POLARITYTE, INC.
Form 8-K
November 03, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)

of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 1, 2017

POLARITYTE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-51128**	**06-1529524**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

615 Arapeen Drive

Salt Lake City, UT 84108

(Address of principal executive offices and zip code)

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

Please send copies of all communications to:

Harvey J. Kesner, Esq.

Sichenzia Ross Ference Kesner LLP

1185 Avenue of the Americas, 37th Floor

New York, New York 10036

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(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. [ ]

Item 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing

On November 1, 2017, PolarityTE, Inc. (the "Company") was notified by The NASDAQ Stock Market ("NASDAQ") that the Company was not in compliance with Listing Rule 5605 (the "Rule"), specifically (i) Listing Rule 5605(b)(1) requiring that a majority of the board of directors must be comprised of "independent" directors, as such term is defined under the Rule and (ii) Listing Rule 5605(c)(2)(a) requiring an audit committee to be comprised of at least three independent directors. Michael Beeghley, a former independent director and audit committee member, declined to stand for re-election following the Annual Meeting of Shareholders on October 18, 2017. The notice provided that consistent with Listing Rules 5605(b)(1)(A) and 5605(c)(4), NASDAQ will provide the Company a cure period in order to regain compliance as follows: (x) until the earlier of the Company's next annual shareholders' meeting or October 18, 2018 or (y) if the next annual shareholders' meeting is held before April 30, 2018, then the Company must evidence compliance no later than April 30, 2018.

The notice has no immediate effect on the listing or trading of the Company's common stock on NASDAQ and, at this time, the common stock will continue to trade on NASDAQ under the symbol "COOL". The Company plans to regain compliance upon appointment of one or more additional independent directors prior to deadline. In the event the Company does not regain compliance with the Rule by such date, the Company's securities may be delisted from NASDAQ, a determination the Company can appeal to a Hearings Panel.

Item 8.01. Other Events.

On December 1, 2016, the Company entered into an agreement to acquire PolarityTE, Inc., a Nevada corporation, a regenerative medicine company (the "Acquisition"). The Acquisition was subject to shareholder approval, which was received on March 10, 2017 and the Acquisition closed on April 7, 2017, as more fully described below. In January, 2017, the Company changed its name to "PolarityTE, Inc." On June 23, 2017, the Company sold Majesco Entertainment Company, a Nevada corporation and wholly-owned subsidiary of the Company ("Majesco Sub") to Zift Interactive LLC, a Nevada limited liability company pursuant to a purchase agreement (the "Majesco Disposition"; the Acquisition and the Majesco Disposition are referred to collectively as the "Reorganization Transactions"). As a result of the Reorganization Transactions, the Company now solely operates in its Regenerative Medicine segment and is updating its Risk Factors accordingly.

Our business is subject to numerous risks and uncertainties. Any reader should carefully consider the risks described below before making any decision. The risks described below are not the only ones the Company faces. Additional risks the Company is not presently aware of or that the Company currently believes are immaterial may also impair the Company's business operations. The Company's business and operations could be harmed by any of these risks. The trading price of the Company's common stock could decline due to any of these risks.

Risks Related to Our Business

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

Our near-term prospects depend upon our ability to effectively market our lead product candidate, SkinTE, and to demonstrate its safety and effectiveness in humans, as well as its superiority over existing therapies and standards of care. We currently expect to initiate a human clinical trial evaluating the SkinTE construct and other clinical evaluations in the fourth quarter of 2017. Our ability to finance our company and to generate revenues will depend in part on our ability to obtain favorable results in the planned clinical evaluations of SkinTE and to successfully develop and commercialize SkinTE.

SkinTE could be unsuccessful if it:

- does not demonstrate acceptable safety and efficacy in humans, or otherwise does not meet applicable regulatory standards;
- does not offer sufficient, clinically meaningful therapeutic or other improvements over existing or future therapies used to treat burns or other defects of skin tissues/integument for which it is being tested and evaluated;
- is not capable of being produced in commercial quantities at acceptable costs or acceptable timelines; or
- is not accepted as safe, efficacious, cost-effective, less costly and preferable to current therapies in the medical community and by third-party payers.

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

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

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

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

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

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

Additionally, we are defendants in a patent infringement lawsuit filed against Majesco Entertainment Company. On February 26, 2015, a complaint for patent infringement was filed in the United States District Court for the Eastern District of Texas by Richard Baker, an individual residing in Australia, against Microsoft, Nintendo, us and a number of other game publisher defendants. The complaint alleged that our Zumba Fitness Kinect game infringed plaintiff's patents in motion tracking technology and the plaintiff sought damages in the amount of $1.3 million. In August 2015, the defendants jointly moved to transfer the case to the Western District of Washington. On May 17, 2016, the Washington Court issued a scheduling order that provides that defendants leave to jointly file an early motion for summary judgement in June 2016. On June 17, 2016, the defendants jointly filed a motion for summary judgment that stated that none of the defendants, including us, infringed upon the asserted patent. On July 9, 2016, Mr. Baker opposed the motion. On January 3, 2017, the Court granted the defendants' motion for summary judgment and the case was dismissed. On June 16, 2017, final judgment was entered in favor of the defendants. On July 5, 2017, Baker filed an appeal of the District Court's Final Order of Judgment in favor of the Defendants' to the Court of Appeals for the Federal Circuit. The appeal is currently pending. An adverse determination of the appeal can result in significant liability against us.

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

We have to date incurred, and may continue to incur significant operating losses over the next several years. We have incurred significant net losses in each year since our inceptions, and have a net loss of $120.9 million as of July 31, 2017. Our ability to achieve profitable operations in the future will depend in large part upon the successful development and commercialization of our product candidates and technologies. Factors impacting our ability to successfully develop and commercialize our product candidates include:

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

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

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

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

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

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

Our product development programs are based on novel technologies and have not been tested in humans. As result, our product candidates are inherently risky.

To date we have not tested any of our product candidates in humans. We intend to initiate a clinical trial and other clinical evaluations of our lead product candidate, SkinTE, in the fourth quarter of 2017. We cannot guarantee that the results we see in clinical trials will be comparable to the preclinical results we have observed in animals. We also cannot at this stage be certain of the safety of our platform technology in humans.

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

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

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

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

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

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

- The clinical safety and effectiveness of our products and their perceived advantage over alternative treatment methods;
- Our ability to convince healthcare providers that the use of our products in a particular procedure is more beneficial than the standard of care or other available methods;
- Our ability to explain clearly and educate others on the autologous use of patient-specific human cells and tissue-based products, to avoid potential confusion with and differentiate ourselves from the ethical controversies associated with human fetal tissue and engineered human tissue;
- Adverse reactions involving our products or the products or product candidates of others that are cell or tissue-based;
- Our ability to supply a sufficient amount of our product to meet regular and repeated demand in order to develop a core group of medical professionals familiar with and committed to the use of our products; and
- The cost of our products and the reimbursement policies of government and third-party payers.

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

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

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

Commercial third-party payers and government payers are increasingly attempting to contain healthcare costs by demanding price discounts, by limiting coverage on which products they will pay for and the amounts that they will

pay for new products, and by creating conditions to reimbursement, such as coverage eligibility requirements based upon clinical evidence development involving research studies and the collection of physician decision impact and patient outcomes data. Because of these cost-containment trends, commercial third-party payers and government payers that currently provide or in the future may provide reimbursement for one or more of our product candidates may reduce, suspend, revoke, or discontinue payments or coverage at any time, including those payers that designate one or more of our product candidates as experimental and investigational. Payers may also create conditions to coverage or contract with third-party vendors to manage laboratory benefit coverage, in both cases creating burdens for ordering physicians and patients that may make our product candidates more difficult to sell. The percentage of submitted claims that are ultimately paid, the length of time to receive payment on claims, and the average reimbursement of those paid claims, is likely to vary from period to period.

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

not experimental or investigational;

medically reasonable and necessary;

appropriate for the specific patient;

cost effective;

supported by peer-reviewed publications;

included in clinical practice guidelines and pathways; and

supported by clinical utility and health economic studies demonstrating improved outcomes and cost effectiveness.

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

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

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

There are numerous laws and regulations that govern the means by which companies in the healthcare industry may market their treatments to healthcare professionals and may compete by discounting the prices of their treatments,

including for example, the federal Anti-Kickback Statute, the federal False Claims Act ("FCA"), the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and state law equivalents to these federal laws that are meant to protect against fraud and abuse and analogous laws in foreign countries. Violations of these laws are punishable by criminal and civil sanctions, including, but not limited to, in some instances civil and criminal penalties, damages, fines, exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid. In addition, federal and state laws are also sometimes open to interpretation, and from time to time we may find ourselves at a competitive disadvantage if our interpretation differs from that of our competitors.

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

Also, the FCA imposes civil liability on any person or entity that submits, or causes the submission of, a false or fraudulent claim to the federal government. Damages under the FCA can be significant and consist of the imposition of fines and penalties. The FCA also allows a private individual or entity with knowledge of past or present fraud against the federal government to sue on behalf of the government to recover the civil penalties and treble damages. The U.S. Department of Justice ("DOJ") on behalf of the government has previously alleged that the marketing and promotional practices of pharmaceutical and medical device manufacturers, including the off-label promotion of products or the payment of prohibited kickbacks to doctors, violated the FCA, resulting in the submission of improper claims to federal and state healthcare entitlement programs such as Medicaid. In certain cases, manufacturers have entered into criminal and civil settlements with the federal government under which they entered into plea agreements, paid substantial monetary amounts and entered into corporate integrity agreements that require, among other things, substantial reporting and remedial actions going forward.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Rapid technological change could cause our business to become obsolete.

The technologies underlying our product candidates are subject to rapid and profound technological change. Competition intensifies as technical advances in each field are made and become more widely known. We can give no assurance that others will not develop services, products, or processes with significant advantages over the products, services, and processes that we offer or are seeking to develop. Any such occurrence could have a material and adverse effect on our business, results of operations and financial condition.

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

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

If we do not develop and, when necessary, obtain regulatory clearance, registration, or approval for product candidates or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our results of operations will suffer. Our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material or other innovation. In addition, even if we are able to successfully develop enhancements or new generations of our product candidates, these enhancements or new generations of product candidates may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of product candidates embodying new technologies or features.

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

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

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

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

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

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

resources for countries or regions of countries in which we determine to commercialize our product candidates on our own, if any.

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

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

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

We rely to a large extent upon sophisticated information technology systems to protect our intellectual property and to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, our trade secrets and data, personal information, and intellectual property). The size and complexity of our information technology and information security systems make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from malicious attacks by third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. There can be no assurance that our efforts to protect our data and related information technology and intellectual property will prevent service interruptions or security breaches. Any interruption or breach in our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us or allow third parties to gain material, inside information that they use to trade in our securities.

We face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance.

Our business exposes us to the risk of product liability claims that are inherent in the manufacturing, processing and marketing of human cellular and tissue-based products. We may be subject to such claims if our product candidates cause, or appear to have caused, an injury during clinical trials or after commercialization. Claims may be made by patients, healthcare providers or others selling our product candidates. Defending a lawsuit, regardless of merit, could be costly, divert management attention and result in adverse publicity, which could result in the withdrawal of, or reduced acceptance of, our product candidates in the market.

Although we have obtained product liability insurance, such insurance is subject to deductibles and coverage limitations and we may not be able to maintain this insurance. Also, it is possible that claims could exceed the limits of our coverage. If we are unable to obtain or maintain product liability insurance at an acceptable cost or on

acceptable terms with adequate coverage or otherwise protect ourselves against potential product liability claims or we underestimate the amount of insurance we need, we could be exposed to significant liabilities, which may harm our business. A product liability claim or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could result in significant costs and significant harm to our business.

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

The manufacturing, marketing and processing of our product candidates involves an inherent risk that our tissue products or processes do not meet applicable quality standards and requirements. In that event, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority. A recall or market withdrawal of one of our product candidates would be costly and would divert management resources. A recall or withdrawal of one of our product candidates, or a similar product processed by another entity, also could impair sales of our product candidates as a result of confusion concerning the scope of the recall or withdrawal, or as a result of the damage to our reputation for quality and safety.

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

Prior to October 2016, we had limited experience operating as a public company. As a public company, we are required to establish and maintain disclosure controls and procedures and internal control over financial reporting. Our limited public company experience could impair our ability to comply with legal and regulatory requirements such as those imposed by Sarbanes-Oxley Act of 2002. Such responsibilities include complying with federal securities laws and making required disclosures on a timely basis. We may not be able to implement programs and policies in an effective and timely manner that adequately respond to such increased legal, regulatory compliance and reporting requirements, including the establishing and maintaining internal controls over financial reporting. Any such deficiencies, weaknesses or lack of compliance could have a materially adverse effect on our ability to comply with SEC reporting requirements, which may be necessary in the future to maintain our public company status. If we were to fail to fulfill those obligations, our ability to continue as a public company would be in jeopardy.

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

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

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

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

Our results may fluctuate significantly as a result of a variety of factors, many of which are outside of our control.

We are subject to the following factors, among others, that may negatively affect our operating results:

- the announcement or introduction of new products by our competitors;
- failure of government and private health plans to adequately and timely reimburse the users of our potential products;
- our ability to upgrade and develop our systems and infrastructure to accommodate growth;
- the continued availability of Dr. Denver Lough and other key executives and our ability to attract and retain additional key personnel in a timely and cost effective manner;
- the amount and timing of operating costs and capital expenditures relating to the expansion of our business, operations and infrastructure;
- regulation by federal, state or local governments; and
- general economic conditions as well as economic conditions specific to the healthcare industry.

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

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

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

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

Risks Related to Our Intellectual Property

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

Our success depends significantly on our ability to protect our proprietary rights in technologies that presently consist of trade secrets and patent applications. We currently have no issued patents relating to any of our product candidates. We intend to expand our patenting activities and rely on patent protection, as well as a combination of copyright, trade secret and trademark laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology, and there can be no assurance these methods of protection will be effective. These legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. In addition, our presently pending patent applications include claims to material aspects of our activities that are not currently protected by issued patents. The patent application process can be time consuming and expensive. We cannot ensure that any of the pending patent applications we acquire, have acquired, or may file will result in issued patents. Competitors may be able to design around our patents or develop procedures that provide outcomes that are comparable or even superior to ours. We also cannot assure you that the inventors of the patents and applications that we expect to own or license were the first-to-invent or the first-inventor-to-file on the inventions, or that a third party will not claim ownership in one of our patents or patent applications. We cannot assure you that a third party does not have or will not obtain patents that dominate the patents we own or license now or in the future.

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

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

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

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

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

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

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

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

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

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

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

obtain any legal opinion with regard to our freedom to practice our technology at this time.

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. In addition, during the course of litigation there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

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

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

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

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

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

applicable premarket regulatory clearances or approvals are obtained.

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

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

- Untitled letters, warning letters, fines, injunctions, and civil penalties;
- Operating restrictions, partial suspension or total shutdown of manufacturing, marketing, or distribution;
- Refusing requests for clearance or approval of new products, processes, or procedures, or for certificates to enable export of the same;
- Withdrawing or suspending current applications for approval or approvals already granted; and
- Civil or criminal prosecution.

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

We believe our current product candidates, including the FDA-registered SkinTE product, satisfy applicable criteria for regulation as a 361 HCT/P. If the FDA disagrees with our interpretation of the relevant laws and regulations as they apply to our product candidates, and requires an IND for any of our product candidates, we may need to delay or abandon our development. The submission of an Investigational New Drug Application ("IND") and a Biologics License Applications ("BLA") or New Drug Application ("NDA") would require us to compile significant amounts of data related to our regulatory process, as well as data from preclinical and clinical testing. We cannot guarantee that we will ever be able to secure such approvals if required.

The FDA regulates HCT/Ps under a two-tiered framework. Certain higher risk HCT/Ps are regulated as new drugs, biologics or medical devices. Manufacturers of new drugs, biologics and some medical devices must complete extensive clinical trials, which must be conducted pursuant to an effective IND or investigational device exemption ("IDE"). The FDA must review and approve a BLA or NDA before a new drug or biologic may be marketed, and in some cases must approve a premarket approval application ("PMA") for medical devices.

By contrast, the FDA exempts 361 HCT/Ps from these requirements if they meet certain specified criteria. We believe that our current product candidates, including SkinTE, meet the criteria for regulation as a 361 HCT/P rather than as a new drug or biologic or medical device and, therefore, we do not currently expect that any of our current product

candidates will be subject to the requirement for an IND or IDE or FDA premarket review and approval. Thus, our financial and business plans assume that we will not need to seek or obtain premarket FDA approval for our product candidates. Rather, we will have to comply with the requirements for 361 HCT/Ps set forth in FDA regulations and develop adequate substantiation to support marketing claims we plan to make.

The Tissue Reference Group ("TRG") is a body within the FDA designed to provide recommendations regarding whether a particular product candidate will be regulated as a 361 HCT/P. The Office of Combination Products ("OCP") at FDA provides informal and formal opinions regarding the classification of products as 361 HCT/Ps or drugs, biologics, or medical devices. Product manufacturers are not required to consult with the TRG or OCP and instead can market their products based on their own conclusion that the product meets the 361 HCT/P criteria.

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

The regulatory pathway for cell and tissue-based products is subject to significant uncertainty. The FDA's criteria for regulation as a 361 HCT/P are complex, and the FDA has provided little or inconclusive guidance on the meaning of certain terms used in the criteria, such as "minimal manipulation," "homologous," or "combination of the cells and tissues with another article." In addition, our product candidates, including SkinTE, use new technology that may present a matter of first impression for the FDA in determining whether to require premarket authorization. Further, our product candidates may receive a high degree of scrutiny from the FDA. The FDA or Congress could change the relevant criteria for determining which products qualify as 361 HCT/Ps or the regulatory requirements for HCT/Ps.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Manufacturing

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

commercialization of our product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

manufacturing from one facility to another, the shift would likely be expensive and time-consuming, particularly since an alternative facility would need to comply with the applicable cGTP and/or cGMP regulatory and quality standard requirements whereby validation and, if applicable, FDA approval would be required before any products manufactured at that facility could be made commercially available.

Risks Related to Liquidity and Capital Resources

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

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

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

In its report dated December 29, 2016, EisnerAmper LLP, our independent registered public accounting firm, expressed substantial doubt about our ability to continue as a going concern as we have suffered recurring losses from operations and have insufficient liquidity to fund our future operations. If we are unable to improve our liquidity position we may not be able to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that might result if we are unable to continue as a going concern and, therefore, be required to realize our assets and discharge our liabilities other than in the normal course of business which could cause investors to suffer the loss of all or a substantial portion of their investment.

As of July 31, 2017, we had $3.027 million of cash, and after the closing of our private placement financing in September 2017, we have approximately $19 million of cash. We anticipate that our principal sources of liquidity will only be sufficient to fund our activities through approximately October 2018. In order to have sufficient cash to fund our operations, we will need to raise additional equity or debt capital and we cannot provide any assurance that we will be successful in doing so.

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

We incurred net losses of $4.6 million in fiscal 2016 and $3.8 million in fiscal 2015. We will require substantial additional capital resources in order to complete our product development programs, complete clinical trials, and market and commercialize our product candidates (including our upcoming human clinical trial to evaluate SkinTE). In order to grow and expand our business, and to introduce our new product candidates into the marketplace, we will need to raise a significant amount of additional funds. We will also need significant additional funds or a collaborative partner, or both, to finance the research and development activities. Accordingly, we are continuing to pursue additional sources of financing.

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

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

our ability to commercialize our product candidates;

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

our ability to obtain valid and enforceable patents;

competing technological and market developments;

our ability to establish collaborative relationships;

market acceptance of our product candidates;

the development of an infrastructure to support or business; and

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

our ability to control costs.

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

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

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

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

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

Risks Related to Our common stock

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

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

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

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

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

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

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

On April 7, 2017, we issued 7,050 shares of our Series E Preferred Stock convertible into an aggregate of 7,050,000 shares of our common stock with a fair value of approximately $104.7 million to Dr. Denver Lough. Pursuant to the Certificate of Designation for the Series E Preferred Stock, such shares are entitled to two votes for each share of common stock into which such shares are convertible. Accordingly, Dr. Lough is entitled to cast votes equivalent to 14,100,000 shares of common stock on all matters presented for a vote of our stockholders on an "as-converted" basis. As of October 5, 2017, there were 6,389,024 shares of common stock issued and outstanding eligible to vote (in addition to our voting preferred stock). As a result, Dr. Lough, together with other executive officers and directors, would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs.

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

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

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

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

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

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

The price of our common stock has experienced significant volatility. The high and low bid quotations for our common stock, as reported by NASDAQ, ranged between a high of $31.68 and a low of $2.79 during the past 12 months. The historic market price of our common stock may be higher or lower than the price paid for our shares and may not be indicative of future market prices, depending on many factors, some of which are beyond our control. In addition, our Chief Executive Officer controls approximately 67.81% of our voting capital stock and maintains effective majority control over decisions affecting our Company and business. As a result investors may be unwilling to purchase our common stock and our market price may be affected. The price of our stock may change dramatically in response to our success or failure and based upon our relationship and the decisions of our chief executive officer.

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

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

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

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

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

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

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

- the right to receive a liquidation preference, prior to any distribution of our assets to the holders of our common stock;

- the right to convert into shares of our common stock at the conversion price set forth in the certificates of designations governing the respective preferred stock, which may be adjusted as set forth therein.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

POLARITYTE, INC.

Dated: November 3, 2017 */s/ John Stetson*
John Stetson
Chief Financial Officer