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

FORM 10-Q

QUARTERLY REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended January 31, 2018

Commission File No. 000-51128

POLARITYTE, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**06-1529524**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

1960 S 4250 W
Salt Lake City, UT 84104
(Address of principal executive offices)

Registrant's Telephone Number, Including Area Code: **(732) 225-8910**

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (232.4.05 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	[ ]		Accelerated filer	[ ]
Non-accelerated filer	[ ]	(Do not check if smaller reporting company)	Smaller reporting company	[X]
Emerging growth company	[ ]			

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

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

As of March 14, 2018, there were 16,457,664 shares of the Registrant's common stock outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	January 31, 2018 (Unaudited)	October 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,990	$ 17,667
Prepaid expenses and other current assets	626	237
Receivable from Zift	60	60
Total current assets	10,676	17,964
Non-current assets:		
Property and equipment, net	4,452	2,173
Security desposits – non-current	111	-
Receivable from Zift, non-current	-	15
Total non-current assets	4,563	2,188
TOTAL ASSETS	**$ 15,239**	**$ 20,152**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,312	$ 1,939
Warrant liability and embedded derivative	10,128	13,502
Total current liabilities	13,440	15,441
Total liabilities	13,440	15,441
Commitments and Contingencies		
Redeemable convertible preferred stock - Series F - 6,455 shares authorized, issued and outstanding at January 31, 2018 and October 31, 2017; liquidation preference - $17,750.	5,414	4,541
STOCKHOLDERS' EQUITY (DEFICIT):		
Convertible preferred stock - 9,993,545 shares authorized, 1,656,838 and 3,230,655 shares issued and outstanding at January 31, 2018 and October 31, 2017, aggregate liquidation preference $1,089 and $2,140, respectively	109,104	109,995
Common stock - $.001 par value; 250,000,000 shares authorized; 7,094,544 and 6,515,524 shares issued and outstanding at January 31, 2018 and October 31, 2017, respectively	7	7
Additional paid-in capital	160,368	149,173
Accumulated deficit	(273,094)	(259,005)
Total stockholders' equity (deficit)	(3,615)	170
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	**$ 15,239**	**$ 20,152**

See accompanying notes to condensed consolidated financial statements.

POLARITYTE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, in thousands, except share and per share amounts)

	For the three months ended January 31,	
	2018	**2017**
Net revenues	$ 13	$ -
Cost of sales	1	-
Gross profit	12	-
Operating costs and expenses		
Research and development	6,602	-
General and administrative	10,898	5,225
	17,500	5,225
Operating loss	(17,488)	(5,225)
Other (expenses) income		
Interest income	25	4
Change in fair value of derivative liabilities	3,374	(8)
Net loss from continuing operations	(14,089)	(5,229)
Loss from discontinued operations	-	(432)
Net loss	(14,089)	(5,661)
Deemed dividend – accretion of discount on Series F preferred stock	(904)	-
Cumulative dividends on Series F preferred stock	(275)	-
Net loss attributable to common shareholders	$ (15,268)	$ (5,661)
Net loss per share, basic and diluted:		
Loss from continuing operations	$ (2.13)	$ (1.56)
Loss from discontinued operations	-	(0.13)
Deemed dividend – accretion of discount on preferred stock	(0.14)	-
Cumulative dividends on Series F preferred stock	(0.04)	-
Net loss attributable to common shareholders	$ (2.31)	$ (1.69)
Weighted average shares outstanding, basic and diluted	6,615,350	3,346,788

See accompanying notes to condensed consolidated financial statements.

POLARITYTE, INC.
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited, in thousands, except share and per share amounts)

	Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Number	Amount	Number	Amount	Capital	Deficit	Equity (Deficit)
Balance as of October 31, 2017	**3,230,655**	**$109,995**	**6,515,524**	**$ 7**	**$ 149,173**	**$ (259,005)**	**$ 170**
Issuance of common stock in connection with:							
Conversion of Series A preferred stock to common stock	(1,544,572)	(378)	350,000	-	378	-	-
Conversion of Series C preferred stock to common stock	(2,578)	(201)	59,950	-	201	-	-
Conversion of Series D preferred stock to common stock	(26,667)	(312)	44,445	-	312	-	-
Proceeds from option exercises	-	-	10,417	-	45	-	45
Stock-based compensation expense	-	-	102,500	-	11,132	-	11,132
Deemed dividend – accretion of discount on Series F preferred stock	-	-	-	-	(904)	-	(904)
Cumulative dividends on Series F preferred stock	-	-	-	-	(275)	-	(275)
Series F preferred stock dividends paid in common stock	-	-	11,708	-	306	-	306
Net loss	-	-	-	-	-	(14,089)	(14,089)
Balance as of January 31, 2018	**1,656,838**	**$109,104**	**7,094,544**	**$ 7**	**$ 160,368**	**$ (273,094)**	**$ (3,615)**

See accompanying notes to condensed consolidated financial statements.

POLARITYTE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, in thousands)

	For the three months ended January 31,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (14,089)	$ (5,661)
Loss from discontinued operations	-	432
Loss from continuing operations	(14,089)	(5,229)
Adjustments to reconcile net loss from continuing operations to net cash used in continuing operating activities:		
Depreciation and amortization	256	-
Stock based compensation expense	11,132	3,975
Change in fair value of warrant liability and embedded derivative	(3,374)	8
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	46	(204)
Security deposits – non-current	(111)	-
Accounts payable and accrued expenses	1,067	694
Net cash used in continuing operating activities	(5,073)	(756)
Net cash provided by discontinued operating activities	-	395
Net cash used in operating activities	(5,073)	(361)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(2,664)	(1,538)
Net cash used in continuing investing activities	(2,664)	(1,538)
Net cash provided by discontinued investing activities	15	-
Net cash used in investing activities	(2,649)	(1,538)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from stock options exercised	45	-
Proceeds from the sale of common stock	-	2,278
Net cash provided by financing activities	45	2,278
Net decrease in cash and cash equivalents	(7,677)	379
Cash and cash equivalents - beginning of period	17,667	6,523
Cash and cash equivalents - end of period	$ 9,990	$ 6,902
Supplemental schedule of non-cash investing and financing activities:		
Conversion of Series A preferred stock to common stock	$ 378	$ 297
Conversion of Series B preferred stock to common stock	$ -	$ 513
Conversion of Series C preferred stock to common stock	$ 201	$ 90
Conversion of Series D preferred stock to common stock	$ 312	$ 721
Unpaid liability for acquisition of property and equipment	$ 360	$ 54
Warrant exchange for common stock shares	$ -	$ 78
Deemed dividend – accretion of discount on preferred stock	$ 904	$ -
Cumulative dividends on Series F preferred stock	$ 275	$ -
Series F preferred stock dividends paid in common stock	$ 306	$ -

See accompanying notes to condensed consolidated financial statements.

POLARITYTE, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. PRINCIPAL BUSINESS ACTIVITY AND BASIS OF PRESENTATION

PolarityTE, Inc. is a commercial-stage biotechnology and regenerative biomaterials company focused on transforming the lives of patients by discovering, designing and developing a range of regenerative tissue products and biomaterials for the fields of medicine, biomedical engineering and material sciences.

Discontinued Operations. On June 23, 2017, the Company sold Majesco Entertainment Company, a Nevada corporation and wholly-owned subsidiary of the Company ("Majesco Sub") to Zift Interactive LLC, a Nevada limited liability company pursuant to a purchase agreement. Pursuant to the terms of the agreement, the Company sold 100% of the issued and outstanding shares of common stock of Majesco to Zift, including all of the right, title and interest in and to Majesco Sub's business of developing, publishing and distributing video game products through mobile and online digital downloading. Pursuant to the terms of the agreement, the Company will receive total cash consideration of approximately $100,000 ($5,000 upon signing the agreement and 19 additional monthly payments of $5,000) plus contingent consideration based on net revenues valued at $0. As of January 31, 2018, the Company received $40,000 in cash consideration and $60,000 remains receivable.

Segments. With the sale of Majesco Sub on June 23, 2017, the Company now solely operates in its Regenerative Medicine segment.

The accompanying interim condensed consolidated financial statements of the Company are unaudited, but in the opinion of management, reflect all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the results for the interim period. Accordingly, they do not include all information and notes required by generally accepted accounting principles for complete financial statements. The Company's financial results are impacted by the seasonality of the retail selling season and the timing of the release of new titles. The results of operations for interim periods are not necessarily indicative of results to be expected for the entire fiscal year. The balance sheet at October 31, 2017 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. These interim condensed consolidated financial statements should be read in conjunction with the Company's consolidated financial statements and notes thereto for the year ended October 31, 2017 filed with the Securities and Exchange Commission on Form 10-K on January 30, 2018.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation. The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries: Polarity NV and Majesco Sub (through the date sold). Majesco Sub was sold on June 23, 2017. Significant intercompany accounts and transactions have been eliminated in consolidation.

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

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

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

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

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

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

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

Loss Per Share. Basic loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted loss per share excludes the potential impact of common stock options, unvested shares of restricted stock and outstanding common stock purchase warrants because their effect would be anti-dilutive due to our net loss.

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

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

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

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

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

Recently Adopted Accounting Pronouncements

In April 2016, the FASB issued ASU No. 2016-09, *Share-Based Payment: Simplifying the Accounting for Share-Based Payments*. The standard addresses several aspects of the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures and statutory tax withholding requirements, as well as classification in the statement of cash flows. The Company adopted ASU 2016-09 during the first quarter of 2018 and the Company elected to account for forfeitures as they occur. The amendment was applied using a modified retrospective transition method. The provisions of ASU 2016-09 had no impact on the Company's consolidated financial statements.

Recent Accounting Pronouncements.

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

In May 2017, the FASB issued ASU 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting. ASU 2017-09 provides clarity and reduces both (1) diversity in practice and (2) cost and complexity when applying the guidance in Topic 718, to a change to the terms or conditions of a share-based payment award. The amendments in ASU 2017-09 should be applied prospectively to an award modified on or after the adoption date. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. The Company is currently assessing the potential impact of adopting ASU 2017-09 on its consolidated financial statements and related disclosures.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815)*: *I. Accounting for Certain Financial Instruments with Down Round Features; II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception,* (ASU 2017-11). Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. The Company is currently assessing the potential impact of adopting ASU 2017-11 on its financial statements and related disclosures.

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

In May 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers (Topic 606)", a new accounting standard that requires recognition of revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which an entity expects to be entitled in exchange for those goods or services. The FASB has also issued several updates to ASU 2014-09. The new standard supersedes U.S. GAAP guidance on revenue recognition and requires the use of more estimates and judgments than the present standards. It also requires additional disclosures regarding the nature, amount, timing and uncertainty of cash flows arising from contracts with customers. Topic 606 is effective for our fiscal year 2019 beginning on November 1, 2018. We are still evaluating the overall effect that the standard will have on our consolidated financial statements and accompanying notes to the consolidated financial statements.

3. GOING CONCERN

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has experienced net losses and negative cash flows from operations during each of the last two fiscal years. The Company has experienced negative cash flows from continuing operations of approximately $5.1 million for the three months ended January 31, 2018. Given these negative cash flows and forecasted increased spending, the continuation of the Company as a going concern is dependent upon continued financial support from its shareholders, potential collaborations, the ability of the Company to obtain necessary equity and/or debt financing to continue operations, and the attainment of profitable operations. The Company cannot make any assurances that additional financings will be available to it and, if available, completed on a timely basis, on acceptable terms or at all. If the Company is unable to complete a debt or equity offering, execute a collaboration arrangement or otherwise obtain sufficient financing when and if needed, it would negatively impact its business and operations and could also lead to the reduction or suspension of the Company's operations and ultimately force the Company to cease operations. These factors raise substantial doubt regarding the Company's ability to continue as a going concern. These financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

4. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consist of the following (in thousands):

	January 31, 2018	October 31, 2017
Legal retainer	$ -	$ 15
Prepaid insurance	64	69
Other prepaids	88	126
Advances on equipment purchases	435	-
Other assets	39	27
Total prepaid expenses and other current assets	$ 626	$ 237

5. PROPERTY AND EQUIPMENT, NET

Property and equipment, net, consist of the following (in thousands):

	January 31, 2018	October 31, 2017
Medical equipment	$ 4,911	$ 2,418
Computers and software	238	211
Furniture and equipment	45	30
Total property and equipment, gross	5,194	2,659
Accumulated depreciation	(742)	(486)
Total property and equipment, net	$ 4,452	$ 2,173

Depreciation expense for the three months ended January 31, 2018 and 2017 was approximately $256,000 and $83,000, respectively.

6. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following (in thousands):

	January 31, 2018	October 31, 2017
Accounts payable	$ 25	$ 25
Due to Zift	-	36
Medical study and supplies	511	362
Medical equipment purchase	360	54
Salaries and other compensation	1,312	574
Legal and accounting	737	555
Other accruals	367	333
Total accounts payable and accrued expenses	$ 3,312	$ 1,939

Salaries and other compensation include accrued payroll expense and employer 401K plan contributions.

7. PREFERRED SHARES AND COMMON SHARES

Convertible preferred stock as of January 31, 2018 consisted of the following (in thousands, except share amounts):

	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	Aggregate Liquidation Preference	Common Shares Issuable Upon Conversion
Series A	8,830,000	1,602,099	$ 391	$ 1,089	363,142
Series B	54,250	47,689	4,020	-	794,816
Series C	26,000	-	-	-	-
Series D	170,000	-	-	-	-
Series E	7,050	7,050	104,693	-	7,050,000
Series F	6,455	6,455	5,414	17,750	645,455
Other authorized, unissued	906,245	-	-	-	-
Total	10,000,000	1,663,293	$ 114,518	$ 18,839	8,853,413

Convertible preferred stock as of October 31, 2017 consisted of the following (in thousands, except share amounts):

	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	Aggregate Liquidation Preference	Common Shares Issuable Upon Conversion
Series A	8,830,000	3,146,671	$ 769	$ 2,140	713,245
Series B	54,250	47,689	4,020	-	794,816
Series C	26,000	2,578	201	-	59,953
Series D	170,000	26,667	312	-	44,445
Series E	7,050	7,050	104,693	-	7,050,000
Series F	6,455	6,455	4,541	17,750	645,455
Other authorized, unissued	906,245	-	-	-	-
Total	10,000,000	3,237,110	$ 114,536	$ 19,890	9,307,914

Series A Convertible Preferred Stock

The Series A Convertible Preferred Stock ("Series A Preferred Shares") is convertible into shares of common stock based on a conversion calculation equal to the stated value of such Series A Preferred Share, plus all accrued and unpaid dividends, if any, on such Series A Preferred Share, as of such date of determination, divided by the conversion price. The stated value of each Series A Preferred Share is $0.68 and the initial conversion price was $4.08 (current conversion price at January 31, 2018 is $3.00) per share, each subject to adjustment for stock splits, stock dividends, recapitalizations, combinations, subdivisions or other similar events. In addition, in the event the Company issues or sells, or is deemed to issue or sell, shares of its common stock at a per share price that is less than the conversion price then in effect, the conversion price shall be reduced to such lower price, subject to certain exceptions. Pursuant to the Certificate of Designations, Preferences and Rights of the 0% Series A Convertible Preferred Stock of PolarityTE, Inc., the Company is prohibited from incurring debt or liens, or entering into new financing transactions without the consent of the lead investor in the Company's December 2016 private placement as long as any of the Series A Preferred Shares are outstanding. The Series A Preferred Shares bear no dividends.

The holders of Series A Preferred Shares shall vote together with the holders of common stock on all matters on an as if converted basis, subject to certain conversion and ownership limitations, and shall not vote as a separate class. Notwithstanding the foregoing, the conversion price for purposes of calculating voting power shall in no event be lower than $3.54 per share. At no time may all or a portion of the Series A Preferred Shares be converted if the number of shares of common stock to be issued pursuant to such conversion would exceed, when aggregated with all other shares of common stock owned by the holder at such time, the number of shares of common stock which would result in such Holder beneficially owning (as determined in accordance with Section 13(d) of the 1934 Act and the rules thereunder) more than 4.99% of all of the common stock outstanding at such time; provided, however, that the holder may waive the 4.99% limitation at which time he may not own beneficially own more than 9.99% of all the common stock outstanding at such time.

The Series A Preferred Shares do not represent an unconditional obligation to be settled in a variable number of shares of common stock, are not redeemable and do not contain fixed or indexed conversion provisions similar to debt instruments. Accordingly, the Series A Preferred Shares are considered equity hosts and recorded in stockholders' equity.

Series B Convertible Preferred Stock

The Series B Convertible Preferred Stock ("Series B Preferred Shares") is convertible into shares of common stock based on a conversion calculation equal to the stated value of such Series B Preferred Shares, plus all accrued and unpaid dividends, if any, on such Series B Preferred Shares, as of such date of determination, divided by the conversion price. The stated value of each Series B Preferred Share is $140.00 and the initial conversion price is $8.40 per share, each subject to adjustment for stock splits, stock dividends, recapitalizations, combinations, subdivisions or other similar events. The Company is prohibited from effecting a conversion of the Series B Preferred Shares to the extent that, as a result of such conversion, such holder would beneficially own more than 4.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of shares of common stock upon conversion of the Series B Preferred Shares, which beneficial ownership limitation may be increased by the holder up to, but not exceeding, 9.99%. Subject to such beneficial ownership limitations, each holder is entitled to vote on all matters submitted to stockholders of the Company on an as converted basis, based on a conversion price of $8.40 per shares. The Series B Preferred Shares rank junior to the Series A Preferred Shares and bear no dividends. The Series B Preferred Shares do not represent an unconditional obligation to be settled in a variable number of shares, are not redeemable and do not contain fixed or indexed conversion provisions similar to debt instruments. Accordingly, the Series B Preferred Shares are considered equity hosts and recorded in stockholders' equity.

Series C Convertible Preferred Stock

The Series C Convertible Preferred Stock ("Series C Preferred Shares") is convertible into shares of common stock based on a conversion calculation equal to the stated value of such Series C Preferred Shares, plus all accrued and unpaid dividends, if any, on such Series C Preferred Shares, as of such date of determination, divided by the conversion price. The stated value of each Series C Preferred Share is $120.00 per share, and the initial conversion price was $7.20 (current conversion price was $5.16) per share, each subject to adjustment for stock splits, stock dividends, recapitalizations, combinations, subdivisions or other similar events. In addition, in the event the Company issues or sells, or is deemed to issue or sell, shares of common stock at a per share price that is less than the conversion price then in effect, the conversion price shall be reduced to such lower price, subject to certain exceptions and provided that the conversion price may not be reduced to less than $5.16, unless and until such time as the Company obtains shareholder approval to allow for a lower conversion price. The Company is prohibited from effecting a conversion of the Series C Preferred Shares to the extent that, as a result of such conversion, a holder would beneficially own more than 4.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of shares of common stock upon conversion of the Series C Preferred Shares, which beneficial ownership limitation may be increased by the holder up to, but not exceeding, 9.99%. Subject to the beneficial ownership limitations discussed previously, each holder is entitled to vote on all matters submitted to stockholders of the Company and shall have the number of votes equal to the number of shares of common stock issuable upon conversion of such holder's Series C Preferred Shares, based on a conversion price of $7.80 per share. The Series C Preferred Shares bear no dividends and shall rank junior to the Company's Series A Preferred Shares but senior to the Company's Series B Preferred Shares.

The Company evaluated the guidance ASC 480-10 *Distinguishing Liabilities from Equity* and ASC 815-40 *Contracts in an Entity's Own Equity* to determine the appropriate classification of the instruments. The Series C Preferred Shares do not represent an unconditional obligation to be settled in a variable number of shares of common stock, are not redeemable and do not contain fixed or indexed conversion provisions similar to debt instruments. Accordingly, the Series C Preferred Shares are considered equity hosts and recorded in stockholders' equity.

Series D Convertible Preferred Stock

The Series D Convertible Preferred Stock ("Series Preferred D Shares") is convertible into shares of common stock based on a conversion calculation equal to the stated value of such Series Preferred D Shares, plus all accrued and unpaid dividends, if any, on such Series Preferred D Share, as of such date of determination, divided by the conversion price. The stated value Series Preferred D Shares is $1,000 per share and the initial conversion price is $600 per share, each subject to adjustment for stock splits, stock dividends, recapitalizations, combinations, subdivisions or other similar events. The Company is prohibited from effecting a conversion of the Series Preferred D Shares to the extent that, as a result of such conversion, such investor would beneficially own more than 4.99% of the number of shares of Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon conversion of the Series Preferred D Shares. Upon 61 days written notice, the beneficial ownership limitation may be increased by the holder up to, but not exceeding, 9.99%. Except as otherwise required by law, holders of Series D Preferred Shares shall not have any voting rights. Pursuant to the Certificate of Designations, Preferences and Rights of the 0% Series D Convertible Preferred Stock, the Series Preferred D Shares bear no dividends and shall rank senior to the Company's other classes of capital stock.

Series E Convertible Preferred Stock

On April 7, 2017, the Company issued 7,050 shares of its newly authorized Series E Convertible Preferred Stock (the "Series E Preferred Shares") convertible into an aggregate of 7,050,000 shares of the Company's common stock with a fair value of approximately $104.7 million which is equal to 7,050,000 common shares times $14.85 (the closing price of the Company's common stock as of April 7, 2017) to Dr. Lough for the purchase of the Polarity NV's assets.

The Preferred E Shares are convertible into shares of common stock based on a conversion calculation equal to the stated value of such Preferred E Shares, plus all accrued and unpaid dividends, if any as of such date of determination, divided by the conversion price. The stated value of each Preferred E Share is $1,000 and the initial conversion price is $1.00 per share, each subject to adjustment for stock splits, stock dividends, recapitalizations, combinations, subdivisions or other similar events. The Preferred E Shares, with respect to dividend rights and rights on liquidation, winding-up and dissolution, in each case will rank senior to the Company's common stock and all other securities of the Company that do not expressly provide that such securities rank on parity with or senior to the Preferred E Shares. Until converted, each Preferred E Share is entitled to two votes for every share of common stock into which it is convertible on any matter submitted for a vote of stockholders. The Preferred E Shares participate on an "as converted" basis with all dividends declared on the Company's common stock.

Redeemable Series F Convertible Preferred Stock

On September 20, 2017, the Company sold an aggregate of $17,750,000 worth of units (the "Units") of the Company's securities to accredited investors at a purchase price of $2,750 per Unit with each Unit consisting of (i) one share of the Company's newly authorized 6% Series F Convertible Preferred Stock, par value $0.001 per share (the "Series F Preferred Shares"), which are convertible into one hundred (100) shares of the Company's common stock, and (ii) a two-year warrant to purchase 322,727 shares of the Company's common stock, at an exercise price of $30.00 per share. The Company incurred issuance costs of approximately $356,000 associated with the Unit offering, of which approximately $82,000 was allocated to the Series F Preferred Shares and netted against the proceeds. The remaining amount was allocated to the warrants and other embedded derivative and was expensed.

The Company entered into separate registration rights agreements, and subsequently amended such agreements, with each of the investors, pursuant to which the Company agreed to undertake to file a registration statement to register the resale of the conversion shares and warrant shares within 150 days of the closing of the transaction, to cause such registration statement to be declared effective by the Securities and Exchange Commission within ninety days following its filing and to maintain the effectiveness of the registration statement until all of such conversion shares and warrant shares have been sold or are otherwise able to be sold pursuant to Rule 144 under the Securities Act, without any restrictions. In the event the Company fails to file, or obtain effectiveness of, such registration statement with the specified period of time, the Company will be obligated to pay liquidated damages equal to the product of one 1% percent multiplied by the aggregate subscription amount paid by such investor for every thirty (30) days during which such filing is not made and/or effectiveness obtained, such fee being subject to certain exceptions, up to a maximum of six (6) percent.

Pursuant to the subscription agreements, for as long as the lead investor holds securities, except with certain issuances, the Company shall not incur any senior debt or issue any preferred stock with liquidation rights senior to the securities sold thereunder. During this period, the Company will not, without the consent of the investors holding a majority of the then issued and outstanding shares on the date of such consent (including the lead investor), enter into any equity line of credit or similar agreement, nor issue nor agree to issue any common stock, common stock equivalents, floating or variable priced equity linked instruments nor any of the foregoing or equity with price reset rights (subject to adjustment for stock splits, distributions, dividends, recapitalizations and the like).

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

Each holder of a Series F Preferred Share is entitled to receive dividends, in cash or in shares of the Company's common stock on the stated value of each share at the dividend rate, which shall be cumulative and shall continue to accrue and compound quarterly whether or not declared and whether or not in any fiscal year there shall be net profits or surplus available for the payment of dividends in such fiscal year. Dividends are payable quarterly in arrears on the fifteenth (15th) day of the next applicable quarter, to the record holders of the Series F Preferred Shares on the last day of the calendar quarter immediately preceding the dividend payment date in shares of common stock, calculated using the VWAP of the common stock on the ninety (90) days immediately preceding the dividend record date; provided, however, that the Company may, at its option, pay dividends in cash or in a combination of common shares and cash.

Upon the liquidation, dissolution or winding up of the business of the Company, whether voluntary or involuntary, each holder of preferred shares shall be entitled to receive, for each share thereof, out of assets of the Company legally available therefor, a preferential amount in cash equal to (and not more than) $2,750.

On the two (2) year anniversary of the initial issuance date, any Series F Preferred Shares outstanding and not otherwise already converted, shall, at the option of the holder, either (i) automatically convert into common stock of the Company at the conversion price then in effect or (ii) be repaid by the Company based on the stated value of such outstanding Series F Preferred Shares. In addition, in the event that the Company's common stock attains a consolidated bid price of $45 or greater for any four (4) trading days during any eight (8) trading day period, the Series F Preferred Shares shall be automatically converted to common stock, without any further action by the holder (subject to the conversion limitation in the event that such conversion would result in such holder holding in excess of four and ninety-nine one-hundredths (4.99%) percent of the common stock of the Company).

The warrants issued in connection with the Series F Preferred Shares are liabilities pursuant to ASC 815. The warrant agreement provides for an adjustment to the number of common shares issuable under the warrant and/or adjustment to the exercise price, including but not limited to, if: (a) the Company issues shares of common stock as a dividend or distribution to holders of its common stock; (b) the Company subdivides or combines its common stock (i.e., stock split); (c) adjustment of exercise price upon issuance of new securities at less than the exercise price. Under ASC 815, warrants that provide for down-round exercise price protection are recognized as derivative liabilities.

The conversion feature within the Series F Preferred Shares is not clearly and closely related to the identified host instrument and, as such, is recognized as a derivative liability measured at fair value pursuant to ASC 815.

The initial fair value of the warrants and bifurcated embedded conversion feature, estimated to be approximately $4.3 million and $9.3 million, respectively, was deducted from the gross proceeds of the Unit offering to arrive at the initial discounted carrying value of the Series F Preferred Shares. The resulting discount to the aggregate stated value of the Series F Preferred Shares of approximately $13.6 million will be recognized as accretion using the effective interest method similar to preferred stock dividends, over the two-year period prior to optional redemption by the holders. The Company recognized accretion of the discount to the stated value of the Series F Preferred Shares of approximately $904,000 in the three months ended January 31, 2018 as a reduction of additional paid-in capital and an increase in the carrying value of the Series F Preferred Shares. The accretion is presented in the Statement of Operations as a deemed dividend, increasing net loss to arrive at net loss attributable to common stockholders.

Preferred Share Conversion Activity

During the three months ended January 31, 2018, 1,544,572 Series A Preferred Shares, 2,578 Series C Preferred Shares and 26,667 Series D Preferred Shares were converted into 454,395 shares of common stock.

8. FAIR VALUE MEASUREMENTS

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

- Level 1: Observable inputs such as quoted prices in active markets for identical instruments
- Level 2: Quoted prices for similar instruments that are directly or indirectly observable in the market
- Level 3: Significant unobservable inputs supported by little or no market activity. Financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, for which determination of fair value requires significant judgment or estimation.

In connection with the offering of Units in September 2017, the Company issued warrants to purchase an aggregate of 322,727 shares of common stock. These warrants are exercisable at $30.00 per share and expire in two years. The warrants are liabilities pursuant to ASC 815. The warrant agreement provides for an adjustment to the number of common shares issuable under the warrant and/or adjustment to the exercise price, including but not limited to, if: (a) the Company issues shares of common stock as a dividend or distribution to holders of its common stock; (b) the Company subdivides or combines its common stock (i.e., stock split); (c) adjustment of exercise price upon issuance of new securities at less than the exercise price. Under ASC 815, warrants that provide for down-round exercise price protection are recognized as derivative liabilities.

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

The fair value of the bifurcated embedded conversion feature was estimated to be approximately $7.4 million and $9.2 million, respectively, at January 31, 2018 and October 31, 2017 as calculated using the Monte Carlo simulation with the following assumptions:

	Series F Conversion Feature	
	January 31, 2018	October 31, 2017
Stock price	$ 21.30	$ 25.87
Exercise price	$ 27.50	$ 27.50
Risk-free rate	2.053%	1.581%
Volatility	86.4%	96.0%
Term	1.64	1.89

The fair value of the warrant liability was estimated to be approximately $2.8 million and $4.3 million, respectively, at January 31, 2018 and October 31, 2017 as calculated using the Monte Carlo simulation with the following assumptions:

	Warrant Liability	
	January 31, 2018	October 31, 2017
Stock price	$ 21.30	$ 25.87
Exercise price	$ 30.00	$ 30.00
Risk-free rate	2.053%	1.581%
Volatility	86.4%	96.0%
Term	1.64	1.89

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

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

	Fair Value Measurement as of January 31, 2018			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities				
Warrant liability	$ -	$ -	$ 2,765	$ 2,765
Derivative liability	-	-	7,363	7,363
Total	$ -	$ -	$ 10,128	$ 10,128

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

The following table sets forth the changes in the estimated fair value for our Level 3 classified derivative warrant liability (in thousands):

	2017 Series F Preferred Stock - Warrant Liability	2017 Series F Preferred Stock - Embedded Derivative	Total Warrant and Derivative Liability
Fair value - October 31, 2017	$ 4,256	$ 9,246	$ 13,502
Change in fair value	(1,491)	(1,883)	(3,374)
Fair value - January 31, 2018	$ 2,765	$ 7,363	$ 10,128

9. STOCK BASED COMPENSATION ARRANGEMENTS

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

	For the Three Months Ended January 31,	
	2018	2017
General and administrative expense:		
Continuing operations	$ 8,910	$ 3,975
Discontinued operations	-	442
	8,910	4,417
Research and development expense:		
Continuing operations	2,221	-
Total stock-based compensation expense	$ 11,132	$ 4,417

A summary of the Company's employee stock option activity in the three months ended January 31, 2018 is presented below:

	Number of shares	Weighted-Average Exercise Price
Outstanding - October 31, 2017	3,525,530	$ 6.34
Granted	1,030,500	$ 24.47
Exercised	(10,794)	$ 5.10
Forfeited	(34,167)	$ 18.90
Outstanding - January 31, 2018	4,511,069	$ 10.39
Options exercisable - January 31, 2018	1,930,500	$ 5.79
Weighted-average fair value of options granted during the period		$ 16.57

A summary of the Company's non-employee stock option activity in the three months ended January 31, 2018 is presented below:

	Number of shares	Weighted-Average Exercise Price
Outstanding - October 31, 2017	293,000	$ 19.61
No activity	-	$ -
Outstanding - January 31, 2018	293,000	$ 19.61
Options exercisable - January 31, 2018	63,292	$ 14.24

Stock options are generally granted to employees or non-employees at exercise prices equal to the fair market value of the Company's stock at the dates of grant. Stock options generally vest over one to three years and have a term of five to ten years. The total fair value of employee options granted during the three months ended January 31, 2018 was approximately $17.1 million. The intrinsic value of options outstanding at January 31, 2018 was $54.7 million. The intrinsic value of options exercised during the three months ended January 31, 2018 was $141,000. The weighted average remaining contractual term of outstanding and exercisable options at January 31, 2018 was 9.1 years and 8.9 years, respectively. As of January 31, 2018, there was approximately $18.3 million of unrecognized compensation cost related to stock options, which is expected to be recognized over a remaining weighted-average vesting period of 0.8 years.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions for the three months ended January 31, 2018:

Risk free annual interest rate	2.01%-2.65%
Expected volatility	81.32-85.54%
Expected life	5.00-6.01
Assumed dividends	None

Restricted stock and restricted stock units activity for employees and non-employees in the fiscal year ended October 31, 2017:

	Number of shares	Weighted-Average Grant-Date Fair Value
Unvested - October 31, 2017	227,132	$ 7.83
Granted	102,500	$ 23.91
Vested	(97,049)	$ 12.53
Unvested - January 31, 2018	232,583	$ 12.95

The total fair value of restricted stock and restricted stock units granted during the three months ended January 31, 2018 was approximately $2.5 million.

The value of restricted stock and restricted stock unit grants is measured based on the fair market value of the Company's common stock on the date of grant and amortized over the vesting period of, generally, six months to three years. As of January 31, 2018, there was approximately $2.1 million of unrecognized compensation cost related to unvested restricted stock and restricted stock unit awards, which is expected to be recognized over a remaining weighted-average vesting period of 0.5 years.

10. INCOME TAXES

The Company calculates its provision for federal and state income taxes based on current tax law. The Tax Cuts and Jobs Act (tax reform) was enacted on December 22, 2017 ("Enactment Date"), and has several key provisions impacting accounting for and reporting of income taxes. The most significant provision reduces the U.S. corporate statutory tax rate from 35% to 21% beginning on January 1, 2018. Although most provisions of tax reform are not effective until 2018, the Company is required to record the effect of a change in tax law as of the Enactment Date on its deferred tax assets. As the Company maintains a full valuation allowance against its deferred tax assets, there is no income tax expense recorded related to this change. As of the Enactment Date, the Company estimates that its deferred tax asset and related valuation allowance were each reduced by approximately $2.2 million.

Additionally, the Securities Exchange Commission staff has issued SAB 118, which allows the Company to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. Because the Company is still in the process of analyzing certain provisions of the Tax Act, the Company has determined that the adjustment to its deferred taxes was a provisional amount as permitted under SAB 118.

Due to the Company's history of losses and uncertainty of future taxable income, a valuation allowance sufficient to fully offset net operating losses and other deferred tax assets has been established. The valuation allowance will be maintained until sufficient positive evidence exists to support a conclusion that a valuation allowance is not necessary. The issuance of Preferred Stock in connection with the Polarity acquisition will likely result in limitations on the utilization of the Company's net operating loss carryforwards under IRS section 382.

11. LOSS PER SHARE

Shares of common stock issuable under convertible preferred stock, warrants and options and shares subject to restricted stock grants were not included in the calculation of diluted earnings per common share for the three months ended January 31, 2018 and 2017, as the effect of their inclusion would be anti-dilutive.

For periods when shares of participating preferred stock (as defined in ASC 260 earnings per share) are outstanding, the two-class method is used to calculate basic and diluted earnings (loss) per common share. The two-class method is an earnings allocation formula that determines earnings per share for each class of common stock and participating security according to dividends declared (or accumulated) and participation rights in undistributed earnings. Under the two-class method, basic earnings (loss) per common share is computed by dividing net earnings (loss) attributable to common share after allocation of earnings to participating securities by the weighted-average number of shares of common stock outstanding during the year. Diluted earnings (loss) per common share, when applicable, is computed using the more dilutive of the two-class method or the if-converted method. In periods of net loss, no effect is given to participating securities since they do not contractually participate in the losses of the Company.

The table below provides total potential shares outstanding, including those that are anti-dilutive, on January 31, 2018 and 2017:

	January 31,	
	2018	2017
Shares issuable upon exercise of warrants	322,727	-
Shares issuable upon conversion of preferred stock	8,853,413	2,357,232
Shares issuable upon exercise of stock options	4,804,069	2,922,020
Non-vested shares under restricted stock grants	232,583	640,184

12. COMMITMENTS AND CONTINGENCIES

Contingencies

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, Majesco Entertainment Company ("Majesco DE"), and a number of other game publisher defendants. The complaint alleged that the Zumba Fitness Kinect game infringed plaintiff's patents in motion tracking technology. The plaintiff is representing himself pro se in the litigation and is seeking monetary damages in the amount of $1.3 million. The case was subsequently transferred to the Western District of Washington. On June 16, 2017, final judgment was entered in favor of the defendants. The plaintiff has appealed that decision to the Court of Appeals for the Federal Circuit. The appeal is currently pending. On June 23, 2017, as part of a purchase agreement, liabilities and claims relating to this litigation were assumed by Zift Interactive LLC. The Company cannot be certain about the outcome of the appeal, or whether litigation regarding the assumption of liabilities by Zift Interactive LLC may occur.

In addition to the item above, the Company at times may be a party to claims and suits in the ordinary course of business. We record a liability when it is both probable that a liability has been incurred and the amount of the loss or range of loss can be reasonably estimated. The Company has not recorded a liability with respect to the matter above. While the Company believes that it has valid defenses with respect to the legal matter pending and intends to vigorously defend the matter above, given the uncertainty surrounding litigation and our inability to assess the likelihood of a favorable or unfavorable outcome, it is possible that the resolution of the matter could have a material adverse effect on our consolidated financial position, cash flows or results of operations.

Commitments

The Company leases office space in Hazlet, New Jersey at a cost of approximately $1,100 per month under a lease agreement that expires on March 31, 2018. This lease has been renewed for another year.

The Company also leases space in Salt Lake City, Utah at a cost of approximately $24,044 per month under a lease agreement that expires on March 31, 2018.

On December 27, 2017, the Company signed a five-year lease with one five-year option to renew on approximately 178,528 rentable square feet. The base rent for the first year of the lease is $1,178,285 and escalates at the rate of 3% per annum thereafter.

Rent expense for the three months ended January 31, 2018 and 2017 was approximately $249,000 and $17,000, respectively.

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

13. RELATED PARTIES

In January 2015, the Company entered into an agreement with Equity Stock Transfer LLC for transfer agent services. A former Board member of the Company is a co-founder and chief executive officer of Equity Stock Transfer LLC. Fees under the agreement were approximately $0 and $2,000, in the three months ended January 31, 2018 and 2017, respectively.

14. DISCONTINUED OPERATIONS

The results of operations from the discontinued business for the three months ended January 31, 2018 and 2017 are as follows (in thousands):

	For the Three Months Ended January 31,	
	2018	2017
Revenues	$ -	$ 156
Expenses	-	588
Loss from discontinued operations	$ -	$ (432)

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

	For the three months ended January 31,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss from discontinued operations	-	(432)
Adjustments to reconcile net loss from discontinued operations to net cash used in discontinued operating activities:		
Depreciation and amortization	-	83
Stock based compensation expense	-	442
Changes in operating assets and liabilities:		
Accounts receivable	-	12
Accounts payable and accrued expenses	-	290
Net cash provided by discontinued operating activities	-	395
CASH FLOWS FROM INVESTING ACTIVITIES		
Cash received from sale of Majesco Sub	15	-
Net cash provided by discontinued investing activities	15	-

15. SUBSEQUENT EVENTS

Asset Purchase Agreement

On March 2, 2018, the Company entered into an asset purchase agreement (the "APA") with a Utah limited liability company ("Seller"), along with its related entity ("Seller Corp."), wherein Seller Corp. agreed to sell the assets and rights to its preclinical research and veterinary sciences business and related real estate (as more fully described below). The business consists of a "*good laboratory practices*" (GLP) compliant preclinical research facility, including vivarium, operating rooms, preparation rooms, storage facilities, and surgical and imaging equipment. A broad range of veterinary services related to orthopedics, soft tissue surgery, neurosurgery, and non-surgical research and development are performed at the facilities and are intended to be utilized by the Company to expand its research and development capabilities for development of its skin, bone, muscle, cartilage, fat, and other technologies and derivative products and technologies related to the Company's "TE" technology pipeline. The Company also intends to continue to operate and expand the contract preclinical research business currently operated by the Seller.

Pursuant to the APA, the $1.6 million purchase price is payable as follows: $266,667 payable in cash and a promissory note for approximately $1.3 million. payable in 5 equal installments beginning on the six (6) month anniversary of issuance and continuing on each 6-month anniversary thereafter with interest at the rate of 3.5% per annum.

Purchase and Sale Agreement

Concurrently with the execution and delivery of the APA, on March 2, 2018, the Company entered into a purchase and sale agreement with Seller to purchase two parcels of real property in Cache County, Utah, consisting of approximately 1.75 combined gross acres of land including all related rights, real and personal property on the land (collectively, the "Property").

The purchase price for the Property is $2.0 million, is payable $25,000 in cash and the remaining will be deposited by the Company into escrow pursuant to a loan to be obtained by the Company from a lender of its choice.

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

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

The Exchange resulted in the following issuances: (A) all outstanding Series F Preferred Shares were converted into 972,067 shares of restricted common stock at an effective conversion price of $18.26 per share of common stock (the closing price of Common Stock on the NASDAQ Capital Market on February 26, 2018); (B) the right to receive 6% dividends underlying Series F Preferred Shares was terminated and in exchange 31,324 shares of restricted common stock was issued; (C) 322,727 Warrants to purchase common stock was exchanged for 151,872 shares of restricted common stock; and (D) the Holders of the Warrants relinquished any and all other rights pursuant to the Warrants, including exercise price adjustments.

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

Preferred Stock Conversion and Elimination

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

On March 6, 2018, the Company received conversion notices from holders of 100% of the outstanding Series A Preferred Shares, Series B Preferred Shares, Series E Preferred Shares and exchanged the Series F Preferred Shares and warrants and issued an aggregate of 9,100,515 shares of common stock to such holders.

The Series E Preferred Shares were held by Dr. Denver Lough, the Company's Chief Executive Officer. On March 6, 2018, the Company entered into a new registration rights agreement (the "Lough Registration Rights Agreement") with Dr. Denver Lough, pursuant to which the Company agreed to file a registration statement to register the resale of 7,050,000 shares of Common Stock issued upon conversion of the Series E Preferred Shares within six months, to cause such registration statement to be declared effective by the Securities and Exchange Commission as promptly as possible following its filing and, with certain exceptions set forth in the Lough Registration Rights Agreement, to maintain the effectiveness of the registration statement until all of such shares have been sold or are otherwise able to be sold pursuant to Rule 144 under the Securities Act without restriction. Any sales of shares under the registration statement are subject to certain limitations as specified with more particularity in the Lough Registration Rights Agreement.

On March 7, 2018, the Company filed a Certificate of Elimination with the Secretary of State of the State of Delaware terminating the Company's Series A, Series B, Series C, Series D, Series E and Series F Preferred Stock and thereafter no shares of Company preferred stock will remain outstanding.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Statements in this quarterly report on Form 10-Q that are not historical facts constitute forward-looking statements that are made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, as amended, or the "Exchange Act". Examples of forward-looking statements include statements relating to industry prospects, our future economic performance including anticipated revenues and expenditures, results of operations or financial position, and other financial items, our business plans and objectives, including our intended product releases, and may include certain assumptions that underlie forward-looking statements. Risks and uncertainties that may affect our future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements include, among other things, those discussed in this section as well as factors described in Part II, Item 1A—"Risk Factors". In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other comparable terminology. These statements are subject to business and economic risk and reflect management's current expectations and involve subjects that are inherently uncertain and difficult to predict. Actual events or results may differ materially. Moreover, neither we nor any other person assumes responsibility for the accuracy or completeness of these statements. We are under no duty to update any of the forward-looking statements after the date of this report to conform these statements to actual results. References herein to "we," "us," and "the Company" are to PolarityTE, Inc. and its consolidated subsidiaries.

Overview

PolarityTE, Inc. is a commercial-stage biotechnology and regenerative biomaterials company focused on transforming the lives of patients by discovering, designing and developing a range of regenerative tissue products and biomaterials for the fields of medicine, biomedical engineering and material sciences.

Research and Development Expenses. Research and development expenses primarily represent employee related costs, including stock compensation, for research and development executives and staff, lab and office expenses and other overhead charges.

General and Administrative Expenses. General and administrative expenses primarily represent employee related costs, including stock compensation, for corporate executive and support staff, general office expenses, professional fees and various other overhead charges. Professional fees, including legal and accounting expenses, typically represent one of the largest components of our general and administrative expenses. These fees are partially attributable to our required activities as a publicly traded company, such as SEC filings, and corporate- and business-development initiatives.

Income Taxes. Income taxes consist of our provisions for income taxes, as affected by our net operating loss carryforwards. Future utilization of our net operating loss, or NOL, carryforwards may be subject to a substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code. The annual limitation may result in the expiration of NOL carryforwards before utilization. Due to our history of losses, a valuation allowance sufficient to fully offset our NOL and other deferred tax assets has been established under current accounting pronouncements, and this valuation allowance will be maintained unless sufficient positive evidence develops to support its reversal.

Critical Accounting Estimates

Our discussion and analysis of the financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP.

The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses, and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from these estimates under different assumptions or conditions.

We have identified the policies below as critical to our business operations and to the understanding of our financial results. The impact and any associated risks related to these policies on our business operations is discussed throughout management's discussion and analysis of financial condition and results of operations when such policies affect our reported and expected financial results.

Accounting for Stock-Based Compensation. Stock-based compensation expense is measured at the grant date based on the fair value of the award and is recognized as expense over the vesting period. Determining the fair value of stock-based awards at the grant date requires judgment, including, in the case of stock option awards, estimating expected stock volatility.

Accounting for Common and Preferred Stock and Warrant transactions. We issued units consisting of preferred shares and warrants and common stock and warrants and subsequently remeasured certain of those warrants. Determining the fair value of the securities in these transactions requires significant judgment, including adjustments to quoted share prices and expected stock volatility. Such estimates may significantly impact our results of operations and losses applicable to common stockholders.

Commitments and Contingencies. We record a liability for contingencies when the amount is both probable and reasonably estimable. We record associated legal fees as incurred.

Results of Operations

Three months ended January 31, 2018 versus three months ended January 31, 2017

Net Revenues. For the three-month period ended January 31, 2018, net revenues from product sales were $13,000 which represents the first sale of the Company's core product SkinTE.

Cost of Sales. For the three-month period ended January 31, 2018, cost of sales was approximately $1,000 and represents the freight charges associated with the $13,000 in product sales.

Research and Development Expenses. For the three-month period ended January 31, 2018, research and development expenses were approximately $6.6 million. Research and development expenses mostly consist of stock-based compensation of approximately $2.2 million, salaries of approximately $1.9 million, medical studies of approximately $0.5 million, bonuses of approximately $0.5 million, medical samples of approximately $0.3 million, medical equipment depreciation of approximately $0.3 million, rent of approximately $0.2 million, and office expense of approximately $0.2 million.

General and Administrative Expenses. For the three-month period ended January 31, 2018, general and administrative expenses were approximately $10.9 million compared to $5.2 million for the three months ended January 31, 2017. The increase is primarily due to increased stock-based compensation of $5.0 million.

Net loss from continuing operations. Net loss for the three months ended January 31, 2018 was approximately $14.1 million, compared to a net loss of approximately $5.2 million in the comparable period in 2017, primarily reflecting the $7.2 million increase in stock-based compensation expenses and research and development offset by the gain from derivative liabilities.

Liquidity and Capital Resources

As of January 31, 2018, our cash and cash equivalents balance was approximately $10.0 million and our working capital deficit was approximately $2.8 million, compared to cash and equivalents of $17.7 million and working capital of $2.5 million at October 31, 2017.

As reflected in the condensed consolidated financial statements, we had an accumulated deficit of approximately $273.1 million at January 31, 2018, a net loss of approximately $14.1 million from continuing operations and approximately $5.1 million net cash used in continuing operating activities for the three months ended January 31, 2018. These factors raise substantial doubt about the Company's ability to continue as a going concern.

We will continue to pursue fundraising opportunities that meet our long-term objectives, however, our cash position is not sufficient to support our operations for the foreseeable future. The condensed consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Based upon the current status of our product development and commercialization plans, we believe that our existing cash, cash equivalents and marketable securities will be adequate to satisfy our capital needs to approximately October 2018. We anticipate needing substantial additional financing to continue clinical deployment and commercialization of our lead product SkinTE, development of our other product candidates, and scaling the manufacturing capacity for our products and product candidates, and prepare for commercial readiness. Such financing may not be available on terms favorable to us if at all, which raises substantial doubt about our ability to continue as a going concern as of the date of this report. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our product development programs. We plan to meet our capital requirements primarily through issuances of equity securities, debt financing, revenue from product sales and future collaborations. Failure to generate revenue or raise additional capital would adversely affect our ability to achieve our intended business objectives.

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

As previously reported, we identified a material weakness in the effectiveness of our internal controls over financial reporting, a factor that could affect our liquidity and capital resources. At present, management believes that the recent improvement of the processes for granting equity awards to certain employees and service providers will ultimately correct the material weakness.

Preferred Share Conversion and Exchange Activity

During the three months ended January 31, 2018, 1,544,572 Series A Preferred Shares, 2,578 Series C Preferred Shares and 26,667 Series D Preferred Shares were converted into 454,395 shares of common stock.

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

On March 6, 2018, the Company received conversion notices from holders of 100% of the outstanding Series A Preferred Shares, Series B Preferred Shares, and Series E Preferred Shares, and the Company completed an exchange of the Series F Preferred Shares. In connection with the conversion and exchange, the Company issued an aggregate of 9,100,515 shares of common stock to such holders. The Company filed a Certificate of Elimination with the Secretary of State of the State of Delaware terminating the Company's Series A, Series B, Series C, Series D, Series E and Series F Preferred Stock and thereafter no shares of Company preferred stock remain outstanding and all rights under the Series F Preferred Shares, among other things, to price adjustment in the event of future issuances will be terminated.

Common Stock

During the three months ended January 31, 2018, certain employees exercised their options at a weighted-average exercise price of $5.10 in exchange for the Company's common stock for an aggregated amount of 10,417 shares.

Off-Balance Sheet Arrangements

As of January 31, 2018, we had no off-balance sheet arrangements.

Inflation

Our management currently believes that inflation has not had, and does not currently have, a material impact on continuing operations.

Cash Flows

Cash and cash equivalents and working capital deficit were approximately $10.0 million and $2.8 million, respectively, as of January 31, 2018 compared to cash and cash equivalents and working capital of approximately $17.7 million and $2.5 million at October 31, 2017, respectively.

Operating Cash Flows. Cash used in continuing operating activities in the three months ended January 31, 2018 amounted to approximately $5.1 million compared to approximately $756,000 for the 2017 period. The increase in net cash used in continuing operating activities mostly relates to the increase in net loss, partially offset by the increase in share-based compensation.

Cash provided by discontinued operating activities in the three months ended January 31, 2018 amounted to approximately $0 compared to approximately $395,000 for the 2017 period.

Investing Cash Flows. Cash used in continuing investing activities in the three months ended January 31, 2018 amounted to approximately $2.7 million compared to $1.5 million for the 2017 period. For both the 2018 and 2017 periods, the activity relates to the purchase of property and equipment (mostly medical equipment).

Financing Cash Flows. Net cash provided by financing activities for the three months ended January 31, 2018 amounted to approximately $45,000 compared to approximately $2.3 million for the 2017 period. For the three months ended January 31, 2018, the $45,000 related to proceeds from option exercises. For the three months ended January 31, 2017, the $2.3 million related to equity capital raises.

Recent Accounting Pronouncements

Refer to our discussion of recent accounting pronouncements in Note 2 - Summary of Significant Accounting Policies to the accompanying condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

Not applicable.

Item 4. Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in the Securities Exchange Act of 1934 Rule 13a-15(e) and 15d-15(e), as of the end of the period covered by this report.

In designing and evaluating our disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Management assessed the effectiveness of our internal control over financial reporting as of January 31, 2018. In making this assessment, management used the framework set forth in the report entitled Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013, or COSO. The COSO framework summarizes each of the components of a company's internal control system, including (i) the control environment, (ii) risk assessment, (iii) control activities, (iv) information and communication, and (v) monitoring. Based on this evaluation, management determined that our system of internal control over financial reporting was not effective as of January 31, 2018.

A material weakness is a deficiency, or a combination of deficiencies, within the meaning of Public Company Accounting Oversight Board ("PCOAB") Audit Standard No. 5, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Management has identified the following material weakness which has caused management to conclude that as of January 31, 2018 our ICFR were not effective at the reasonable assurance level:

Due to a lack of processes in place to address personnel changes, controls over the Company's process of accounting for stock-based compensation failed to ensure the completeness of stock options and restricted stock grants in the Company's calculation of stock-based compensation expense.

During the quarter ended January 31, 2018, the Company started the process to mitigate the weakness above, and expect it to be remediated during fiscal year 2018.

While we believe our disclosure controls and procedures and our internal control over financial reporting are adequate, no system of controls can prevent errors and fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur. Controls can also be circumvented by individual acts of some people, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with its policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Subject to the limitations above, management believes that the condensed consolidated financial statements and other financial information contained in this report, fairly present in all material respects our financial condition, results of operations, and cash flows for the periods presented.

Based on the evaluation of the effectiveness of our disclosure controls and procedures and the material weakness identified at October 31, 2017 that has not yet been remediated, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) were not effective at a reasonable assurance level at January 31, 2018.

Changes in Internal Control Over Financial Reporting

During the three months ended January 31, 2018, there were no changes in our internal control over financial reporting other than the one described above.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

The Company at times may be a party to claims and suits in the ordinary course of business. We record a liability when it is both probable that a liability has been incurred and the amount of the loss or range of loss can be reasonably estimated. The Company has not recorded a liability with respect to the matter above. While the Company believes that it has valid defenses with respect to the legal matter pending and intends to vigorously defend the matter above, given the uncertainty surrounding litigation and our inability to assess the likelihood of a favorable or unfavorable outcome, it is possible that the resolution of the matter could have a material adverse effect on our consolidated financial position, cash flows or results of operations.

Item 1A. Risk Factors

Our business and operations are subject to a number of risks and uncertainties as described below. However, the risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we may currently deem immaterial, may become important factors that could harm our business, financial condition or results of operations. If any of the following risks actually occur, our financial condition or results of operations could suffer.

Risks Related to Our Business

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

Our near-term prospects depend upon our ability to effectively market our lead product candidate, SkinTE, and to demonstrate its safety and effectiveness in humans, as well as its superiority over existing therapies and standards of care. Our ability to finance our company and to generate revenues will depend in part on our ability to obtain favorable results in the planned clinical evaluations of SkinTE and to successfully develop and commercialize SkinTE.

SkinTE could be unsuccessful if it:

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

If we are not successful in developing and commercializing SkinTE or are significantly delayed in doing so, our financial

condition and 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, 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, Majesco Entertainment Company ("Majesco DE"), and a number of other game publisher defendants. The complaint alleged that the Zumba Fitness Kinect game infringed plaintiff's patents in motion tracking technology. The plaintiff is representing himself pro se in the litigation and is seeking monetary damages in the amount of $1.3 million. The case was subsequently transferred to the Western District of Washington. On June 16, 2017, final judgment was entered in favor of the defendants. The plaintiff has appealed that decision to the Court of Appeals for the Federal Circuit. The appeal is currently pending. On June 23, 2017, as part of a purchase agreement, liabilities and claims relating to this litigation were assumed by Zift Interactive LLC. The Company cannot be certain about the outcome of the appeal, or whether litigation regarding the assumption of liabilities by Zift Interactive LLC may occur.

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 $130.8 million for the year ended October 31, 2017, and $14.1 million for the quarter ended January 31, 2018. Our ability to achieve profitable operations in the future will depend in large part upon the successful development and commercialization of our product candidates and technologies. Factors impacting our ability to successfully develop and commercialize our product candidates include:

- approvals by 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;
- 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 products and 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. As result, our product candidates are inherently risky.

We cannot guarantee that the results we see in clinical applications will be comparable to the preclinical results we have observed in animals. 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, and to avoid potential confusion with and differentiate ourselves from the ethical controversies associated with human fetal tissue and engineered human tissue;
- Adverse reactions involving our products or the products or product candidates of others that are cell- or tissue-based;
- 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 other third-party payers, including the amounts of reimbursement made for our products and the conditions for such reimbursement.

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

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

Our success will depend on the extent to which reimbursement for the costs of our treatments will be available from third-party payers, such as public and private insurers and health systems, as well as the amounts that they will agree to reimburse. Government and other third-party payers attempt to contain healthcare costs by limiting both coverage and the level of reimbursement, and the amount of reimbursement 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 at adequate treatment amounts, future changes in reimbursement policies could have a negative impact on our business, financial condition and results of operations.

Commercial third-party payers and government payers are increasingly attempting to contain healthcare costs by demanding price discounts, including by limiting coverage on which products they will pay for and the amounts that they will pay for new products, and by creating conditions to reimbursement, such as coverage eligibility requirements based upon clinical evidence development involving research studies and the collection of physician decision impact and patient outcomes data. Because of these cost-containment trends, commercial third-party payers and government payers that currently provide or in the future may provide reimbursement for one or more of our product candidates may reduce, suspend, revoke, or discontinue payments or coverage at any time, including those payers that designate one or more of our product candidates as experimental and investigational. Payers may also create conditions to coverage or contract with third-party vendors to manage laboratory benefit coverage, in both cases creating burdens for ordering physicians and patients that may make our product candidates more difficult to sell. The percentage of submitted claims that are ultimately paid, the length of time to receive payment on claims, and the average reimbursement of those paid claims, is likely to vary from period to period. Finally, payers may demand discounts or offer reimbursement that minimizes our ability to sell our products profitably, or simply choose to not cover or reimburse our products at all.

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

- not experimental or investigational;
- medically reasonable and necessary;
- appropriate for the specific patient;
- cost effective;
- supported by peer-reviewed publications;
- included in clinical practice guidelines and pathways; and
- supported by clinical utility and health economic studies demonstrating improved outcomes and cost effectiveness.

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

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

We are subject to numerous federal and state healthcare laws 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, and exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid. In addition, federal and state laws are also sometimes open to interpretation. Accordingly, we could potentially face legal risks if our interpretation differs from those of enforcement authorities. Further, from time to time we may find ourselves at a competitive disadvantage if our interpretation differs from that of our competitors.

Specifically, anti-kickback laws and regulations prohibit any knowing and willful offer, payment, solicitation or receipt of any form of remuneration (direct or indirect, in case or in kind) in return for the referral, use, ordering, or recommending of the use of a product or service for which payment may be made by Medicare, Medicaid or other Government-sponsored healthcare programs. We have entered into consulting agreements, research agreements and product development agreements with physicians, including some who may order our products or make decisions to use them. In addition, some of these physicians own our stock, which they purchased in arm's length transactions on terms identical to those offered to non-physicians, or received stock awards from us as consideration for services performed by them. While these transactions were structured with the intention of complying with all applicable laws, including state anti-referral laws and other applicable anti-kickback laws, it is possible that regulatory or enforcement agencies or courts may in the future view these transactions as prohibited arrangements that must be restructured or for which we would be subject to other significant civil or criminal penalties. There can be no assurance that regulatory or enforcement authorities will view these arrangements as 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. Further, even the costs of defending investigations of noncompliance could be substantial.

Also, the FCA imposes civil liability on any person or entity that submits, or causes the submission of, a false or fraudulent claim to the federal government. Damages under the FCA can be significant and consist of the imposition of fines and penalties. The FCA also allows a private individual or entity (i.e., a whistleblower) with knowledge of past or present fraud against the federal government to sue on behalf of the government and to be paid a portion of the government's recovery, which can include both civil penalties and up to three times the amount of the government's damages (usually the amount reimbursed by federal healthcare programs). The U.S. Department of Justice ("DOJ") on behalf of the government takes the position that the marketing and promotional practices of life sciences product manufacturers, including the off-label promotion of products, the provision of inaccurate or misleading reimbursement guidance, or the payment of prohibited kickbacks to doctors or other referral sources may cause the submission of improper claims to federal and state healthcare entitlement programs such as Medicare and Medicaid, by health care providers that use the manufacturer's products, which results in a violation of the FCA. In certain cases, manufacturers have entered into criminal and civil settlements with the federal government under which they entered into plea agreements, paid substantial monetary amounts and entered into corporate integrity agreements that require, among other things, substantial reporting and remedial actions going forward.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other health care providers. In addition to federal laws, some states, such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance 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.

Our use of sensitive patient information is subject to complex regulations at multiple levels and we would be adversely affected if we fail to adequately protect this sensitive information.

We process, maintain and utilize personal health and other confidential and sensitive data. In particular, we have developed a web and mobile application through which our customers can communicate with physicians and others, which may involve sharing patient identifiable health information. The use and disclosure of such information is regulated at the federal, state and international levels, and these laws, rules and regulations are subject to change and increased enforcement activity, such as the audit program implemented by HHS under HIPAA. International laws, rules and regulations governing the use and disclosure of such information are generally more stringent than in the United States, and they vary from jurisdiction to jurisdiction. Noncompliance with any privacy or security laws or regulations, or any security breach, cyber-attack or cybersecurity breach, and any incident involving the theft, misappropriation, loss or other unauthorized disclosure of, or access to, sensitive or confidential information, whether by us or by another third party, could require us to expend significant resources to remediate any damage, interrupt our operations and damage our brand and reputation, and could also result in investigations, regulatory enforcement actions, material fines and penalties, loss of customers, litigation or other actions which could have a material adverse effect on our business, brand, reputation, cash flows and operating results.

Our business depends on provider and patient willingness to entrust us with health related and other sensitive personal information. Events that negatively affect that trust, including inadequate disclosure of our uses of their information, failing to keep our information technology systems and sensitive information secure from significant attack, theft, damage, loss or unauthorized disclosure or access, whether as a result of our action or inaction or that of third parties, could adversely affect our brand, reputation and revenues and also expose us to mandatory disclosure to the media, litigation (including class action litigation) and other enforcement proceedings, material fines, penalties and/or remediation costs, and compensatory, special, punitive and statutory damages, consent orders and/or injunctive relief, any of which could adversely affect our business, cash flows, operating results or financial position. There can be no assurance that any such failure will not occur, or if any does occur, that we will detect it or that it can be sufficiently remediated.

Many of our competitors have substantially greater resources than we do, and we expect that all 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.

Certain key members of our management team may be subject to conflicts of interest.

Certain members of our management team have full or part-time interests outside of our business, including employment at other institutions. Such management team members may face conflicts of interest, including conflicts in allocating time and the ability to present research and business opportunities learned in the scope of other positions. These conflicts could result in unanticipated actions that adversely affect us. Currently, we have no policy in place to address such conflicts of interest. In addition, many universities and medical institutions have policies that apply to faculty members' activities outside the scope of their employment at the university and medical institution. We do not independently review all of these policies or monitor our executive's compliance with these types of third party policies and policies of former employers of our executives. Instead, we rely on representations made by the executive and periodic confirmations from the executive that he or she is in compliance with PolarityTE's employment policies.

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 or amounts of reimbursement from third-party payers.

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

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

We 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.

We have 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 fail to maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required to report upon the effectiveness of our internal control over financial reporting. When and if we are a "large accelerated filer" or an "accelerated filer" and are no longer a "smaller reporting company," each as defined in the Exchange Act, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. However, for so long as we remain a smaller reporting company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to smaller reporting companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer a smaller reporting company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we need to upgrade our systems including information technology; implement additional financial and management controls, reporting systems, and procedures; and ensure we have hired sufficient accounting and finance staff.

We have identified a material weakness in our internal control over financial reporting. If our remedial measures are insufficient to address the material weakness, or if we otherwise fail to establish and maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results, timely file our periodic reports, maintain our reporting status or prevent fraud.

At times we have not had sufficient accounting and supervisory personnel with the appropriate level of technical accounting experience and training necessary or adequate formally documented accounting policies and procedures to support, effective internal controls. As we grow, we will hire additional personnel and engage in external temporary resources and may implement, document and modify policies and procedures to maintain effective internal controls. However, we may identify deficiencies and weaknesses or fail to remediate previously identified deficiencies in our internal controls. If material weaknesses or deficiencies in our internal controls exist and go undetected or un-remediated, our financial statements could contain material misstatements that, when discovered in the future, and our operating results could be material impacted and we could fail to meet our future reporting obligations.

If we discover additional material weaknesses or 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 supervised the completion of the first full audit of our financial statements for the year ending October 31, 2017. A material weakness was identified related to a lack of processes in place to address personnel changes and controls over the Company's process of accounting for stock-based compensation, which resulted in a failure to ensure the completeness of stock options and restricted stock grants in the Company's calculation of stock-based compensation expense. If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, or, if we fail to timely remediate the material weakness or 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 government agencies; and/or
- 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 October 31, 2017 are derivative liabilities related to embedded features bifurcated from our preferred stock and 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 could preclude us from practicing 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 and enforceability of a patent involves complex issues of fact and law. If one or more of any patents we obtain is invalidated and/or held unenforceable, such an outcome could reduce or eliminate any competitive advantage we might otherwise have had.

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

There can be no assurance that a third party, including but not limited to a university or other research institution that our founders were associated with in the past, will not make claims to ownership or other claims related to our technology.

There can be no assurance that a third party, including but not limited to a university or other research institution that our founders were associated with in the past, will not make claims to ownership or other claims related to our technology. We believe we have developed our technology outside of any institutions, but we cannot guarantee such institutions would not assert a claim to the contrary. Even if successful, litigation to enforce or defend our intellectual property rights could be expensive and time consuming, and could divert our management's attention. Further, bringing litigation to enforce our future patent(s) subjects us to the potential for counterclaims. In the event that one or more of our future 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 future patents through any pre- or post-grant patent proceedings, such an outcome could prevent or hinder us from being able to enforce the patent against competitors. Such adverse decisions could negatively affect our future, 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 of 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, do not ensure protection against improper use or disclosure of confidential information, and these agreements may be breached. A breach of confidentiality could affect our competitive position. In addition, in some situations, these agreements and other obligations of our employees to assign intellectual property to the Company may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators or advisors have previous employment or consulting relationships. Also, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets.

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

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

Third parties could assert that our processes, product candidates or technology infringe their patents or other intellectual property rights. Whether a process, product or technology infringes a patent or other intellectual property involves complex legal and factual issues, the determination of which is often uncertain. We cannot be certain that we will not be found to have infringed the intellectual property rights of others. Because patent applications may remain unpublished for certain periods of time and may take years to be issued as patents, there may be applications now pending of which we are unaware 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.

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.

If we are successful in obtaining patent protection, we may not be able to enforce those patent rights against third parties.

Successful challenge of any future patents such as through opposition, reexamination, *inter partes* review, interference, or derivation proceedings could result in a loss of patent rights in the relevant jurisdiction. Furthermore, because of the substantial amount of discovery required 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, consent decrees, product seizures, and/or civil penalties;
- Operating restrictions, partial suspension or total shutdown of clinical studies, manufacturing, marketing, or distribution;
- Refusing requests for clearance or approval of new products, processes, or procedures, or for certificates or approval to enable export of the same;
- Withdrawing or suspending current applications for approval or clearance, or any approvals or clearances already granted; and
- Civil or criminal prosecution.

It is likely that the FDA's regulation of 361 HCT/Ps and other types of products (e.g., drugs, devices, 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 or when such revised draft or final guidance or regulations (if any) will be issued, the scope of such guidance, any new rules or regulations, whether they will apply to our technologies or products, or whether they will be advantageous or disadvantageous to us. In addition, even if it does not issue new regulations or guidance, FDA could in the future adopt more restrictive interpretations of existing regulations or increase its enforcement activity, which may adversely affect our business.

We believe our current product candidates, including the FDA-registered SkinTE product, satisfy applicable criteria for regulation as a 361 HCT/P and are therefore exempt from FDA requirements for premarket approval or clinical studies. If the FDA disagrees with our interpretation of the relevant laws and regulations as they apply to our product candidates, and requires an Investigational New Drug application ("IND") or Investigational Device Exemption application ("IDE") for any of our product candidates, we may need to delay, abandon, or revise our current development plans, discontinue ongoing marketing, and/or recall products. The submission of an IND, Biologics License Applications ("BLA"), New Drug Application ("NDA"), or other medical device clearance or approval application would require us to compile significant amounts of data related to our regulatory process, as well as data from preclinical and/or clinical testing. We cannot guarantee that we will ever be able to secure such approvals if required. Even if such approvals are obtained, regulation as a drug, biologic, or medical device would subject us to additional FDA postmarketing requirements that are complex and involve substantial expense, such as compliance with drug, biologic, or medical device current Good Manufacturing Practice or quality system requirements.

The FDA regulates HCT/Ps under a two-tiered framework. Certain higher risk HCT/Ps are regulated as new drugs, biologics or medical devices. Manufacturers of new drugs, biologics and some medical devices must complete extensive clinical trials, which must be conducted pursuant to an effective IND or IDE. In addition, the FDA must review and approve a BLA or NDA before a new drug or biologic may be marketed. For most medical devices, including novel or high-risk medical devices, FDA must approve a premarket approval application ("PMA") or grant clearance to a premarket notification ("510(k)") application prior to marketing of the device.

By contrast, the FDA exempts 361 HCT/Ps from these requirements if they meet certain specified criteria. We believe that 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 or clearance 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 not provided comprehensive 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 or interpretations for determining which products qualify as 361 HCT/Ps or the regulatory requirements for HCT/Ps.

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

Even if the FDA regulates our product candidates, including SkinTE, 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 or be subject to FDA requirements for labeling or promotion of new drugs, biologics, or medical devices, we still must generate adequate substantiation for claims we make in our marketing materials. Both the Federal Trade Commission ("FTC") and the states retain jurisdiction over the marketing of 361 HCT/Ps (and other) products in commerce and require a reasonable basis for claims made in marketing materials. Through our planned preclinical and clinical studies, as well as other endeavors, we intend to generate such adequate substantiation for any claims we make about our 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 can make about our product candidates.

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

The FDA establishes regulatory requirements based on the classification of a product. An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into a human patient. 361 HCT/Ps are not subject to any premarket clearance or approval requirements and are subject to less extensive post-market regulatory requirements. Because our product development programs are designed to satisfy the standards applicable to 361 HCT/Ps, any change in the regulatory classification or designation of our products would affect our ability to obtain FDA approval or clearance for and marketing of 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 substantially more difficult or expensive for us to conduct our business by requiring extensive clinical trials, premarket clearance or approval and compliance with additional post-market regulatory requirements with respect to those 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 interpretations, restrictions, or requirements with respect to products that qualify as 361 HCT/Ps.

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

Even if the FDA does not object to the marketing of any of our product candidates as a 361 HCT/P and, therefore, without an NDA, BLA, PMA, or 510(k), we will still be subject to numerous post-market requirements, including those related to registration and listing, record keeping, labeling, current good tissue practices, or cGTPs, donor eligibility, deviation and adverse event reporting, and other activities. HCT/Ps that do not meet the definition of a 361 HCT/P and, therefore, are required to be approved or cleared via an NDA, BLA, PMA, or 510(k) are also subject to these and/or additional obligations. If we fail to comply with these requirements, we could be subject to, without limitation, warning letters, product seizures, injunctions or civil and criminal penalties. We are currently relying on a third-party cGTP-compliant facility to conduct the various steps involved in our process. In the future, we plan to establish our own processing facility, which will need to be cGTP compliant. Any failure by us or the third-party facility on which we rely to maintain cGTP compliance would require remedial actions, which could potentially include actions such as product recalls or delays in distribution and sales of our 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 authorization, 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, if applicable, 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, if applicable, and may cause delays or interruptions in the availability of our product candidates for commercial distribution. 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 (if applicable), 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 current 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 clinical trials, product manufacture, commercial sales or exports, 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 primarily on one facility. If this facility is destroyed or we experience any manufacturing difficulties, disruptions or delays, this could limit supply of our product 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 cGTP and/or cGMP (if applicable) regulatory and quality standard requirements and, if applicable, FDA approval would be required before any products manufactured at that facility could be made commercially available.

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 from a gaming business to regenerative medicine. We do not expect to generate any revenues going forward that we have achieved in prior years, and no longer expect to generate any revenues from other segments of our business which have been terminated or disposed of. We will need additional capital to continue to fund our operations and plans to commercialize and develop our tissue products and product candidates. 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 January 29, 2018, 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 January 31, 2018, we had $10.0 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 $130.8 million in fiscal 2017, and additional net losses of $14.1 for the quarter ended January 31, 2018. 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. 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;
    - our need to remediate material weaknesses and implement and maintain additional internal systems, processes and infrastructure, to have an effective system of internal control over financial reporting;
- 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 25,000,000 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 matters submitted to stockholders for approval.

On March 6, 2018, Dr. Denver Lough converted 7,050 shares of our Series E Preferred Stock into 7,050,000 shares of our common stock and received a proxy to vote an additional 797,296 shares of common stock held by certain of our other shareholders. Dr. Lough holds additional shares and/or vested options to purchase shares of our common stock. As of March 14, 2018, there were 16,457,664 shares of common stock issued and outstanding eligible to vote and, accordingly, Dr. Lough currently holds or has the right to vote approximately 53% of the outstanding voting capital of the Company. As a result, Dr. Lough, together with our other executive officers and directors, would be able to control 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, and to date, a significant percentage of our common stock has been held by affiliates and insiders. 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 $3.86 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 53% 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 the 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Schema Document.
101.CAL*	XBRL Calculation Linkbase Document.
101.DEF*	XBRL Definition Linkbase Document.
101.LAB*	XBRL Label Linkbase Document.
101.PRE*	XBRL Presentation Linkbase Document.

* Filed herewith

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 thereunto duly authorized.

POLARITYTE, INC.

/s/ Denver Lough
Denver Lough
Chief Executive Officer
(Principal Executive Officer)

Date: March 19, 2018

/s/ John Stetson
John Stetson
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 19, 2018

EXHIBIT 31.1

CERTIFICATION

I, Denver Lough, certify that:

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

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

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

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

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

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 19, 2018

/s/ Denver Lough

Denver Lough
Title: Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, John Stetson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of PolarityTE, Inc.:

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

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

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

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

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: March 19, 2018

/s/ John Stetson

John Stetson
Title: Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32

Certification
Pursuant To Section 906 of the Sarbanes-Oxley Act Of 2002
(Subsections (A) And (B) Of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officers of PolarityTE, Inc., (the "Company"), do hereby certify, to such officers' knowledge, that:

The Quarterly Report on Form 10-Q for the period ending January 31, 2018 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 19, 2018

/s/ Denver Lough
Denver Lough
Title: Chief Executive Officer
(Principal Executive Officer)

/s/ John Stetson
John Stetson
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)