	3,074
Impairment of goodwill and intangible assets	630	–
Amortization of intangible assets	190	189
Amortization of debt discount	–	19
Bad debt expense	75	148
Inventory write-off	747	–
Gain on extinguishment of debt – PPP loan	(3,612)	–
Change in fair value of common stock warrant liability	(4,995)	(2,914)
Inducement loss on sale of liability classified warrants	5,197	–
Loss on restructuring and other charges	321	–
Loss on sale of property and equipment and ROU assets	12	2,806
Loss on abandonment of property and equipment	209	–
Other non-cash adjustments	(45)	(21)
Changes in operating assets and liabilities:		
Accounts receivable	2,766	(2,236)
Inventory	136	(631)
Prepaid expenses and other current assets	(603)	272
Operating lease right-of-use assets	1,318	1,700
Other assets/liabilities, net	(248)	(200)
Accounts payable and accrued expenses	(1,047)	(2,761)
Other current liabilities	(29)	35
Deferred revenue	(94)	70
Operating lease liabilities	(1,404)	(1,708)
Net cash used in operating activities	(22,630)	(37,754)
CASH FLOWS FROM (USED IN) INVESTING ACTIVITIES		
Purchase of property and equipment	(123)	(1,339)
Proceeds from sale of property and equipment	27	–
Purchase of available-for-sale securities	–	(14,144)
Proceeds from maturities of available-for-sale securities	–	16,945
Proceeds from sale of available-for-sale securities	–	16,171
Net cash provided by/(used in) investing activities	(96)	17,633
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from term note payable and financing arrangements	1,028	4,629
Principal payments on term note payable and financing arrangements	(1,054)	(1,675)
Principal payments on financing leases	(555)	(508)
Net proceeds from the sale of common stock, warrants and pre-funded warrants	9,884	32,020
Proceeds from the sale of new warrants	1,002	–
Proceeds from warrants exercised	6,671	1,008
Proceeds from pre-funded warrants exercised	8	–
Cash paid for tax withholdings related to net share settlement	(463)	(155)
Proceeds from stock options exercised	3	31
Proceeds from ESPP purchase	55	75
Net cash provided by financing activities	16,579	35,425
Net increase (decrease) in cash and cash equivalents	(6,147)	15,304
Cash and cash equivalents - beginning of period	25,522	10,218
Cash and cash equivalents - end of period	$ 19,375	$ 25,522
Supplemental cash flow information:		
Cash paid for interest	$ 118	$ 187
Supplemental schedule of non-cash investing and financing activities:		
Fair value of placement agent warrants issued in connection with offering	$ 838	$ –
Reclassification of warrant liability to stockholders' equity upon exercise of warrant	$ 8,964	$ 8,265
Allocation of proceeds from sale of common stock and warrants to warrant liability	$ 8,629	$ 17,154
Unpaid liability for acquisition of property and equipment	$ 21	$ 87
Right-of-use asset obtained in exchange for new lease liability	$ 42	$ 82
Accrued offering costs	$ 400	$ –
Reclassification of equipment to assets held for sale	$ 441	$ –

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

1. PRINCIPAL BUSINESS ACTIVITY AND BASIS OF PRESENTATION

PolarityTE, Inc. (together with its subsidiaries, the "Company") is a clinical stage biotechnology company developing regenerative tissue products and biomaterials. The Company also operates a laboratory testing and clinical research business.

The Company's first regenerative tissue product is SkinTE. In July 2021, the Company submitted an investigational new drug application ("IND") for SkinTE to the United States Food and Drug Administration (the "FDA") through its subsidiary, PolarityTE MD, Inc. Prior to June 1, 2021, the Company sold SkinTE under Section 361 of the Public Health Service Act in 2020 and into 2021 and, after the Company's decision to file an IND under Section 351 of that Act, under an enforcement discretion position stated by the FDA in a regenerative medicine policy framework to help facilitate regenerative medicine therapies. The FDA's stated period of enforcement discretion ended May 31, 2021. Consequently, the Company terminated commercial sales of SkinTE on May 31, 2021, and ceased its SkinTE commercial operations, and has transitioned to a clinical stage company pursuing an IND for SkinTE. As a result, there are no product sales from commercial SkinTE after June 2021. The only revenues recognized subsequent to June 2021 for SkinTE were nominal amounts collected on accounts for product shipped prior to the end of May 2021 that were not previously recognized because of concerns with collectability.

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 with customers, stock-based compensation, the valuation allowances for deferred tax assets, the valuation of common stock warrant liabilities, and impairment 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), is the Company's Chief Executive Officer (CEO), who 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. As of December 31, 2021, the Company did not hold any cash equivalents.

Accounts Receivable. Accounts receivable at December 31, 2020 consists of amounts due to the Company related to the sale of the Company's core product SkinTE and contract services. Amounts at December 31, 2021 are due from the Company's contract services customers. 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, 2021 and 2020, the Company recorded an allowance of approximately $202,000 and $174,000, 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 to record an inventory reserve. The Company recorded inventory write-offs of $0.7 million for the year ended December 31, 2021, of which $0.3 million and $0.4 million were recorded in research and development and cost of sales, respectively, within the accompanying consolidated statement of operations. No inventory reserve was recorded as of December 31, 2021 or December 31, 2020.

Assets Held for Sale. Assets to be disposed ("disposal group") of by sale are reclassified into assets held for sale on the Company's consolidated balance sheet. The reclassification occurs when an agreement to sell exists, or management has committed to a plan to sell the assets within one year. Disposal groups are measured at the lower of carrying value or fair value less costs to sell and are not depreciated or amortized. The fair value of a disposal group, less any costs to sell, is assessed each reporting period it remains classified as held for sale and any remeasurement to the lower of carrying value or fair value less costs to sell is reported as an adjustment to the carrying value of the disposal group.

In November 2021, the Company committed to a plan to sell a variety of lab equipment within the regenerative medicine products reporting segment. The lab equipment has been designated as held for sale and is presented as such within the consolidated balance sheet as of December 31, 2021.

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 current 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. For the year ended December 31, 2021, the Company performed a qualitative assessment and concluded that it is more likely than not that the fair value of the IBEX reporting unit was less than its carrying value which resulted in the Company also performing a quantitative analysis. The results of the quantitative analysis showed the carrying value of the reporting unit exceeding its fair value.

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. For the year ended December 31, 2021, the Company identified indicators of impairment which led the Company to perform an assessment that resulted in carrying values of the intangible assets exceeding the undiscounted cash flows.

As a result of the goodwill and intangible assets impairment analyses, the Company determined that goodwill and intangible assets of the IBEX reporting unit were fully impaired and recorded impairment charges of $0.6 million for the year ended December 31, 2021 within the Company's contract services business segment and are included in impairment of goodwill and intangible assets within the accompanying consolidated statement of operations.

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.

Offering Costs. The Company capitalizes direct and incremental costs (i.e., consisting of legal, accounting, and other fees and costs) associated with equity financings until such financings are consummated, at which time such costs are recorded in additional paid-in capital against the gross proceeds of the equity financings. If the related equity financing is abandoned, the previously deferred offering costs will be charged to expense in the period in which the offering is abandoned.

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 that the Company 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 recorded product revenues primarily from the sale of SkinTE, its regenerative tissue products. When the Company marketed its SkinTE product, it was sold to healthcare providers (customers), primarily through direct sales representatives. Product revenues consisted of a single performance obligation that the Company satisfies at a point in time. In general, the Company recognized product revenue upon delivery to the customer.

In the contract services segment, the Company records service revenues from the sale of its preclinical 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 an appropriate measure 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 also includes research and laboratory testing services to unrelated third parties on a contract basis. Due to the short-term nature of the services, these customer contracts generally consist of a single performance obligation that the Company satisfies at a point in time. The Company satisfies the single performance obligation and recognizes revenue upon delivery of testing results to the customer. As of December 31, 2021 and 2020, the Company had unbilled receivables of $0.5 million and $0.2 million, respectively, and deferred revenue of $0.1 million and $0.2 million, respectively. The unbilled receivables balance is included in consolidated accounts receivable. Revenue of $0.2 million was recognized during the year ended December 31, 2021 that was included in the deferred revenue balance as of December 31, 2020.

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. Customers that accounted for 10% or more of net revenues were as follows:

	Segment	For the Year Ended December 31, 2021 % of Revenue	For the Year Ended December 31, 2020 % of Revenue
Customer A	Contract Services	20%	–%
Customer B	Regenerative Medicine Products	13%	13%
Customer C	Contract Services	18%	41%

Customers that accounted for 10% or more of accounts receivable were as follows:

	Segment	December 31, 2021 % of Accounts Receivable	December 31, 2020 % of Accounts Receivable
Customer A	Contract Services	31%	–%
Customer B	Regenerative Medicine Products	–%	14%
Customer C	Contract Services	–%	46%
Customer F	Contract Services	17%	–%
Customer G	Contract Services	12%	–%

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

	For the Year Ended December 31, 2021	For the Year Ended December 31, 2020
Regenerative Medicine Products		
SkinTE Products	$ 3,076	$ 3,730
Contract Services		
Lab Testing Services	1,877	4,454
Preclinical Research Services	4,451	1,942
	6,328	6,396
Total Net Revenues	$ 9,404	$ 10,126

Research and Development Expenses. Costs incurred for research and development are expensed as incurred. Nonrefundable advance payments for goods or services 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 at fair value each period until settled or until classified as equity.

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 commensurate with the expected term of the option. 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 recognized as compensation expense 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. All common stock warrants issued participate on a one-for-one basis with common stock in the distribution of dividends, if and when declared by the Board of Directors, on the Company's common stock. For purposes of computing earnings per share (EPS), these warrants are considered to participate with common stock in earnings of the Company. Therefore, the Company calculates basic and diluted EPS using the two-class method. Under the two-class method, net income for the period is allocated between common stockholders and participating securities according to dividends declared and participation rights in undistributed earnings. No loss was allocated to the warrants for the years ended December 31, 2021 and 2020 as results of operations were a loss for each period and the warrant holders are not required to absorb losses. The Company has issued pre-funded warrants from time to time at an exercise 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 basic 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.

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 was 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 August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* (ASU 2020-06). ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. Those instruments that do not have a separately recognized embedded conversion feature will no longer recognize a debt issuance discount related to such a conversion feature and would recognize less interest expense on a periodic basis. It also removes from ASC 815-40-25-10 certain conditions for equity classification and amends certain guidance in ASC Topic 260 on the computation of EPS for convertible instruments and contracts in an entity's own equity. An entity can use either a full or modified retrospective approach to adopt the ASU's guidance. As a smaller reporting company, the Company is required to adopt this ASU for the fiscal year beginning January 1, 2024, with early adoption permitted for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company is currently assessing the impact and timing of adoption of this ASU.

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt— Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging— Contracts in Entity's Own Equity (Subtopic 815-40)* (ASU 2021-04). ASU 2021-04 updates current accounting guidance for modifications or exchanges of freestanding equity-classified written call options that remain equity-classified after modification or exchange as an exchange of the original instrument for a new instrument. The ASU specifies that the effects of modifications or exchanges of freestanding equity-classified written call options that remain equity after modification or exchange should be recognized depending on the substance of the transaction, whether it be a financing transaction to raise equity (topic 340), to raise or modify debt (topic 470 and 835), or other modifications or exchanges. If the modification or exchange does not fall under topics 340, 470, or 835, an entity may be required to account for the effects of such modifications or exchanges as dividends which should adjust net income (or loss) in the basic EPS calculation. The Company is required to apply the amendments within this ASU prospectively to modifications or exchanges occurring on or after the effective date of the amendment. The Company plans to adopt this ASU on January 1, 2022. The Company does not expect the adoption of the new guidance to have a significant impact on its consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncements

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 Company adopted this standard prospectively on January 1, 2021. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements and related disclosures.

3. LIQUIDITY AND GOING CONCERN

The Company has experienced recurring losses and cash outflows from operating activities. As of December 31, 2021, the Company had an accumulated deficit of $508.4 million. As of December 31, 2021, the Company had cash and cash equivalents of $19.4 million. The Company has been funded historically through sales of equity and debt.

These financial statements have been prepared on a going concern basis, which assumes the Company will continue to realize its assets and settle its liabilities in the normal course of business. The Company's significant operating losses raise substantial doubt regarding the Company's ability to continue as a going concern for at least one year from the date of issuance of these consolidated financial statements. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might result from the outcome of this uncertainty. The Company is a clinical stage biotechnology company that has historically incurred losses and negative cash flows. Consequently, the future success of the Company depends on its ability to attract additional capital and, ultimately, on its ability to successfully complete the regulatory approval process for its product, SkinTE, and develop future profitable operations. The Company will seek additional capital through equity offerings or debt financing. However, such financing may not be available in the future on favorable terms, if at all.

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.
- Level 2: Quoted prices for similar instruments that are directly or indirectly observable in the market.
- Level 3: Significant unobservable inputs supported by little or no market activity. Financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, for which determination of fair value requires significant judgment or estimation.

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.

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 (in thousands):

	December 31, 2021			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities				
Common stock warrant liability	$ –	$ –	$ 6,844	$ 6,844
Total	$ –	$ –	$ 6,844	$ 6,844

	December 31, 2020			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities				
Common stock warrant liability	$ –	$ –	$ 5,975	$ 5,975
Total	$ –	$ –	$ 5,975	$ 5,975

The Company assesses its long-lived assets, including property, plant, and equipment, ROU assets, intangible assets, and goodwill, at fair value on a non-recurring basis. The Company reviews the carrying amounts of such assets when events indicate that their carrying amounts may not be recoverable. Any resulting impairment would require that the asset be recorded at its fair value. During the year ended December 31, 2021, the Company recognized an impairment charge of $0.6 million related to definite-lived intangible assets and goodwill and $0.4 million related to property and equipment. As of each measurement date, the fair value of goodwill, intangibles and property and equipment was determined utilizing Level 3 inputs. Fair values of goodwill and intangibles and property and equipment was determined based on a market approach and income approach, respectively. See Note 8 and Note 15 for additional details.

The following table presents the change in fair value of the liability classified common stock warrants for the year ended December 31, 2021 (in thousands):

	Fair Value at December 31, 2020	Initial Fair Value at Issuance	(Gain) Loss Upon Change in Fair Value	Liability Reduction Due to Exercises	Fair Value at December 31, 2021
Warrant liabilities					
February 14, 2020 issuance	$ 328	$ –	$ (37)	$ –	$ 291
December 23, 2020 issuance	5,647	–	3,556	(8,964)	239
January 14, 2021 issuance	–	8,629	(5,284)	–	3,345
January 25, 2021 issuance[1]	–	6,199	(3,230)	–	2,969
Total	$ 5,975	$ 14,828	$ (4,995)	$ (8,964)	$ 6,844

(1) Concurrent with the issuance of the January 25, 2021 warrants, upon the exercise of the December 23, 2020 warrants, an inducement loss of $5.2 million was recorded as the fair value of the initial warrant liability for the new warrants of $6.2 million exceeded the gross proceeds received upon sale of the new warrants of approximately $1.0 million

The following table presents the change in fair value of the liability classified common stock warrants for the year ended December 31, 2020 (in thousands):

	Initial Fair Value at Issuance	Liability Reduction Due to Exercises	(Gain) Loss Upon Change in Fair Value	Fair Value at 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 2021 and 2020. Input assumptions for these freestanding instruments are as follows:

	For the Year Ended December 31, 2021
Stock price	$ 0.59 - 1.21
Exercise price	$ 0.10 - 1.38
Risk-free rate	0.42 - 1.27 %
Volatility	99.0 – 103.9 %
Remaining term (years)	4.0 - 5.9

	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

5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

The following table presents the major components of prepaid expenses and other current assets (in thousands):

	December 31, 2021	December 31, 2020
Other current receivable	$ 67	$ 306
Short term deposit	150	–
Prepaid insurance	239	201
Prepaid expenses	445	485
Deferred offering costs	694	–
Total prepaid expenses and other current assets	$ 1,595	$ 992

6. PROPERTY AND EQUIPMENT, NET

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

	December 31, 2021	December 31, 2020
Machinery and equipment	$ 8,502	$ 12,232
Land and buildings	2,000	2,000
Computers and software	1,129	1,240
Leasehold improvements	2,107	2,107
Construction in progress	133	87
Furniture and equipment	123	148
Total property and equipment, gross	13,994	17,814
Accumulated depreciation	(7,071)	(7,264)
Total property and equipment, net	$ 6,923	$ 10,550

The Company sold SkinTE under Section 361 of the Public Health Service Act in 2020 and into 2021 and, after the Company's decision to file an IND under Section 351 of that Act, under an enforcement discretion position stated by the FDA in a regenerative medicine policy framework to help facilitate regenerative medicine therapies. The FDA's stated period of enforcement discretion ended May 31, 2021. Consequently, the Company terminated commercial sales of SkinTE on May 31, 2021, and ceased its SkinTE commercial operations. As a result, there are no product sales from commercial SkinTE after June 2021 and the Company has eliminated or reduced costs associated with commercial sale of SkinTE.

The Company evaluated the future use of its commercial property and equipment and recorded an impairment charge of approximately $0.4 million during the year ended December 31, 2021. The impairment charges occurred within the Company's regenerative medicine products business segment and are included in restructuring and other charges within the accompanying consolidated statement of operations for the year ended December 31, 2021. There were no other impairment charges recorded for the year ended December 31, 2021. See Note 15.

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,	
	2021	2020
General and administrative expense	$ 739	$ 1,533
Research and development expense	1,913	1,541
Total depreciation and amortization expense	$ 2,652	$ 3,074

7. LEASES

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

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 was two 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 provided for monthly lease payments subject to annual increases and had an expiration date in April 2024. 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 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 $1.2 million were reduced to $0 as of December 31, 2020. During the second quarter of 2021, the Company terminated the lease effective June 30, 2021. The Company recorded a net gain on termination of $0.3 million which was included in restructuring and other charges on the consolidated statement of operations.

In November 2021, the Company entered into an operating lease to obtain office equipment with Pacific Office Automation, Inc. The initial term of the lease is three years and it expires on November 2024. The initial base rent under this lease is $3,983 per month for the entire lease term and includes a cash incentive of $0.1 million. Because the rate implicit in the lease is not readily determinable, the Company has used an incremental borrowing rate of 7.42% to determine the present value of the lease payments.

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 3 to 28 months as of December 31, 2021 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.

In the fourth quarter of 2021, management recorded $0.2 million in charges related to the abandonment of finance lease right of use assets. The charges were recorded within the Company's regenerative medicine products business segment and are included in general and administrative expenses within the accompanying consolidated statement of operations.

As of December 31, 2021, the maturities of operating and finance lease liabilities were as follows (in thousands):

Year ending December 31:	Operating leases	Finance leases
2022	$ 1,185	$ 377
2023	48	316
2024	42	42
Total lease payments	1,275	735
Less:		
Imputed interest	(63)	(68)
Total	$ 1,212	$ 667

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

Finance leases

	December 31, 2021	December 31, 2020
Finance lease right-of-use assets included within property and equipment, net	$ 461	$ 1,301
Current finance lease liabilities included within other current liabilities	$ 329	$ 556
Non-current finance lease liabilities included within other long-term liabilities	338	711
Total	$ 667	$ 1,267

Operating leases

	December 31, 2021	December 31, 2020
Current operating lease liabilities included within other current liabilities	$ 1,169	$ 1,485
Operating lease liabilities – non-current	43	1,476
Total	$ 1,212	$ 2,961

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

	For the Year Ended December 31,	
	2021	2020
Operating lease costs included within operating costs and expenses	$ 1,511	$ 2,428
Finance lease costs:		
Amortization of right of use assets	$ 617	$ 698
Interest on lease liabilities	99	151
Total	$ 716	$ 849

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

	For the Year Ended December 31,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash out flows from operating leases	$ 1,596	$ 2,070
Operating cash out flows from finance leases	$ 99	$ 151
Financing cash out flows from finance leases	$ 555	$ 508
Lease liabilities arising from obtaining right-of-use assets:		
Operating leases	$ 42	$ –
Remeasurement of operating lease liability due to lease modification/termination	$ 386	$ 154

As of December 31, 2021, the weighted average remaining operating lease term is 1.0 years and the weighted average discount rate used to determine the operating lease liability was 9.96%. The weighted average remaining finance lease term is 2.0 years and the weighted average discount rate used to determine the finance lease liability was 9.63%.

8. INTANGIBLE ASSETS AND GOODWILL

In March 2022, the Company reached a non-binding understanding with an unrelated third party that contemplates the sale of IBEX and the real property used in the operation of IBEX. The potential sale is subject to a number of contingencies. Even though the proposed sale may not materialize, the Company is exploring its options with respect to IBEX, which is likely to result in curtailed operation of the business or some other disposition in 2022. For the year ended December 31, 2021, the Company performed an impairment review and concluded that goodwill and intangible assets were impaired. This resulted in the Company writing off the goodwill and intangible assets.

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

	December 31, 2021	December 31, 2020
Non-compete agreement	$ –	$ 410
Customer contracts and relationships	–	534
Trade names and trademarks	–	101
Backlog	–	12
Total intangible assets, gross	–	1,057
Accumulated amortization	–	(515)
Total intangible assets, net	$ –	$ 542

Amortization expense for the years ended December 31, 2021 and December 31, 2020 was approximately $0.2 million for each period.

Changes to goodwill during the year ended December 31, 2021 were as follows:

	Total
Balance – December 31, 2020	$ 278
Impairment charge to goodwill	(278)
Balance – December 31, 2021	$ –

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

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

	December 31, 2021	December 31, 2020
Accounts payable	$ 173	$ 1,193
Salaries and other compensation	722	1,129
Legal and accounting	1,082	241
Accrued severance	111	330
Benefit plan accrual	102	659
Clinical trials	161	–
Accrued offering costs	400	–
Other	364	596
Total accounts payable and accrued expenses	$ 3,115	$ 4,148

10. OTHER CURRENT LIABILITIES

The following table presents the major components of other current liabilities (in thousands):

	December 31, 2021	December 31, 2020
Current finance lease liabilities	$ 329	$ 556
Current operating lease liabilities	1,169	1,485
Other	22	65
Total other current liabilities	$ 1,520	$ 2,106

11. 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 Board designated the Compensation Committee of the Board the administrator of 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 7,191,917 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. The 2020 Plan provides that effective on January 1 of each year the number of shares of common stock reserved and available for issuance under the 2020 Plan shall be cumulatively increased by the lesser of 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31 or such lesser number of shares as determined by the 2020 plan administrator. As of December 31, 2021, the Company had 153,927 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 Board designated the Compensation Committee of the Board the administrator of 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, 2021, the Company had 1,361 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 Board designated the Compensation Committee of the Board the administrator of 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, 2021, the Company had 38,814 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, 2020	4,794,567	$	10.03
Granted	1,476,731	$	1.25
Exercised[(1)]	(2,500)	$	1.10
Forfeited	(495,996)	$	8.63
Outstanding – December 31, 2021	5,772,802	$	7.91
Options exercisable, December 31, 2021	4,734,311	$	9.32

(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, 2021 and 2020, the estimated weighted-average grant-date fair value of options granted was $0.91 for both periods. The intrinsic value of options exercised for the years ended December 31, 2021 and 2020 was $0 for both periods. During the years ended December 31, 2021 and 2020, the estimated total grant-date fair value of options vested was $2.6 million and $8.4 million, respectively.

The aggregate intrinsic value of options outstanding and exercisable at December 31, 2021 was $0. The weighted average remaining contractual term of options outstanding and exercisable at December 31, 2021 was 6.15 years. As of December 31, 2021, there was approximately $0.3 million of unrecognized compensation cost related to stock option awards, which is expected to be recognized over a remaining weighted-average vesting period of 1.5 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 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. As of December 31, 2021, the Company had 264,478 shares available for future issuances under the ESPP.

Stock-based compensation related to the ESPP for the years ended December 31, 2021 and 2020 was $40,000 and $64,000, respectively. During the year ended December 31, 2021 a total of 101,900 shares of common stock were purchased at a weighted-average purchase price of $0.54 for total proceeds of $0.1 million pursuant to the ESPP. During the year ended December 31, 2020 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.

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,	
	2021	**2020**
Option grants		
Risk free annual interest rate	0.3% - 1.2 %	0.2% - 1.7 %
Expected volatility	97.9% - 104.7 %	94.3% - 100.9 %
Expected term of options (years)	4.6 – 4.7	4.4 – 4.6
Assumed dividends	–	–
ESPP		
Risk free annual interest rate	0.1% - 0.2 %	0.2% - 1.6 %
Expected volatility	98.4% - 125.2 %	100.5% - 143.2 %
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, 2020	3,468,969
Granted	5,769,593
Vested[(1)]	(3,480,366)
Forfeited	(594,511)
Unvested – December 31, 2021	5,163,685

(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, 2021 and 2020 was $0.73 and $1.18 per share, respectively. The total fair value of restricted stock vested during the years ended December 31, 2021 and 2020 was approximately $4.7 million and $9.0 million, respectively.

As of December 31, 2021, there was approximately $1.3 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 2.3 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,	
	2021	**2020**
General and administrative expense	$ 4,097	$ 5,879
Research and development expense	1,146	943
Sales and marketing expense	357	436
Total stock-based compensation expense	$ 5,600	$ 7,258

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

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 will expire February 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 were classified 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 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 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 was exercisable for one share of the Company's common stock at an exercise price of $0.624 per share. The warrants were immediately exercisable and expire five years from the date of issuance. The holder of the warrants could 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 could 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.

Transaction	Warrants Issued	Warrants Exercised	Outstanding December 31, 2020
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

The Company measured the fair value of the liability-classified warrants issued during 2020 as of December 31, 2021 using the Monte Carlo simulation model using the following inputs:

February 14, 2020 Warrants	December 31, 2021
Stock price	$ 0.59
Exercise price	$ 0.10
Risk-free rate	1.27%
Volatility	102.0%
Remaining term (years)	5.1

December 23, 2020 Warrants	December 31, 2021
Stock price	$ 0.59
Exercise price	$ 0.94
Risk-free rate	1.11%
Volatility	103.9%
Remaining term (years)	4.0

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 (the "January 14 Warrants"). 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 $1.10 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. Each January 14 Warrant is exercisable for one share of the Company's common stock at an exercise price of $1.20 per share. The January 14 Warrants are immediately exercisable and will expire five years from the date of issuance. The holder of the January 14 Warrants may not exercise any portion of such 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 warrants to purchase 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 net proceeds to the Company from the offering were $9.2 million, after direct offering expenses of $0.8 million payable by the Company.

As the January 14 Warrants and placement agent common stock warrants could each require cash settlement in certain scenarios, the January 14 Warrants and placement agent common stock warrants were classified as liabilities upon issuance and were initially recorded at estimated fair values of $8.1 million and $0.5 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 were equity classified because they met 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 $1.4 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 $0.1 million were recorded as a reduction to paid-in capital. Issuance costs allocated to the liability classified warrants of $0.7 million were recorded as an expense. The Company measured the fair value of the accompanying January 14 Warrants and placement agent warrants using the Monte Carlo simulation model at issuance and at December 31, 2021 using the following inputs:

Accompanying common warrants:

	January 14, 2021	December 31, 2021
Stock price	$ 1.21	$ 0.59
Exercise price	$ 1.20	$ 1.20
Risk-free rate	0.49%	1.12%
Volatility	100.1%	103.0%
Remaining term (years)	5.0	4.0

Placement agent warrants:

	January 14, 2021	December 31, 2021
Stock price	$ 1.21	$ 0.59
Exercise price	$ 1.38	$ 1.38
Risk-free rate	0.49%	1.12%
Volatility	99.3%	103.0%
Remaining term (years)	5.0	4.0

On January 22, 2021, the Company entered into a letter agreement with the holder of warrants to exercise the warrants and purchase 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 (the "January 25 Warrants"). Each January 25 Warrant is exercisable for one share of Common Stock at an exercise price of $1.20 per share. The January 25 Warrants are immediately exercisable and will expire five years from the date of issuance. A holder may not exercise any portion of the January 25 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, warrants to purchase 6.0% of the aggregate number of common stock shares and pre-funded warrants sold in the offering (or warrants to purchase up to 480,962 shares of common stock). The placement agent warrants have substantially the same terms as the new warrants. The 10,688,043 warrants issued on December 23, 2020, were exercised on January 22, 2021, and closing of the offering occurred on January 25, 2021. The Company received gross proceeds of approximately $6.7 million from the exercise of the existing warrants and gross proceeds of approximately $1.0 million from the sale of the new warrants.

Immediately prior to the exercise of the existing 10,688,043 liability classified common stock warrants, a remeasurement loss of $3.6 million was recorded. The Company measured the fair value of the common stock warrants using the Monte Carlo simulation model on January 22, 2021, using the following inputs:

	January 22, 2021
Stock price	$ 1.05
Exercise price	$ 0.62
Risk-free rate	0.43%
Volatility	99.4%
Remaining term (years)	4.9

As the new January 25 Warrants and placement agent common stock warrants could each require cash settlement in certain scenarios, the new January 25 Warrants and placement agent common stock warrants were classified as liabilities upon issuance and were initially recorded at estimated fair values of $5.8 million and $0.4 million, respectively. Cash issuance costs of $0.1 million were recorded as an expense. The Company measured the fair value of the accompanying January 25 Warrants and placement agent common stock warrants using the Monte Carlo simulation model at issuance and at December 31, 2021, using the following inputs:

Accompanying new common stock warrants:

	January 25, 2021	December 31, 2021
Stock price	$ 1.02	$ 0.59
Exercise price	$ 1.20	$ 1.20
Risk-free rate	0.42%	1.13%
Volatility	99.0%	103.0%
Remaining term (years)	5.0	4.1

Placement agent warrants:

	January 22, 2021	December 31, 2021
Stock price	$ 1.05	$ 0.59
Exercise price	$ 1.20	$ 1.20
Risk-free rate	0.44%	1.12%
Volatility	99.6%	103.0%
Remaining term (years)	5.0	4.1

The following table summarizes warrant activity for the year ended December 31, 2021.

	Outstanding December 31, 2020	Warrants Issued	Warrants Exercised	Outstanding December 31, 2021
Transaction				
February 14, 2020 common warrants	565,000	–	(25,500)	539,500
December 23, 2020 common warrants	10,688,043	–	(10,688,043)	–
December 23, 2020 placement agent warrants	641,283	–	–	641,283
December 23, 2020 pre-funded warrants	5,238,043	–	(5,238,043)	–
January 14, 2021 common warrants	–	9,090,910	–	9,090,910
January 14, 2021 placement agent warrants	–	545,455	–	545,455
January 14, 2021 pre-funded warrants	–	2,420,910	(2,420,910)	–
January 25, 2021 common warrants	–	8,016,033	–	8,016,033
January 22, 2021 placement agent warrants	–	480,962	–	480,962
Total	17,132,369	20,554,270	(18,372,496)	19,314,143

Pursuant to an Equity Purchase Agreement dated as of December 5, 2019 (the "Purchase Agreement") that the Company 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 below, the Company provided notice to Keystone of its decision to terminate the Purchase Agreement, which was effective on March 26, 2021.

On March 30, 2021, the Company entered into a sales agreement ("Sales Agreement") with an investment banking firm to sell shares of 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 the investment banking firm would act as sales agent for a fee equal to 4% of gross proceeds sold in the offering with a minimum payment of $400,000 if the Sales Agreement was terminated within one year. As of December 31, 2021, no common stock had been sold. The Sales Agreement continues until the earlier of the date shares having aggregate sales proceeds of $50.0 million are sold or the date either party terminates the Sales Agreement by giving three days' prior notice to the other party. On February 28, 2022, the Company exercised its right to terminate the Sales Agreement and was obligated to make a one-time payment to the investment banking firm of $400,000. See Note 21 for additional details.

13. 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 Year Ended December 31,	
Numerator:	**2021**	**2020**
Net loss, primary	$ (30,187)	$ (42,854)
Gain from change in fair value of warrant liabilities	–	2,914
Net loss, diluted	$ (30,187)	$ (45,768)

	For the Year Ended December 31,	
Denominator:	**2021**	**2020**
Basic weighted average number of common shares[(1)]	80,014,014	38,779,316
Potentially dilutive effect of warrants	–	588,074
Diluted weighted average number of common shares	80,014,014	39,367,390

(1) In December 2020 and January 2021, the Company sold pre-funded warrants to purchase up to 5,238,043 and 2,420,910 shares of common stock, respectively. The shares of common stock associated with the pre-funded warrants are considered outstanding for the purposes of computing earnings per share prior to exercise because the shares may be issued for little or no consideration, are fully vested, and are exercisable after the original issuance date. The pre-funded warrants sold in December 2020 and January 2021 were exercised in January 2021and included in the denominator for the period of time the warrants were outstanding.

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:

	For the Year Ended December 31,	
	2021	**2020**
Stock options	5,772,802	4,794,567
Restricted stock	5,163,685	3,468,969
Common stock warrants	19,314,143	–

14. 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. In June of 2021, the Company received notice of forgiveness of the PPP Loan in whole and the Lender was paid by the SBA, including all accrued unpaid interest. The Company recorded the forgiveness of $3.6 million of principal and accrued interest, which were included in gain on extinguishment of debt on the consolidated statement of operations for the year ended December 31, 2021.

On September 17, 2021, the Company received notice from the Lender that the SBA is continuing to review the PPP Loan. As part of this review, the SBA requested documents that the Company is required to maintain but may not have been required to submit with its application for the PPP Loan. These documents included an affiliation worksheet showing the relationship between the Company and Borrower and affiliated subsidiaries, documents showing the use of the PPP Loan proceeds, documents showing the calculation of the loan amount requested in the Company's loan application, federal tax returns, and documents showing employee compensation information. The Company submitted the documents to the SBA through the Lender on September 28, 2021. There has been no additional communication from the SBA as of December 31, 2021.

15. RESTRUCTURING

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.

As discussed in Note 6, the Company decided to file an IND in the second half of 2021, cease commercial sales of SkinTE by May 31, 2021, and wind down its SkinTE commercial operations. As a result, management approved several actions as part of a restructuring plan. Costs associated with the restructuring plan were included in restructuring and other charges on the consolidated statement of operations.

The following table presents the components of incremental restructuring costs and gains associated with the cessation of commercial operations and wind down on SkinTE commercial operation (in thousands):

	Year Ended December 31, 2021	Year Ended December 31, 2020
Property and equipment impairment and disposal	$ 425	$ 2,443
Employee severance and benefit arrangements	390	1,025
Modification of employee stock options	187	–
Net gain on lease termination[(1)]	(324)	–
Abandonment of ROU assets	–	366
Net restructuring costs	$ 678	$ 3,834

(1) During the second quarter of 2021 and effective June 30, 2021, the Company terminated a lease which included manufacturing, laboratory, and office space. The Company recorded a net gain on termination of $0.3 million.

16. COMMITMENTS AND CONTINGENCIES

Contingencies

Securities Class Action and Derivative Lawsuits

On September 24, 2021, a class action complaint alleging violations of the Federal securities laws was filed in the United States District Court, District of Utah, by Marc Richfield against the Company and certain officers of the Company, Case No. 2:21-cv-00561-BSJ. The Court subsequently appointed a Lead Plaintiff and ordered the Lead Plaintiff to file an amended Complaint by February 7, 2022, which was extended to February 21, 2022. The Lead Plaintiff filed an amended complaint on February 21, 2022, against the Company, two current officers of the Company, and three former officers of the Company (the "Complaint"). The Complaint alleges that during the period from January 30, 2018, through November 9, 2021, the defendants made or were responsible for, disseminating information to the public through reports filed with the Securities and Exchange Commission and other channels that contained material misstatements or omissions in violation of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, as amended, and Rule 10b-5 adopted thereunder. Specifically, the Complaint alleges that the defendants misrepresented or failed to disclose that: (i) the Company's product, SkinTE, was improperly registered as a 361 HCT/P under Section 361 of the Public Health Service Act and that, as a result, the Company's ability to commercialize SkinTE as a 361 HCT/P was not sustainable because it was inevitable SkinTE would need to be registered under Section 351 of the Public Health Service Act; (ii) the Company characterized itself as a commercial stage company when it knew sales of SkinTE as a 361 HCT/P were unsustainable and that, as a result, it would need to file an IND and become a development stage company; (iii) issues arising from an FDA inspection of the Company's facility in July 2018, were not resolved even though the Company stated they were resolved; and (iv) the IND for SkinTE was deficient with respect to certain chemistry, manufacturing, and control items, including items identified by the FDA in July 2018, and as a result it was unlikely that the FDA would approve the IND in the form it was originally filed. The Company believes the allegations in the Complaint are without merit, and intends to defend the litigation, vigorously. At this early stage of the proceedings, we are unable to make any prediction regarding the outcome of the litigation.

On October 25, 2021, a stockholder derivative complaint alleging violations of the Federal securities laws was filed in the United States District Court, District of Utah, by Steven Battams against the Company, each member of the Board of directors, and two officers of the Company, Case No. 2:21-cv-00632-DBB (the "Stockholder Derivative Complaint"). The Stockholder Derivative Complaint alleges that the defendants made, or were responsible for, disseminating information to the public through reports filed with the Securities and Exchange Commission and other channels that contained material misstatements or omissions in violation of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, as amended, and Rule 10b-5 adopted thereunder. Specifically, the Stockholder Derivative Complaint alleges that the defendants misrepresented or failed to disclose that: (i) the IND for the Company's product, SkinTE, filed with the FDA was deficient with respect to certain chemistry, manufacturing, and control items; (ii) as a result, it was unlikely that the FDA would approve the IND in its current form; (iii) accordingly, the Company had materially overstated the likelihood that the SkinTE IND would obtain FDA approval; and (iv) as a result, the public statements regarding the IND were materially false and misleading. The parties have stipulated to stay the Stockholder Derivative Complaint until (1) the dismissal of the Complaint described above, (2) denial of a motion to dismiss the Complaint, or (3) notice is given that any party is withdrawing its consent to the stipulated stay of the Stockholder Derivative Complaint proceeding. At this early stage of the proceedings the Company is unable to make any prediction regarding the outcome of the litigation.

Other Matters

In the ordinary course of business, the Company may become involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements, employment, regulatory compliance, and other matters. Except as noted above, at December 31, 2021, 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 provided that Arches would perform specimen testing services for customers referred by Co-Diagnostics to Arches. Co-Diagnostics would arrange all logistics for delivering specimens to Arches for COVID-19 testing for those customers of Co-Diagnostics electing to use the service. Arches would bill Co-Diagnostics for the testing services and Co-Diagnostics would manage all customer billing. The Rental Agreement for LGC Genomics Oktopure Extraction Machine between Arches and Co-Diagnostics provided that Co-Diagnostics would make available to Arches the Oktopure high throughput extraction machine that Arches will use to perform COVID-19 testing. The term of the rental agreement was 12 months and required Arches to use Co-Diagnostics tests exclusively in the machine. In the second quarter of 2021, the rental agreement was amended to remove the minimum monthly purchase obligation of reagents and was replaced by a $3,300 monthly rental fee. The COVID-19 Laboratory Services Agreement could be canceled by the Company at any time by providing 60 days written notice, and the Rental Agreement could be canceled at any time by written notice given within 60 days after termination of the Laboratory Services Agreement. On May 27, 2021, the Company gave written notice to Co-Diagnostics of termination of the COVID-19 Laboratory Services Agreement, so the last day of that agreement was July 26, 2021, and no longer in effect on July 27, 2021. On July 27, 2021, the Company gave written notice to Co-Diagnostics of termination of the Rental Agreement, so the last day of that agreement was July 29, 2021.

On June 25, 2021, the Company entered into a statement of work with a contract research organization to provide services for a proposed clinical trial described as a multi-center, prospective, randomized controlled trial evaluating the effects of SkinTE in the treatment of full-thickness diabetic foot ulcers at a cost of approximately $6.5 million consisting of $3.1 million of service fees and $3.4 million of estimated costs. The estimate increased $1.4 million from the $5.1 million estimated at September 30, 2021, due to additional costs expected for longer trial subject follow up (6 months versus 3 months) and a corresponding increase in trial subject visits. In July 2021 the Company prepaid 10% of the total cost recited in the original work order, or $0.5 million, which will be applied to payment of the final invoice under the work order. Over the approximately three-year term of the clinical trial the service provider shall submit to the Company for payment invoices on a monthly basis for units of work stated in the work order that are completed and billable expenses incurred. During the year ended December 31, 2021, the Company received invoices for work performed and expenses incurred totaling $0.4 million. Either party may terminate the agreement without cause on 60 days' notice to the other party.

17. 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. As of December 31, 2021, the Company has no remaining liability related to future cash payments under the agreement. The fair value of the restricted stock units was $0.8 million and was fully expensed upon Dr. Lough's termination.

In October 2018, the Company entered into an office lease covering approximately 7,250 square feet of rental space in the building located at 40 West 57th Street in New York City. The lease is for a term of three years. The annual lease rate is $60 per square foot. Initially the Company would occupy and pay for only 3,275 square feet of space, and the Company was not obligated under the lease to pay for the remaining 3,975 square feet covered by the lease unless it elected to occupy that additional space. The Company believes the terms of the lease were very favorable to it, and the Company obtained the 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. The lease expired on October 31, 2021. The Company recognized $182,000 and $250,000 of sublease income for the years ended December 31, 2021 and 2020, respectively. The sublease income is included in other income, net in the statement of operations. As of December 31, 2021, and December 31, 2020, there were no significant amounts due from the related party under this agreement.

18. SEGMENT REPORTING

Reportable segments are presented in a manner consistent with the internal reporting provided to the chief operating decision maker (CODM), the Chief Executive Officer of the Company. The CODM allocates resources to and assesses the performance of each segment using information about its revenue and operating income (loss). The Company's operations involve products and services which are managed separately. Accordingly, it operates in two segments: 1) regenerative medicine products 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,	
	2021	2020
Net revenues:		
Reportable segments:		
Regenerative medicine products	$ 3,076	$ 3,730
Contract services	6,328	6,396
Total net revenues	$ 9,404	$ 10,126
Net income/(loss):		
Reportable segments:		
Regenerative medicine products	$ (29,568)	$ (42,815)
Contract services	(619)	(39)
Total net loss	$ (30,187)	$ (42,854)

	December 31, 2021	December 31, 2020
Identifiable assets employed:		
Reportable segments:		
Regenerative medicine products	$ 25,344	$ 36,858
Contract services	5,834	8,652
Total assets	$ 31,178	$ 45,510

19. 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 2021). The Company contributes 3% of employee's eligible earnings. The Company recorded contribution expense related to its 401(k) Plan of $0.3 million and $0.2 million for the years ended December 31, 2021 and 2020, respectively.

20. 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,	
	2021	2020
Current:		
Federal	$ –	$ –
State	–	–
Deferred:		
Federal	(5,484)	(593)
State	605	(79)
Change in valuation allowance	4,879	672
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,			
	2021		2020	
	Amount	Percent of Pretax Loss	Amount	Percent of Pretax Loss
Tax (benefit) at federal statutory rate	$ (6,340)	21%	$ (8,999)	21%
State income taxes, net of federal income taxes	605	(2)%	(79)	–%
Effect of warrant liability	215	(1)%	(209)	1%
Effect of other permanent items	16	–%	65	–%
Effect of stock compensation	238	(1)%	9,032	(21)%
Change in valuation allowance	4,879	(16)%	672	(2)%
Other	387	(1)%	(482)	1%
	$ –	–%	$ –	–%

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

	December 31,	
	2021	2020
Leases	$ 17	$ 132
Depreciation and amortization	(38)	(784)
Compensation expense not deductible until options are exercised	8,343	9,494
All other temporary differences	430	488
Net operating loss carry forwards	47,223	41,766
Less valuation allowance	(55,975)	(51,096)
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, 2021 amounts to approximately $185.8 million. Of this amount, $38.4 million will expire between 2038 and 2039 and $147.4 million will have an indefinite life. Approximately $195.7 million for state income taxes will begin to expire starting in 2034.

The Company files income tax returns in the U.S. and various states. As of December 31, 2021, the Company had no unrecognized tax benefits, which would impact its tax rate if recognized. As of December 31, 2021, the Company had no accrual for the potential payment of penalties. As of December 31, 2021, 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.

21. SUBSEQUENT EVENTS

On March 30, 2021, the Company entered into a sales agreement ("Sales Agreement") with an investment banking firm to sell shares of 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 the investment banking firm would act as sales agent. By written notice given by the Company to the investment banking company on February 28, 2022, the Company exercised its right to terminate the Sales Agreement and the "at the market" equity offering program. As of the date of termination, no common stock had been sold under the Sales Agreement and all previously deferred offering costs will be immediately expensed. Upon such termination the Company was obligated to make a one-time payment to the investment banking firm of $400,000.

On March 16, 2022, the Company completed a registered direct offering of (i) 3,000.000435 shares of Series A Convertible Preferred Stock, par value $0.001 per share ("Series A"); (ii) 2,000.00029 shares of Series B Convertible Preferred Stock, par value $0.001 per share ("Series B," and together with the Series A, the "Preferred Stock"); and (iii) warrants to purchase up to 16,393,445 shares of common stock ("Common Warrants"). The shares of Preferred Stock have a stated value of $1,000 per share and are convertible, following the date of the issuance thereof, into an aggregate of 9,836,067 shares of common stock of the Company upon the conversion of Series A and into an aggregate of 6,557,378 shares of common stock of the Company upon the conversion of Series B, at a conversion price of $0.305 per share each. Each Common Warrant has an exercise price of $0.35 per share and will become exercisable six months after the original issuance date and will expire two years following the original issuance. The Company issued to designees of the placement agent for the registered direct offering as part of the placement agent's compensation warrants to purchase up to 819,672 shares of common stock at an exercise price of $0.38125 per share. The Company expects to realize net proceeds of approximately $4,485,000 from the offering after deducting offering expenses. On March 17, 2022, the holder of the Series B converted the shares to 6,557,378 shares of common stock of the Company. On March 29, 2022, the holder of the Series A converted the shares to 9,836,067 shares of common stock of the Company.

The investor in the forgoing offering is a holder of the January 14 Warrants and January 25 Warrants described in Note 12, above. Concurrent with the offering, the Company entered into a Warrant Amendment Agreement with the investor pursuant to which, in consideration for the investor's purchase of $5 million of securities in this offering, the Company agreed to reduce the exercise price of the January 14 Warrants and January 25 Warrants to $0.35 per share, effective upon the consummation of the offering, and confirmation by the placement agent that the investor satisfied the purchase commitment. Pursuant to the Warrant Amendment Agreement, the January 14 Warrants and January 25 Warrants will not be exercisable at the adjusted price until the date that is six months after the consummation of this offering. Except for these amendments, no other changes have been made to the January 14 Warrants and January 25 Warrants. The Company is currently assessing the impact of the warrant exercise price reduction to its consolidated financial statements.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of PolarityTE, Inc. on Form S-3 (Nos. 333-262671 and 333-229584) and Form S-8 (Nos. 333-261981, 333-254861, 333-251795, 333-237189, 333-227721, and 333-225264) of our report dated March 29, 2022, on our audits of the financial statements as of December 31, 2021 and 2020 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, 2022. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Iselin, NJ
March 29, 2022

EXHIBIT 31.1

CERTIFICATION

I, Richard Hague, certify that:

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

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

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

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

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

b) designed such internal control over 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, 2022

/s/ Richard Hague

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, 2022

/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, 2021 (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, 2022

/s/ Richard Hague

Richard Hague
Chief Executive Officer

/s/ Jacob Patterson

Jacob Patterson
Chief Financial Officer