

---

---

**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 September 30, 2019**

**Commission File No. 000-51128**

**POLARITYTE, INC.**

(Exact name of registrant as specified in its charter)

**DELAWARE**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**06-1529524**  
(I.R.S. Employer  
Identification No.)

**123 Wright Brothers Drive  
Salt Lake City, UT 84116**  
(Address of principal executive offices)

Registrant's Telephone Number, Including Area Code: **(800) 560-3983**

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

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, Par Value \$0.001	PTE	Nasdaq Capital Market

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

Indicate by check mark whether the registrant has submitted electronically 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  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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

As of November 8, 2019, there were 26,985,630 shares of the Registrant's common stock outstanding.

---

---

## INDEX

	<b>Page</b>
<b><u>PART I - FINANCIAL INFORMATION</u></b>	
<u>Item 1. Financial Statements:</u>	4
<u>Condensed Consolidated Balance Sheets as of September 30, 2019 (unaudited) and December 31, 2018</u>	4
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2019 and 2018 (unaudited)</u>	5
<u>Condensed Consolidated Statements of Comprehensive Loss for the three and nine months ended September 30, 2019 and 2018 (unaudited)</u>	6
<u>Condensed Consolidated Statements of Stockholders' Equity for the nine months ended September 30, 2019 and 2018 (unaudited)</u>	7
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2019 and 2018 (unaudited)</u>	8
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	9
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	26
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	32
<u>Item 4. Controls and Procedures</u>	32
<b><u>PART II - OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings</u>	34
<u>Item 6. Exhibits</u>	34
<u>SIGNATURES</u>	35

### Forward-looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements. Risks and uncertainties are inherent in forward-looking statements. Furthermore, such statements may be based on assumptions that fail to materialize or prove incorrect. Consequently, our business development, operations, and results could differ materially from those expressed in forward-looking statements made in this Quarterly Report. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “would,” or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the initiation, timing, progress, and results of our research and development programs;
- the timing or success of commercialization of our products;
- the pricing and reimbursement of our products;
- the initiation, timing, progress, and results of our preclinical and clinical studies;
- the scope of protection we can establish and maintain for intellectual property rights covering our product candidates and technology;
- estimates of our expenses, future revenues, and capital requirements;
- our need for, and ability to obtain, additional financing in the future;
- our ability to comply with regulations applicable to the manufacture, marketing, sale and distribution of our products;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- our views about our prospects in ongoing litigation and SEC investigation;
- developments relating to our competitors and industry; and
- other risks and uncertainties, including those listed under Part I, Item 1A. Risk Factors of our Transition Report on Form 10-K filed with the Securities and Exchange Commission on March 18, 2019.

Given the known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by our forward-looking statements, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

**PART I - FINANCIAL INFORMATION**  
**Item 1. Financial Statements:**

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

	<u>September 30, 2019</u> (Unaudited)	<u>December 31, 2018</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 27,273	\$ 55,673
Short-term investments	18,675	6,162
Accounts receivable	1,593	712
Inventory	346	336
Prepaid expenses and other current assets	1,306	1,432
Total current assets	<u>49,193</u>	<u>64,315</u>
Property and equipment, net	15,662	13,736
Operating lease right-of-use assets	5,028	-
Intangible assets, net	778	924
Goodwill	278	278
Other assets	353	913
<b>TOTAL ASSETS</b>	<u>\$ 71,292</u>	<u>\$ 80,166</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 10,233	\$ 6,508
Other current liabilities	2,582	316
Current portion of long-term note payable	538	529
Deferred revenue	134	170
Total current liabilities	<u>13,487</u>	<u>7,523</u>
Long-term note payable, net	247	479
Operating lease liabilities	3,358	-
Other long-term liabilities	1,808	131
Total liabilities	<u>18,900</u>	<u>8,133</u>
Commitments and Contingencies		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock - 25,000,000 shares authorized, 0 shares issued and outstanding at September 30, 2019 and December 31, 2018	-	-
Common stock - \$.001 par value; 250,000,000 shares authorized; 26,932,764 and 21,447,088 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	27	21
Additional paid-in capital	466,514	414,840
Accumulated other comprehensive income	63	36
Accumulated deficit	(414,212)	(342,864)
Total stockholders' equity	<u>52,392</u>	<u>72,033</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<u>\$ 71,292</u>	<u>\$ 80,166</u>

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

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

	For the three months ended		For the nine months ended	
	September 30,		September 30,	
	2019	2018	2019	2018
<b>Net revenues</b>				
Products	\$ 839	\$ 197	\$ 1,640	\$ 389
Services	556	528	2,546	659
Total net revenues	<u>1,395</u>	<u>725</u>	<u>4,186</u>	<u>1,048</u>
<b>Cost of sales</b>				
Products	315	267	930	393
Services	330	400	1,087	441
Total cost of sales	<u>645</u>	<u>667</u>	<u>2,017</u>	<u>834</u>
<b>Gross profit</b>	<u>750</u>	<u>58</u>	<u>2,169</u>	<u>214</u>
<b>Operating costs and expenses</b>				
Research and development	2,956	4,111	13,072	12,598
General and administrative	16,044	15,135	48,299	33,998
Sales and marketing	4,988	1,618	12,922	1,618
Total operating costs and expenses	<u>23,988</u>	<u>20,864</u>	<u>74,293</u>	<u>48,214</u>
<b>Operating loss</b>	<u>(23,238)</u>	<u>(20,806)</u>	<u>(72,124)</u>	<u>(48,000)</u>
<b>Other income (expenses)</b>				
Interest income, net	27	227	126	314
Other (expense) income, net	228	–	650	–
Change in fair value of derivatives	–	–	–	1,850
Loss on extinguishment of warrant liability	–	–	–	(520)
<b>Net loss</b>	<u>(22,983)</u>	<u>(20,579)</u>	<u>(71,348)</u>	<u>(46,356)</u>
Deemed dividend – accretion of discount on Series F preferred stock	–	–	–	(698)
Deemed dividend – exchange of Series F preferred stock	–	–	–	(7,057)
Cumulative dividends on Series F preferred stock	–	–	–	(191)
<b>Net loss attributable to common stockholders</b>	<u>\$ (22,983)</u>	<u>\$ (20,579)</u>	<u>\$ (71,348)</u>	<u>\$ (54,302)</u>
<b>Net loss per share, basic and diluted:</b>				
Net loss	\$ (0.87)	\$ (0.97)	\$ (2.94)	\$ (2.80)
Deemed dividend – accretion of discount on Series F preferred stock	–	–	–	(0.04)
Deemed dividend – exchange of Series F preferred stock	–	–	–	(0.43)
Cumulative dividends on Series F preferred stock	–	–	–	(0.01)
<b>Net loss attributable to common stockholders</b>	<u>\$ (0.87)</u>	<u>\$ (0.97)</u>	<u>\$ (2.94)</u>	<u>\$ (3.28)</u>
<b>Weighted average shares outstanding, basic and diluted:</b>	<u>26,405,307</u>	<u>21,154,661</u>	<u>24,273,774</u>	<u>16,535,419</u>

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

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

	For the three months ended		For the nine months ended	
	September 30,		September 30,	
	2019	2018	2019	2018
<b>Net loss</b>	\$ (22,983)	\$ (20,579)	\$ (71,348)	\$ (46,356)
Other comprehensive income:				
Unrealized (loss)/gain on available-for-sale securities	(16)	-	27	-
<b>Comprehensive loss</b>	<u>\$ (22,999)</u>	<u>\$ (20,579)</u>	<u>\$ (71,321)</u>	<u>\$ (46,356)</u>

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

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

**For the nine months ended September 30, 2019**

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Number	Amount				
<b>December 31, 2018</b>	21,447,088	\$ 21	\$ 414,840	\$ 36	\$ (342,864)	\$ 72,033
Stock-based compensation expense	–	–	10,327	–	–	10,327
Stock option exercises	283,250	1	528	–	–	529
Vesting of restricted stock units	100,912	–	–	–	–	–
Shares withheld for tax withholding	(82,011)	–	(740)	–	–	(740)
Other comprehensive income	–	–	–	17	–	17
Net loss	–	–	–	–	(25,573)	(25,573)
<b>March 31, 2019</b>	21,749,239	\$ 22	\$ 424,955	\$ 53	\$ (368,437)	\$ 56,593
Proceeds received from issuance of common stock, net of issuance costs of \$1,146	3,418,918	3	27,945	–	–	27,948
Stock-based compensation expense	–	–	8,618	–	–	8,618
Stock option exercises	9,167	–	–	–	–	–
Shares issued under the ESPP	7,260	–	35	–	–	35
Vesting of restricted stock units	51,440	–	–	–	–	–
Shares withheld for tax withholding	(17,418)	–	(62)	–	–	(62)
Other comprehensive income	–	–	–	26	–	26
Net loss	–	–	–	–	(22,792)	(22,792)
<b>June 30, 2019</b>	25,218,606	\$ 25	\$ 461,491	\$ 79	\$ (391,229)	\$ 70,366
Stock-based compensation expense	–	–	5,025	–	–	5,025
Issuance of restricted stock awards	1,590,710	2	(2)	–	–	–
Vesting of restricted stock units	123,448	–	–	–	–	–
Other comprehensive income	–	–	–	(16)	–	(16)
Net loss	–	–	–	–	(22,983)	(22,983)
<b>September 30, 2019</b>	26,932,764	\$ 27	\$ 466,514	\$ 63	\$ (414,212)	\$ 52,392

**For the nine months ended September 30, 2018**

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Number	Amount	Number	Amount			
<b>December 31, 2017</b>	1,656,838	\$ 109,104	7,082,836	\$ 7	\$ 157,395	\$ (269,920)	\$ (3,414)
Issuance of common stock in connection with:							
Conversion of Series A preferred stock to common stock	(1,602,099)	(391)	363,036	–	391	–	–
Conversion of Series B preferred stock to common stock	(47,689)	(4,020)	794,820	1	4,019	–	–
Conversion of Series E preferred stock to common stock	(7,050)	(104,693)	7,050,000	7	104,686	–	–
Exchange of Series F preferred stock and dividends to common stock	–	–	1,003,393	1	13,060	–	13,061
Extinguishment of warrant liability	–	–	151,871	–	3,045	–	3,045
Stock-based compensation expense	–	–	–	–	7,445	–	7,445
Deemed dividend – accretion of discount on Series F preferred stock	–	–	–	–	(698)	–	(698)
Cumulative dividends on Series F preferred stock	–	–	–	–	(191)	–	(191)
Series F preferred stock dividends paid in common stock	–	–	11,708	–	306	–	306
Net loss	–	–	–	–	–	(11,777)	(11,777)
<b>March 31, 2018</b>	–	\$ –	16,457,664	\$ 16	\$ 289,458	\$ (281,697)	\$ 7,777
Proceeds received from issuance of common stock, net of issuance costs of \$2,782	–	–	4,791,819	4	92,672	–	92,676
Stock-based compensation expense	–	–	–	–	8,344	–	8,344
Issuance of restricted stock awards	–	–	175,887	–	–	–	–
Stock option exercises	–	–	20,000	–	64	–	64
Net loss	–	–	–	–	–	(14,000)	(14,000)
<b>June 30, 2018</b>	–	\$ –	21,445,370	\$ 20	\$ 390,538	\$ (295,697)	\$ 94,861
Stock-based compensation expense	–	–	–	–	10,453	–	10,453
Issuance of restricted stock awards	–	–	7,613	–	–	–	–
Stock option exercises	–	–	43,516	1	157	–	158
Net loss	–	–	–	–	–	(20,579)	(20,579)
<b>September 30, 2018</b>	–	\$ –	21,496,499	\$ 21	\$ 401,148	\$ (316,276)	\$ 84,893

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

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

	<b>For the nine months ended September 30,</b>	
	<b>2019</b>	<b>2018</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (71,348)	\$ (46,356)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation expense	23,932	26,242
Change in fair value of derivatives	–	(1,850)
Depreciation and amortization	2,243	1,088
Loss on extinguishment of warrant liability	–	520
Amortization of intangible assets	146	83
Amortization of debt discount	40	30
Change in fair value of contingent consideration	(48)	20
Loss on disposal of property and equipment	265	–
Other non-cash adjustments	3	–
Changes in operating assets and liabilities:		
Accounts receivable	(881)	(788)
Inventory	(10)	(238)
Prepaid expenses and other current assets	126	(561)
Operating lease right-of-use assets	1,214	–
Other assets	25	(210)
Accounts payable and accrued expenses	4,095	2,484
Other current liabilities	155	–
Deferred revenue	(36)	116
Operating lease liabilities	(1,142)	–
Other long-term liabilities	571	–
Net cash used in operating activities	<u>(40,650)</u>	<u>(19,420)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property and equipment	(2,386)	(6,640)
Purchase of available-for-sale securities	(29,002)	–
Proceeds from maturities of available-for-sale securities	14,636	–
Proceeds from sale of available-for-sale securities	1,877	–
Acquisition of IBEX	–	(2,258)
Net cash used in investing activities	<u>(14,875)</u>	<u>(8,898)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Net proceeds from the sale of common stock	27,948	92,676
Proceeds from stock options exercised	529	222
Proceeds from ESPP purchase	35	–
Cash paid for tax withholdings related to net share settlement	(679)	–
Payment of contingent consideration liability	(109)	(30)
Principal payments on financing leases	(336)	(39)
Principal payments on term note payable	(263)	–
Net cash provided by financing activities	<u>27,125</u>	<u>92,829</u>
Net (decrease) increase in cash and cash equivalents	(28,400)	64,511
Cash and cash equivalents - beginning of period	55,673	12,517
Cash and cash equivalents - end of period	<u>\$ 27,273</u>	<u>\$ 77,028</u>
<b>Supplemental schedule of non-cash investing and financing activities:</b>		
Conversion of Series A, B, E preferred stock to common stock	\$ –	\$ 109,104
Exchange of Series F preferred stock for common stock	–	13,061
Extinguishment of warrant liability	–	2,525
Unpaid liability for acquisition of property and equipment	249	699
Deemed dividend – accretion of discount on Series F preferred stock	–	698
Cumulative dividends on Series F preferred stock	–	191
Series F preferred stock dividends paid in common stock	–	306
Reclassification of stock-based compensation expense that was previously classified as a liability to paid-in capital	38	–
Contingent consideration for IBEX acquisition	–	278
Contingent consideration earned and recorded in accounts payable	–	33
Note payable issued as partial consideration for IBEX acquisition	–	1,220
Property and equipment acquired through finance lease	2,341	141
Property and equipment acquired through financing arrangement	58	–
Unrealized gain on short-term investments	27	–

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



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

**1. PRINCIPAL BUSINESS ACTIVITY AND BASIS OF PRESENTATION**

PolarityTE, Inc. and subsidiaries (the “Company”) 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.

*Change in Fiscal Year end.* On January 11, 2019, the Board approved an amendment to the Restated Bylaws of the Company changing the Company’s fiscal year end from October 31 to December 31. As such, the end of the quarters in the new fiscal year do not coincide with the end of the quarters in the Company’s previous fiscal years. The Company made this change to align its fiscal year end with other companies within its industry.

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 results of operations for interim periods are not necessarily indicative of results to be expected for the entire fiscal year. The balance sheet at December 31, 2018 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 audited consolidated financial statements and notes thereto for the two-month period ended December 31, 2018 included in the Company’s Transition Report on Form 10-KT filed with the Securities and Exchange Commission on March 18, 2019.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Principles of Consolidation.* The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Significant intercompany accounts and transactions have been eliminated in consolidation.

*Use of estimates.* The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities or the disclosure of gain or loss contingencies at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Among the more significant estimates included in these financial statements is the extent of progress toward completion of contracts, stock-based compensation, the valuation allowances for deferred tax benefits, and the valuation of tangible and intangible assets included in acquisitions. Actual results could differ from those estimates.

*Segments.* The Company’s operations are based in the United States and involve products and services which are managed separately. Accordingly, it operates in two segments: 1) regenerative medicine products and 2) contract services. The Chief Operating Decision Maker (CODM) is our Office of the Chief Executive consisting of the Chief Operating Officer, the Chief Financial Officer, and the President of Corporate Development. The CODM allocates resources to and assesses the performance of each operating segment using information about its revenue and operating income (loss). Prior to the acquisition of IBEX, the Company operated in one segment.

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

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

*Loss Per Share.* Basic loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share since the effects of potentially dilutive securities are antidilutive.

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

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

*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, research and development, and sales and marketing expenses. For stock options with graded vesting, the Company recognizes compensation expense over the service period for each separately vesting tranche of the award as though the award were in substance, multiple awards based on the fair value on the date of grant.

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

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

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

*Research and Development Expenses.* Costs incurred for research and development are expensed as incurred.

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

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

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

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

In the contract services segment, the Company records services revenues from the sale of its contract research services, which includes delivery of preclinical studies and other research services to unrelated third parties. Services revenues generally consist of a single performance obligation that the Company satisfies over time using an input method based on costs incurred to date relative to the total costs expected to be required to satisfy the performance obligation. The Company believes that this method provides a faithful depiction of the transfer of services over the term of the performance obligation based on the remaining services needed to satisfy the obligation. This requires the Company to make reasonable estimates of the extent of progress toward completion of the contract. As a result, unbilled receivables and deferred revenue are recognized based on payment timing and work completed. Generally, a portion of the payment is due upfront and the remainder upon completion of the study, with most studies completing in less than a year. As of September 30, 2019 and December 31, 2018, the Company had unbilled receivables of \$222,000 and \$157,000 and deferred revenue of \$134,000 and \$170,000, respectively. The unbilled receivables balance is included in consolidated accounts receivable. Revenues of \$170,000 were recognized during the nine months ended September 30, 2019 that were included in the deferred revenue balance at the beginning of the period.

Costs to obtain the contract are incurred for products revenues as they are shipped and are expensed as incurred.

#### ***Recent Accounting Pronouncements***

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820), Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*. The ASU modifies the disclosure requirements for fair value measurements by removing, modifying or adding certain disclosures. The standard is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years with early adoption permitted. The Company is currently evaluating the impact that the standard will have on its consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses (Topic 326)*, which requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost. This standard is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years with early adoption permitted. The Company is currently evaluating the impact that the standard will have on its consolidated financial statements and related disclosures.

#### **Recently Adopted Accounting Pronouncements**

On January 1, 2019 the Company adopted ASU 2016-02, *Leases (ASC 842)* and related amendments, which require lease assets and liabilities to be recorded on the balance sheet for leases with terms greater than twelve months. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. The standard was adopted using the modified retrospective transition approach by applying the new standard to all leases existing at the date of the initial application and not restating comparative periods.

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

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

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

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-based Payment Accounting*. The standard expands the scope of Topic 718 to include share-based payments issued to nonemployees for goods or services, simplifying the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years with early adoption permitted, including adoption in an interim period. The Company adopted this ASU on January 1, 2019. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements and related disclosures.

### **3. LIQUIDITY**

The Company has experienced recurring losses and cash outflows from operating activities. Since inception through September 30, 2019, the Company has an accumulated deficit of \$414.2 million. As of September 30, 2019, the Company had cash and cash equivalents and short-term investments of \$45.9 million.

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

Based upon the current status of the Company's product development and commercialization plans, the Company believes that its existing cash, cash equivalents and short-term investments will be adequate to satisfy its capital needs for at least the next 12 months from the date of filing. The Company anticipates needing substantial additional financing to continue clinical deployment and commercialization of its lead product SkinTE, development of its other product candidates, and scaling the manufacturing capacity for its products and product candidates and prepare for commercial readiness. However, the Company will continue to pursue fundraising opportunities when available, but such financing may not be available in the future on terms favorable to the Company, if at all. If adequate financing is not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its product development programs. The Company may also implement additional spending reductions. The Company plans to meet its 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 the Company's ability to achieve its intended business objectives.

#### 4. FAIR VALUE

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

- Level 1: Observable inputs such as quoted prices in active markets for identical instruments. This methodology applies to our Level 1 investments, which are composed of money market funds.
- Level 2: Quoted prices for similar instruments that are directly or indirectly observable in the market. This methodology applies to our Level 2 investments, which are composed of corporate debt securities, commercial paper, and U.S. government debt securities.
- Level 3: Significant unobservable inputs supported by little or no market activity. Financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, for which determination of fair value requires significant judgment or estimation. This methodology applies to our Level 3 financial instruments, which are composed of contingent consideration.

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. There were no transfers within the hierarchy for any of the periods presented.

In connection with the offering of Units in September 2017 (see Note 10), the Company issued Series F Preferred Shares and warrants to purchase an aggregate of 322,727 shares of common stock. The Series F Preferred Shares contained an embedded conversion feature that was not clearly and closely related to the identified host instrument and, as such, was recognized as a derivative liability measured at fair value. The Company classified these derivatives on the consolidated balance sheet as a current liability. The warrants were exercisable at \$30.00 per share and had a two year expiration. The warrants were liabilities pursuant to ASC 815. The warrant agreement provided for an adjustment to the number of common shares issuable under the warrant or adjustment to the exercise price, including but not limited to, if: (a) the Company issues shares of common stock as a dividend or distribution to holders of its common stock; (b) the Company subdivides or combines its common stock (i.e., stock split); or (c) the Company issues new securities for consideration less than the exercise price. Under ASC 815, warrants that provide for down-round exercise price protection are recognized as derivative liabilities.

As discussed in Note 10, both the warrants and the Series F Preferred Shares were exchanged for common stock on March 6, 2018.

The fair value of the bifurcated embedded conversion feature was estimated to be approximately \$7.2 million at March 5, 2018, as calculated using the Monte Carlo simulation with the following assumptions:

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

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

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

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

	2017 Series F Preferred Stock – Warrant Liability	2017 Series F Preferred Stock – Embedded Derivative	Total Warrant and Derivative Liability
Fair value – December 31, 2017	\$ 3,388	\$ 8,150	\$ 11,538
Change in fair value	(863)	(987)	(1,850)
Exchange / conversion to common shares	(2,525)	(7,163)	(9,688)
Fair value – September 30, 2018	\$ –	\$ –	\$ –

The following table sets forth the fair value of the Company's financial assets and liabilities measured on a recurring basis by level within the fair value hierarchy as of September 30, 2019 and December 31, 2018 (in thousands):

	Fair Value Measurement as of September 30, 2019			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds	\$ 7	\$ –	\$ –	\$ 7
Commercial paper	–	12,053	–	12,053
Corporate debt securities	–	13,995	–	13,995
U.S. government debt securities	–	4,632	–	4,632
<b>Total</b>	<b>\$ 7</b>	<b>\$ 30,680</b>	<b>\$ –</b>	<b>\$ 30,687</b>
<b>Liabilities:</b>				
Contingent consideration	\$ –	\$ –	\$ 135	\$ 135
<b>Total</b>	<b>\$ –</b>	<b>\$ –</b>	<b>\$ 135</b>	<b>\$ 135</b>

  

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

In May 2018, the Company purchased the assets of a preclinical research sciences business and related real estate from Ibex Group, L.L.C., a Utah limited liability company, and Ibex Preclinical Research, Inc., a Utah corporation (collectively, "IBEX"). The aggregate purchase price was \$3.8 million, of which \$2.3 million was paid at closing and the balance satisfied by a promissory note payable to IBEX with an initial fair value of \$1.2 million and contingent consideration with an initial fair value of \$0.3 million.

The contingent consideration represents the estimated fair value of future payments due to the Seller of IBEX based on IBEX's revenue generated from studies quoted prior to but completed after the transaction. Contingent consideration was initially recognized at fair value as purchase consideration and is subsequently remeasured at fair value through earnings. The initial fair value of the contingent consideration was based on the present value of estimated future cash flows using a 20% discount rate. The contingent consideration is the payment of 15% of the actual revenues received for work on any study initiated within 18 months following the closing of the purchase on the basis of certain specific customer prospects that received service proposals prior to the closing, provided that the total payments will not exceed \$650,000. Adjustments to the fair value of the contingent consideration liability is included in general and administrative expense in the accompanying consolidated statements of operations.

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

	<b>Contingent Consideration</b>
Fair value – December 31, 2018	\$ 261
Change in fair value	(48)
Earned and paid	(78)
Fair value – September 30, 2019	<u>\$ 135</u>

## 5. CASH EQUIVALENTS AND AVAILABLE FOR SALE MARKETABLE SECURITIES

Cash equivalents and available-for-sale marketable securities consisted of the following as of September 30, 2019 and December 31, 2018 (in thousands):

	September 30, 2019			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Market Value
<b>Cash equivalents:</b>				
Money market funds	\$ 7	\$ –	\$ –	\$ 7
Commercial paper	10,037	32	–	10,069
U.S. government debt securities	1,930	6	–	1,936
<b>Total cash equivalents (1)</b>	<b>11,974</b>	<b>38</b>	<b>–</b>	<b>12,012</b>
<b>Short-term investments:</b>				
Commercial paper	1,980	4	–	1,984
U.S. government debt securities	2,686	10	–	2,696
Corporate debt securities	13,984	11	–	13,995
<b>Total short-term investments</b>	<b>18,650</b>	<b>25</b>	<b>–</b>	<b>18,675</b>
<b>Total</b>	<b>\$ 30,624</b>	<b>\$ 63</b>	<b>\$ –</b>	<b>\$ 30,687</b>

(1) Included in cash and cash equivalents in the Company's consolidated balance sheet as of September 30, 2019 in addition to \$15.3 million of cash.

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

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

All investments in debt securities held as of September 30, 2019 and December 31, 2018 had maturities of less than one year. For the three and nine months ended September 30, 2019, the Company recognized net realized gains on available-for-sale securities and cash equivalents of \$0.1 million and \$0.4 million, respectively.

## 6. PROPERTY AND EQUIPMENT, NET

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

	<b>September 30, 2019</b>	<b>December 31, 2018</b>
Machinery and equipment	\$ 11,814	\$ 8,276
Land and buildings	2,000	2,000
Computers and software	1,173	1,372
Leasehold improvements	2,272	1,230
Construction in progress	1,903	2,402
Furniture and equipment	470	614
Total property and equipment, gross	<u>19,632</u>	<u>15,894</u>
Accumulated depreciation	<u>(3,970)</u>	<u>(2,158)</u>
Total property and equipment, net	<u>\$ 15,662</u>	<u>\$ 13,736</u>

Depreciation and amortization expense for property and equipment, including assets acquired under financing leases for the three and nine months ended September 30, 2019 and 2018 was as follows (in thousands):

	<b>For the three months ended</b>		<b>For the nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
General and administrative expense	\$ 407	\$ 80	\$ 1,171	\$ 89
Research and development expense	390	336	1,072	999
Total depreciation and amortization expense	<u>\$ 797</u>	<u>\$ 416</u>	<u>\$ 2,243</u>	<u>\$ 1,088</u>

For the three and nine months ended September 30, 2019, the Company recognized a loss on disposal of property and equipment of \$265,000.



## 7. LEASES

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

In April 2019, the Company entered into an operating lease to obtain 6,307 square feet of manufacturing, laboratory, and office space. The lease expires April 2024 and requires monthly lease payments subject to annual increases. During the nine months ended September 30, 2019, the Company also increased office space under an existing lease, which requires additional monthly lease payments.

As of September 30, 2019, the maturities of our operating and finance lease liabilities were as follows (in thousands):

	Operating leases	Finance leases
2019 (excluding the nine months ended September 30, 2019)	\$ 551	\$ 149
2020	2,114	597
2021	1,730	594
2022	1,345	329
2023	132	253
Thereafter	87	43
Total lease payments	<u>5,959</u>	<u>1,965</u>
Less:		
Imputed interest	(787)	(310)
Total	<u>\$ 5,172</u>	<u>\$ 1,655</u>

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

### Finance leases

	As of September 30, 2019
Finance lease right-of-use assets included within property and equipment, net	\$ 2,112
Current finance lease liabilities included within other current liabilities	\$ 456
Non-current finance lease liabilities included within other long-term liabilities	1,199
Total	<u>\$ 1,655</u>

### Operating leases

	As of September 30, 2019
Current operating lease liabilities included within other current liabilities	\$ 1,814
Operating lease liabilities – non current	3,358
Total	<u>\$ 5,172</u>

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

	<b>Three months ended September 30, 2019</b>	<b>Nine months ended September 30, 2019</b>
Operating lease costs included within operating costs and expenses	\$ 556	\$ 1,617
Finance lease costs:		
Amortization of right of use assets	\$ 171	\$ 479
Interest on lease liabilities	42	109
Total	<u>\$ 213</u>	<u>\$ 588</u>

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

	<b>Nine months ended September 30, 2019</b>
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash out flows from operating leases	\$ 1,550
Operating cash out flows from finance leases	109
Financing cash out flows from finance leases	336
Lease liabilities arising from obtaining right-of-use assets:	
Finance leases	\$ 1,828
Lease payments made in prior period reclassified to property and equipment	535
Remeasurement of finance lease liability due to lease modification	(22)
Operating leases	936

As of September 30, 2019, the weighted average remaining operating lease term is 3.0 years and the weighted average discount rate used to determine the operating lease liability was 9.82%. The weighted average remaining finance lease term is 3.6 years and the weighted average discount rate used to determine the finance lease liability was 9.70%.

## 8. ACCOUNTS PAYABLE AND ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	<b>September 30, 2019</b>	<b>December 31, 2018</b>
Accounts payable	\$ 3,716	\$ 2,918
Salaries and other compensation	1,263	1,280
Legal and accounting	1,905	640
Accrued severance	2,519	-
Other accruals	830	1,670
Total accounts payable and accrued expenses	<u>\$ 10,233</u>	<u>\$ 6,508</u>

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

Accrued severance includes \$2.3 million for accrued compensation due to Dr. Denver Lough, a former officer and director, under a settlement terms agreement dated August 21, 2019. The remaining amount due of \$0.6 million is included in other long-term liabilities.

Other current liabilities are comprised of the current portion of operating lease liabilities and finance lease liabilities, contingent consideration, and short-term debt. The short-term debt had a balance of \$0.2 million as of September 30, 2019, while the other components are disclosed in the footnotes above.

## 9. LONG TERM NOTE PAYABLE

In connection with the IBEX Acquisition in May 2018, the Company issued a promissory note payable to the Seller with an initial fair value of \$1.2 million. The promissory note has a principal balance of \$1.3 million and bears interest at a rate of 3.5% interest per annum. Principal and interest are payable in five equal installments that began on November 3, 2018 and continuing on each six-month anniversary thereafter ("Payment Date"). The promissory note may be prepaid by the Company at any time and becomes due and payable at the earlier of the maturity date of November 3, 2020 or upon an event of default, which includes failure to pay any installment on each Payment Date, breach of any negative covenants, insolvency or bankruptcy. Upon the occurrence of an event of default, the promissory note will bear an accelerated interest rate of 7% per annum from the date of the event of default.

The Company initially recognized the promissory note at its fair value, using an estimated market rate of interest for the Company, which was higher than the promissory note's stated rate. The result of imputing a market rate of interest resulted in an initial discount to the principal balance of approximately \$113,000, which is being amortized to interest expense over the term of the promissory note using the effective interest method. The unamortized debt discount was approximately \$28,000 and \$68,000 at September 30, 2019 and December 31, 2018, respectively. Amortization of debt discount of \$12,000 and \$40,000 was included in interest income, net for the three and nine months ended September 30, 2019.

## 10. PREFERRED SHARES AND COMMON SHARES

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

On September 20, 2017, the Company sold an aggregate of \$17,750,000 worth of units of the Company's securities (the "Units") to accredited investors at a purchase price of \$2,750 per Unit. Each Unit consisted of (i) one share of the Company's newly authorized 6% Series F Convertible Preferred Stock, par value \$0.001 per share (the "Series F Preferred Shares"), convertible into one hundred (100) shares of the Company's common stock, and (ii) a two-year warrant to purchase up to 322,727 shares of the Company's common stock, at an exercise price of \$30.00 per share.

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

On the two-year anniversary of the initial issuance date, any Series F Preferred Shares outstanding and not otherwise already converted, would, 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.

The warrants issued in connection with the Series F Preferred Shares were determined to be liabilities pursuant to ASC 815. The warrant agreement provided for an adjustment to the number of common shares issuable under the warrant or adjustment to the exercise price, including but not limited to, if: (a) the Company issued shares of common stock as a dividend or distribution to holders of its common stock; (b) the Company subdivided or combined its common stock (i.e., stock split); or (c) the Company issues new securities for consideration less than the exercise price. Prior to the adoption of ASU 2017-11, warrants that provide for down-round exercise price protection were recognized as derivative liabilities.

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

The initial fair value of the warrants and bifurcated embedded conversion feature, estimated to be approximately \$4.3 million and \$9.3 million, respectively, was deducted from the gross proceeds of the Unit offering to arrive at the initial discounted carrying value of the Series F Preferred Shares. The resulting discount to the aggregate stated value of the Series F Preferred Shares of approximately \$13.6 million was recognized as accretion using the effective interest method similar to preferred stock dividends, over the two-year period prior to optional redemption by the holders.

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

The Exchange resulted in the following issuances: (A) all outstanding Series F Preferred Shares were converted into 972,070 shares of restricted common stock at an effective conversion price of \$18.26 per share of common stock (the closing price of Common Stock on the NASDAQ Capital Market on February 26, 2018); (B) the right to receive 6% dividends underlying Series F Preferred Shares was terminated in exchange for 31,321 shares of restricted common stock; (C) 322,727 Warrants to purchase common stock were exchanged for 151,871 shares of restricted common stock; and (D) the Holders of the Warrants relinquished any and all other rights pursuant to the Warrants, including exercise price adjustments.

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

The exchange of all outstanding Series F Preferred Shares, and the holders’ right to receive 6% dividends, for common stock of the Company was recognized as follows:

Fair market value of 1,003,393 shares of common stock issued at \$20.05 (Company’s closing stock price on March 5, 2018) in exchange for Series F Preferred Shares and accrued dividends	\$	20,117,990
Carrying value of Series F Preferred Shares at March 5, 2018, including dividends		(5,898,274)
Carrying value of bifurcated conversion option at March 5, 2018		(7,162,587)
Deemed dividend on Series F Preferred Shares exchange	\$	<u>7,057,129</u>

As the Warrants were classified as a liability, the exchange of the Warrants for common shares was recognized as a liability extinguishment. As of March 5, 2018, the fair market value of the 151,871 common shares issued in the Exchange was \$3,045,034 and the fair value of the common stock warrant liability was \$2,525,567 resulting in a loss on extinguishment of warrant liability of \$519,467 during the nine months ended September 30, 2018.

The Company recognized accretion of the discount to the stated value of the Series F Preferred Shares of approximately \$698,000 during the nine months ended September 30, 2018, as a reduction of additional paid-in capital and an increase in the carrying value of the Series F Preferred Shares. The accretion is presented in the Statement of Operations as a deemed dividend, increasing net loss to arrive at net loss attributable to common stockholders.

#### *Preferred Stock Conversion and Elimination*

On February 6, 2018, 15,756 shares of Series B Convertible Preferred Stock (“Series B Preferred Shares”) were converted into 262,606 shares of common stock.

On March 6, 2018, the Company received conversion notices (in accordance with original terms) from holders of 100% of the outstanding shares of Series A Convertible Preferred Stock (the “Series A Preferred Shares”), Series B Preferred Shares and Series E Convertible Preferred Stock (the “Series E Preferred Shares”) and issued an aggregate of 7,945,250 shares of common stock to such holders.

The shares of Series E Preferred Stock were held by Dr. Denver Lough, the Company's former Chief Executive Officer. On March 6, 2018, the Company entered into a new registration rights agreement (the "Lough Registration Rights Agreement") with Dr. Lough, pursuant to which the Company agreed to file a registration statement to register the resale of 7,050,000 shares of common stock issued upon conversion of the Series E Preferred Shares within six months, to cause such registration statement to be declared effective by the Securities and Exchange Commission as promptly as possible following its filing. On March 14, 2019, the Company's registration obligation was waived, and the Lough Registration Rights Agreement amended to provide that Dr. Lough may demand registration by written request to the Company. Dr. Lough demanded registration of his 7,050,000 common shares in August 2019, and pursuant to that demand a registration statement on Form S-3 was filed with the Securities and Exchange Commission in October 2019. Once the registration statement is effective, the Company is obligated to keep it effective until the earlier of the date all the registered shares have been sold pursuant to the registration statement or the date one year from the date the registration statement is first effective.

On March 7, 2018, the Company filed a Certificate of Elimination with the Secretary of State of the State of Delaware terminating the Company's Series A, Series B, Series C, Series D, Series E and Series F Preferred Stock. As a result, the Company has 25,000,000 shares of authorized and unissued preferred stock as of September 30, 2019 with no designation as to series.

There was no convertible preferred stock outstanding as of September 30, 2019 and December 31, 2018.

## 11. STOCK-BASED COMPENSATION

For the three and nine months ended September 30, 2019 and 2018, the Company recorded stock-based compensation expense related to stock options, restricted stock awards, and the employee stock purchase plan as follows (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2019	2018	2019	2018
General and administrative expense	\$ 4,822	\$ 10,118	\$ 20,751	\$ 22,925
Research and development expense	(164)	335	2,401	3,317
Sales and marketing expense	367	—	780	—
Total stock-based compensation expense	\$ 5,025	\$ 10,453	\$ 23,932	\$ 26,242

### *Incentive Compensation Plans*

#### *2019 Plan*

On October 5, 2018, the Company's Board of Directors (the "Board") approved the Company's 2019 Equity Incentive Plan (the "2019 Plan"). The 2019 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights and other types of stock-based awards to the Company's employees, officers, directors and consultants. The Compensation Committee of the Board will administer the 2019 Plan, including determining which eligible participants will receive awards, the number of shares of common stock subject to the awards and the terms and conditions of such awards. Up to 3,000,000 shares of common stock are issuable pursuant to awards under the 2019 Plan. Unless earlier terminated by the Board, the 2019 Plan shall terminate at the close of business on October 5, 2028. As of September 30, 2019, the Company had approximately 290,875 shares available for future issuances under the 2019 Plan.

2017 Plan

On December 1, 2016, the Company's Board of Directors (the "Board") approved the Company's 2017 Equity Incentive Plan (the "2017 Plan"). The purpose of the 2017 Plan is to promote the success of the Company and to increase stockholder value by providing an additional means through the grant of awards to attract, motivate, retain and reward selected employees, consultants and other eligible persons. The 2017 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights and other types of stock-based awards to the Company's employees, officers, directors and consultants. The Compensation Committee of the Board will administer the 2017 Plan, including determining which eligible participants will receive awards, the number of shares of common stock subject to the awards and the terms and conditions of such awards. Up to 7,300,000 (increased from 3,450,000 in October 2017) shares of common stock are issuable pursuant to awards under the 2017 Plan. Unless earlier terminated by the Board, the 2017 Plan shall terminate at the close of business on December 1, 2026. As of September 30, 2019, the Company had approximately 379,641 shares available for future issuances under the 2017 Plan.

Stock Options

A summary of the Company's employee and non-employee stock option activity for the nine months ended September 30, 2019 is presented below:

	Number of shares	Weighted-Average Exercise Price
Outstanding – December 31, 2018	6,499,885	\$ 14.02
Granted	818,403	\$ 13.75
Exercised (1)	(292,417)	\$ 4.31
Forfeited	(668,842)	\$ 20.50
Outstanding – September 30, 2019	<u>6,357,029</u>	\$ 13.91
Options exercisable – September 30, 2019	<u>4,815,831</u>	\$ 12.69
Weighted-average grant date fair value of options granted during the nine months ended September 30, 2019		\$ 9.84

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

Restricted Stock

A summary of the Company's employee and non-employee restricted-stock activity for the nine months ended September 30, 2019 is presented below:

	Number of shares	Weighted-Average Grant-Date Fair Value
Unvested - December 31, 2018	651,110	\$ 23.65
Granted	1,919,675	\$ 5.03
Vested (1)	(415,290)	\$ 20.84
Forfeited	(128,395)	\$ 22.44
Unvested – September 30, 2019	<u>2,027,100</u>	\$ 7.64

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

Employee Stock Purchase Plan (ESPP)

In May 2018, the Company adopted the Employee Stock Purchase Plan ("ESPP"). The Company has initially reserved 500,000 shares of common stock for purchase under the ESPP. The initial offering period began January 1, 2019 and ended on June 30, 2019 with the first purchase date. Subsequent offering periods will automatically commence on each January 1 and July 1 and will have a duration of six months ending with a purchase date June 30 and December 31 of each year. On each purchase date, ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of (1) the fair market value per share of the common stock on the offering date or (2) the fair market value of the common stock on the purchase date. Total stock-based compensation related to the ESPP for the three and nine months ended September 30, 2019 was \$14,000 and \$33,000, respectively. A total of 7,260 shares of common stock were purchased pursuant to the ESPP during the nine months ended September 30, 2019 for total proceeds of \$35,000.

## 12. INCOME TAXES

The Company has evaluated its income tax positions and determined that no material uncertain tax positions existed at September 30, 2019. The Company does not expect a significant change in its unrecognized tax benefits within the next twelve months.

As of September 30, 2019 and December 31, 2018, the Company maintained a valuation allowance to fully offset its net deferred tax assets primarily attributable to operations in the United States, as the realization of such assets was not considered more likely than not.

The Company files income tax returns in the U.S. Federal and various state and local jurisdictions.

## 13. LOSS PER SHARE

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

	As of September 30,	
	2019	2018
Stock options	6,357,029	6,125,628
Restricted stock	2,027,100	685,730
Shares committed under ESPP	15,235	—

## 14. COMMITMENTS AND CONTINGENCIES

### *Contingencies*

On June 26, 2018, a class action complaint alleging violations of the Federal securities laws was filed in the United States District Court, District of Utah, by Jose Moreno against the Company and two directors of the Company, Case No. 2:18-cv-00510-JNP (the "Moreno Complaint"). On July 6, 2018, a similar complaint was filed in the same court against the same defendants by Yedid Lawi, Case No. 2:18-cv-00541-PMW (the "Lawi Complaint"). Both the Moreno Complaint and Lawi Complaint allege that the defendants made or were responsible for, disseminating information to the public through reports filed with the Securities and Exchange Commission and other channels that contained material misstatements or omissions in violation of Sections 10 and 20(a) of the Exchange Act and Rule 10b-5 adopted thereunder. Specifically, both complaints allege that the defendants misrepresented the status of one of the Company's patent applications while touting the unique nature of the Company's technology and its effectiveness. Plaintiffs are seeking damages suffered by them and the class consisting of the persons who acquired the publicly-traded securities of the Company between March 31, 2017, and June 22, 2018. Plaintiffs have filed motions to consolidate and for appointment as lead plaintiff. On November 28, 2018, the Court consolidated the Moreno and Lawi cases under the caption *In re PolarityTE, Inc. Securities Litigation* (the "Consolidated Securities Litigation"), and requested the appointment of the plaintiff in Lawi as the lead plaintiff. On January 16, 2019, the Court granted the motion of Yedid Lawi for appointment as lead plaintiff, and on February 1, 2019, the Court granted the lead plaintiff's motion for approval of lead counsel and liaison counsel. The Court ordered that the lead plaintiff file and serve a consolidated complaint no later than 60 days after February 1, 2019, the defendants shall have 60 days after filing and service of the consolidated complaint to answer or otherwise respond, and the lead plaintiff must file a motion for class certification within 90 days of service of the consolidated complaint. The Lead Plaintiff filed a consolidated complaint on April 2, 2019 and asserted essentially the same violations of Federal securities laws recited in the original complaints. The Company believes the allegations in the consolidated complaint are without merit, and intends to defend the litigation, vigorously. The Company filed a motion to dismiss the consolidated complaint on June 3, 2019. Plaintiffs' opposition to the Company's motion to dismiss was filed on August 2, 2019, and the Company filed a reply to the opposition on September 13, 2019. A hearing on the Company's motion to dismiss is scheduled for November 19, 2019. At this early stage of the proceedings the Company is unable to make any prediction regarding the outcome of the litigation.

In the ordinary course of business, we may become involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements, regulatory compliance, and other matters. Except as noted above, at September 30, 2019, we were not party to any legal or arbitration proceedings that may have significant effects on our financial position or results of operations. We are not a party to any material proceedings in which any director, member of senior management or affiliate of ours is either a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

#### *Commitments*

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

### **15. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

On August 21, 2019, the Company and Dr. Denver Lough, a principal shareholder and former officer and director, signed a settlement terms agreement that provides, in part, that the Company pay to Dr. Lough \$1,500,000 in cash on October 1, 2019 and an additional \$1,500,000 in cash in equal monthly installments beginning November 1, 2019 and ending April 1, 2021. In addition, the Company agreed to award to Dr. Lough 200,000 restricted stock units that vest in 18 equal monthly installments beginning October 1, 2019.

In October 2018, the Company entered into an office lease covering approximately 7,250 square feet of rental space in the building located at 40 West 5<sup>th</sup> Street in New York City. The lease is for a term of three years. The annual lease rate is \$60 per square foot. Initially the Company will occupy and pay for only 3,275 square feet of space, and the Company is not obligated under the lease to pay for the remaining 3,975 square feet covered by the lease unless we elect to occupy that additional space. The Company believes the terms of the lease are very favorable to us, and the Company obtained these favorable terms through the assistance of Peter A. Cohen, a director, which he provided so that the company he owns, Peter A. Cohen, LLC ("Cohen LLC"), could sublease a portion of the office space.

The Company is using 1,648 square feet, and Cohen LLC is using approximately 4,584 square feet as of September 30, 2019. The monthly lease payment for 6,232 square feet is \$31,160. Of this amount \$22,920 is allocated pro rata to Cohen LLC based on square footage occupied. Additional lease charges for operating expenses and taxes are allocated under the sublease based on the ratio of rent paid by the Company and Cohen LLC to total rent. Once the space is fully occupied, the Company will reduce the overall annual lease rate for the Cohen LLC space to \$58.60 per square foot. The Company recognized \$69,000 and \$195,000 of sublease income related to this agreement for the three and nine months ended September 30, 2019, respectively. The sublease income is included in other income, net in the statement of operations. As of September 30, 2019 and December 31, 2018, there was \$17,000 and \$0 due from the related party under this agreement.

### **16. SEGMENT REPORTING**

The Company's current operations involve products and services which are managed separately. Accordingly, it operates in two segments: 1) regenerative medicine and 2) contract services.

During the three months ended September 30, 2019, the Company's CODM changed the reporting of segment net income and loss to allocate additional noncash expenses from the regenerative medicine segment to the contract services segment. For the three months ended September 30, 2019 and 2018, this resulted in reallocation of noncash expense of \$0.4 million and \$0.2 million, respectively. For the nine months ended September 30, 2019 and 2018, this resulted in reallocation of noncash expense of \$1.4 million and \$0.3 million, respectively. The change is reflected in the three and nine months ended September 30, 2019 and 2018 net loss amounts presented below.



Certain information concerning our segments for the three and nine months ended September 30, 2019 and 2018 is presented in the following table (in thousands):

	For the three months ended September 30,		For the nine months ended September 30,	
	2019	2018	2019	2018
Net revenues:				
Reportable segments:				
Regenerative medicine	\$ 839	\$ 197	\$ 1,640	\$ 389
Contract services	556	528	2,546	659
Total net revenues	<u>\$ 1,395</u>	<u>\$ 725</u>	<u>\$ 4,186</u>	<u>\$ 1,048</u>
Net (loss) income:				
Reportable segments:				
Regenerative medicine	\$ (22,466)	\$ (20,332)	\$ (70,247)	\$ (45,845)
Contract services	(517)	(247)	(1,101)	(511)
Total net loss	<u>\$ (22,983)</u>	<u>\$ (20,579)</u>	<u>\$ (71,348)</u>	<u>\$ (46,356)</u>

## 17. SUBSEQUENT EVENTS

Pursuant to the demand made by Dr. Denver Lough under his Registration Rights Agreement in August 2019, the Company filed a registration statement on Form S-3 with the Securities and Exchange Commission on October 21, 2019 to register 7,050,000 shares of common stock held by Dr. Lough, which was declared effective November 1, 2019.

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

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

In addition to historical information, this report contains forward-looking statements that involve risks and uncertainties that may cause our actual results to differ materially from plans and results discussed in forward-looking statements. We encourage you to review the risks and uncertainties discussed in the section entitled "Forward-Looking Statements" included at the beginning of this *Quarterly Report on Form 10-Q* and under Part I, Item 1A. Risk Factors of our Transition Report on Form 10-K filed with the Securities and Exchange Commission on March 18, 2019. The risks and uncertainties can cause actual results to differ significantly from those in our forward-looking statements or implied in historical results and trends. We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

### Overview

We are a commercial-stage biotechnology and regenerative biomaterials company focused on transforming the lives of patients by discovering, designing and developing a range of regenerative tissue products and biomaterials for the fields of medicine, biomedical engineering and material sciences. We operate two segments; the regenerative medicine business segment and the contract services segment.

#### *Segment Reporting*

The regenerative medicine business segment over the last year has established and advanced our core "TE" program, which includes our first commercial product, SkinTE. The commercial launch of SkinTE has included the build out of commercial, manufacturing, and corporate structure to support the growth of SkinTE revenue and deployments in 2019 and beyond. This includes equipment, personnel, systems, and leased properties. Research and development continue to expand to advance the product development pipeline.

In May 2018 we acquired assets of a preclinical research and veterinary sciences business and related real estate, which we now operate through our subsidiary, Ibx Preclinical Research, Inc. The aggregate purchase price was \$3.8 million, of which \$2.3 million was paid at closing and the balance satisfied by a promissory note payable to the Seller with an initial fair value of \$1.2 million and contingent consideration with an initial fair value of approximately \$0.3 million. As a result, we have significant research facilities and a well-educated and skilled team of scientists and researchers that comprise the contract research segment of our business. These resources are highly beneficial to the work we are doing on our TE products and other research initiatives. We also offer research services to unrelated third parties on a contract basis, which we offer under the trademark POLARITYRD. Contract research services help us defray the costs of maintaining a first-rate research facility and allow us to meet companies pursuing new technologies that may be opportunities for collaborative or strategic relationships going forward.

*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 filings with the Securities and Exchange Commission (SEC), 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 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, the valuation allowances for deferred tax benefits, and the valuation of tangible and intangible assets included in acquisitions. Actual results could differ from those estimates.

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.

*Goodwill and Intangible Assets.* Goodwill represents the excess acquisition cost over the fair value of net tangible and intangible assets acquired. Goodwill is not amortized and is subject to annual impairment testing or between annual tests if an event or change in circumstance occurs that would more likely than not reduce the fair value of a reporting unit below its carrying value. In testing for goodwill impairment, the Company has the option to first assess qualitative factors to determine whether the existence of events or circumstances lead to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If, after assessing the totality of events and circumstances, the Company concludes that it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is not required. If the Company concludes otherwise, the first step of the two-step process must be performed. The goodwill impairment test is performed at the reporting unit level by comparing the estimated fair value of a reporting unit with its respective carrying value. If the estimated fair value exceeds the carrying value, goodwill at the reporting unit level is not impaired and the second step of the impairment test is unnecessary. If the estimated fair value is less than carrying value, the second step of the impairment test must be performed. The second step of the goodwill impairment test would be to record an impairment charge, if any, based on the excess of a reporting unit's carrying amount over its fair value.

The fair value of reporting units is based on widely accepted valuation techniques that the Company believes market participants would use, although the valuation process requires significant judgment and often involves the use of significant estimates and assumptions. The Company utilizes a market cap approach in estimating the fair value of reporting units. The estimates and assumptions used in determining fair value could have a significant effect on whether or not an impairment charge is recorded and the magnitude of such a charge. Adverse market or economic events could result in impairment charges in future periods.

Intangible assets deemed to have finite lives are amortized on a straight-line basis over their estimated useful lives, which generally range from one to eleven years. The useful life is the period over which the asset is expected to contribute directly, or indirectly, to its future cash flows. Intangible assets are reviewed for impairment when certain events or circumstances exist. For amortizable intangible assets, impairment exists when the undiscounted cash flows exceed its carrying value. At least annually, the remaining useful life is evaluated.

*Impairment of Long-Lived Assets.* The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. No impairment loss has been recognized.

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

*Stock Based Compensation.* The Company measures all stock-based compensation using a fair value method and records such expense in research and development, general and administrative and sales and marketing expenses. Compensation Expense for stock options with graded vesting is recognized over the service period for each separately vesting tranche of the award as though the award were in substance, multiple awards.

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

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

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

*Leases.* On January 1, 2019 the Company adopted ASU 2016-02, *Leases (ASC 842)* and related amendments, which require lease assets and liabilities to be recorded on the balance sheet for leases with terms greater than twelve months. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. The standard was adopted using the modified retrospective transition approach by applying the new standard to all leases existing at the date of the initial application and not restating comparative periods. The most significant impact was the recognition of ROU assets and lease liabilities for operating leases, while our accounting for finance leases remained substantially unchanged. See Note 2 – Summary of Significant Accounting Policies and Note 7 – Leases in the notes to the condensed consolidated financial statements included in Part I, Item 1, of this Quarterly Report on Form 10-Q for additional information regarding the adoption.

## Results of Operations

### *Three months ended September 30, 2019 versus three months ended September 30, 2018*

**Net Revenues.** For the three-month period ended September 30, 2019, total net revenues were \$1.4 million. Products revenues from the sale of SkinTE were \$0.8 million for the three months ended September 30, 2019 compared to \$0.2 million for the three months ended September 30, 2018. Net revenues from services for the three months ended September 30, 2019 were \$0.6 million compared to \$0.5 million for the three months ended September 30, 2018.

**Cost of Sales.** For the three-month period ended September 30, 2019, total cost of sales was approximately \$0.6 million and approximately 46% of total net revenues. Products cost of sales were \$0.3 million or approximately 38% of products revenues for the three-month period ended September 30, 2019. Products cost of sales consists primarily of direct manufacturing costs (materials, freight and labor) and fixed overhead costs. Products cost of sales as a percentage of products revenues has declined quarter over quarter during the first nine months of 2019, primarily due to a reduction in direct manufacturing costs. Services cost of sales were \$0.3 million or approximately 59% of services revenues. Product cost of sales for the three-month period ended September 30, 2018 were \$0.3 million or approximately 136% of products revenues. Services cost of sales for the three-month period ended September 30, 2018 were \$0.4 million or approximately 76% of services revenues.

**Research and Development Expenses.** Research and development expenses decreased \$1.1 million, or 28%, in the three-month period ended September 30, 2019, compared to the three-month period ended September 30, 2018. The decrease is primarily driven by a shift in mix between commercial and operational infrastructure build out in the current period as well as research and development costs in the prior period.

**General and Administrative Expenses.** General and administrative expenses increased \$0.9 million, or 6%, in the three-month period ended September 30, 2019 compared to the three-month period ended September 30, 2018. The Company expanded its infrastructure to support the commercial launch of SkinTE. The resulting increase in expenses is driven primarily by employee-related costs, salaries, and benefits, and increased outside services expense, including legal and accounting fees and consulting expenses.

**Sales and Marketing Expenses.** For the three-month period ended September 30, 2019, sales and marketing expenses increased \$3.4 million or 208%, in the three-month period ended September 30, 2019 compared to the three-month period ended September 30, 2018. This represents increased sales personnel and marketing costs due to the expansion and commercialization of SkinTE.

**Other Income (Expenses).** For the three-month period ended September 30, 2019, other income (expenses) increased approximately 12% compared to the three-month period ended September 30, 2018. This increase is due to rental income offset by a decrease in interest income.

**Net loss.** Net loss for the three-month period ended September 30, 2019 was approximately \$23.0 million compared to a net loss of approximately \$20.6 million for the three-month period ended September 30, 2018, primarily reflecting the increase in operating costs and expenses driven by expanding operations discussed above.

### *Nine months ended September 30, 2019 versus nine months ended September 30, 2018*

**Net Revenues.** For the nine-month period ended September 30, 2019, total net revenues were \$4.2 million. Products revenues from the sale of SkinTE were \$1.6 million for the nine months ended September 30, 2019 compared to \$0.4 million for the nine months ended September 30, 2018. Net revenues from services were \$2.5 million for the nine months ended September 30, 2019 compared to \$0.7 million for the nine months ended September 30, 2018. The IBEX business was acquired in May 2018 and contributed \$0.7 million to revenues in the nine months ending September 30, 2018.

**Cost of Sales.** For the nine-month period ended September 30, 2019, total cost of sales was approximately \$2.0 million and approximately 48% of total net revenues. Products cost of sales were \$0.9 million or approximately 57% of products revenues primarily due to fixed overhead costs. Services cost of sales were \$1.1 million or approximately 43% of services revenues. Products cost of sales for the nine-month period ended September 30, 2018 were \$0.4 million and approximately 101% of products revenues. Services cost of sales for the nine-month period ended September 30, 2018 were \$0.4 million or approximately 67% of services revenues.

**Research and Development Expenses.** Research and development expenses increased \$0.5 million, or approximately 4%, in the nine-month period ended September 30, 2019, compared to the nine-month period ended September 30, 2018. The increase is primarily driven by an increase in research and clinical support personnel with associated wage and benefits cost, offset by a shift in mix between commercial and operational infrastructure build out in the current period as well as research and development costs in the prior period.

**General and Administrative Expenses.** General and administrative expenses increased \$14.3 million, or approximately 42%, in the nine-month period ended September 30, 2019 compared to the nine-month period ended September 30, 2018. The Company expanded its infrastructure to support the commercial launch of SkinTE. The resulting increase in expenses is driven primarily by employee-related costs, salaries, and benefits, and increased outside services expense, including legal and accounting fees and consulting expenses.

**Sales and Marketing Expenses.** For the nine-month period ended September 30, 2019, sales and marketing expenses increased \$11.3 million or 699%, in the nine-month period ended September 30, 2019 compared to the nine-month period ended September 30, 2018. This represents increased sales personnel and marketing costs due to the expansion and commercialization of SkinTE.

**Other Income (Expenses).** For the nine-month period ended September 30, 2019, other income (expenses) decreased \$0.9 million or approximately 53% compared to the nine-month period ended September 30, 2018. This decrease is due to a change in the fair value of derivatives of \$1.9 million and a reduction of interest income of \$0.2 million offset by loss on extinguishment of warrant liability of \$0.5 million, realized investment gains of \$0.4 million and rental income of \$0.3 million. There were no warrants outstanding for the nine-month period ended September 30, 2019.

**Net loss.** Net loss for the nine-month period ended September 30, 2019 was approximately \$71.3 million compared to a net loss of approximately \$46.4 million for the nine-month period ended September 30, 2018, primarily reflecting the increase in operating costs and expenses driven by expanding operations discussed above.

### **Liquidity and Capital Resources**

As of September 30, 2019, our cash, cash equivalents and short-term investments balance was approximately \$45.9 million and our working capital was approximately \$35.7 million, compared to cash and cash equivalents and short-term investments of \$61.8 million and working capital of \$56.8 million at December 31, 2018.

As reflected in the condensed consolidated financial statements, we had an accumulated deficit of approximately \$414.2 million at September 30, 2019, and approximately \$40.7 million net cash used in operating activities for the nine-month period then ended. At December 31, 2018, we had an accumulated deficit of approximately \$342.9 million and approximately \$19.4 million net cash used in operating activities for the nine-months ended September 30, 2018.

On April 10 and May 6, 2019, the Company completed an underwritten offering providing for the issuance and sale of 3,418,918 shares of the Company's common stock, par value \$0.001 per share, at an offering price of \$8.51 per share, for net proceeds of approximately \$27.9 million, after deducting offering expenses payable by the Company.

The Company has taken numerous steps to further reduce its cash burn during the three months ended September 30, 2019, including outsourcing various aspects of our business, conducting a thorough budget review by department, enhancing fiscal discipline and prioritizing resource allocation to those areas of the business that are most likely to generate revenue in the near term. We expect these efforts will continue in the fourth quarter of 2019, but the results of these efforts will be offset by the agreement on settlement terms we signed on August 21, 2019, with Dr. Denver Lough, a principal shareholder and former officer and director, that provides, in part, that the Company pay to Dr. Lough \$1,500,000 in cash on October 1, 2019, pay an additional \$1,500,000 in cash in equal monthly installments beginning November 1, 2019 and ending April 1, 2021, and award to Dr. Lough 200,000 restricted stock units that vest in 18 equal monthly installments beginning October 1, 2019. Approximately \$2.3 million is included in accounts payable and accrued expenses at September 30, 2019, for the payment obligations to Dr. Lough. The remaining amount due is included in other long-term liabilities.

Based upon the current status of our product development and commercialization plans, we believe that our existing cash, cash equivalents and short-term investments will be adequate to satisfy our capital needs for at least the next 12 months from the date of filing. Nevertheless, it is likely in the future we may need additional financing to continue clinical deployment and commercialization of our TE products, development of our other product candidates, and scaling the manufacturing capacity for our products and product candidates. Accordingly, we will continue to pursue fundraising opportunities when available, however, such financing may not be available on terms favorable to us, if at all. If adequate funds are not available in the future, we may be required to delay, reduce the scope of, or eliminate one or more of our operational or development programs. The Company may also implement additional spending reductions. We plan to meet our future 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 as needed in the future would adversely affect our ability to achieve our 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 statements regarding 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 Part I, Item 1A. Risk Factors of our Transition Report on Form 10-K filed with the SEC on March 18, 2019 will impact our future capital requirements and the adequacy of our available funds. If we are required to raise additional funds, any additional equity financing may be highly dilutive, or otherwise disadvantageous, to existing stockholders, and debt financing, if available, may involve restrictive covenants. If we elect to pursue collaborative arrangements, the terms of such arrangements may require us to relinquish rights to certain of our technologies, products or marketing territories. Our failure to raise capital when needed, and on acceptable terms, would require us to reduce our operating expenses and would limit our ability to respond to competitive pressures or unanticipated requirements to develop our product candidates and to continue operations, any of which would have a material adverse effect on our business, financial condition and results of operation.

#### **Off-Balance Sheet Arrangements**

As of September 30, 2019, 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, cash equivalents and short-term investments were approximately \$45.9 million as of September 30, 2019, compared to cash and cash equivalents and short-term investments of approximately \$61.8 million as of December 31, 2018. Working capital was approximately \$35.7 million as of September 30, 2019, compared to working capital of approximately \$56.8 million as of December 31, 2018.

##### *Operating Cash Flows*

Cash used in operating activities for the nine-month period ended September 30, 2019, was approximately \$40.7 million. Approximately \$19.4 million of cash was used in operating activities for the nine-month period ended September 30, 2018. The increase in net cash used in operating activities mostly relates to the expansion of infrastructure and sales and marketing expenses related to the commercial expansion of SkinTE.

### *Investing Cash Flows*

Cash used in investing activities for the nine-month period ended September 30, 2019, was approximately \$14.9 million. Cash used in investing activities for the nine-month period ended September 30, 2018 amounted to approximately \$8.9 million. For the nine-month period ended September 30, 2019, the activity relates to the net purchase of available-for-sale securities and the purchase of property and equipment. For the nine-month period ended September 30, 2018, the activity relates to the purchase of property and equipment and the acquisition of IBEX.

### *Financing Cash Flows*

Net cash provided by financing activities for the nine-month period ended September 30, 2019, was approximately \$27.1 million. \$92.8 million of cash was provided by financing activities for the nine-month period ended September 30, 2018. For the nine-month period ended September 30, 2019, the activity relates to proceeds from stock options exercised and the Company completed an underwritten offering providing for the issuance and sale of 3,418,918 shares of the Company's common stock, par value \$0.001 per share, at an offering price of \$8.51 per share, for net proceeds of approximately \$27.9 million, after deducting offering expenses payable by the Company, offset by principal payments on finance leases and contingent consideration liability payments. For the nine-month period ended September 30, 2018, the activity relates to a public offering of 2,335,937 shares of our common stock at an offering price of \$16.00 per share, resulting in net proceeds of \$34.6 million, after deducting offering expenses and another underwritten offering of 2,455,882 shares of our common stock at an offering price of \$23.65 per share, resulting in net proceeds of approximately \$58.0 million, after deducting offering expenses.

### **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**

#### *Evaluation of Disclosure Controls and Procedures.*

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

Our management, with the participation of our principal executive and financial officers, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on the evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2019, our principal executive and financial officers concluded that, as of such date, were not effective due to the material weaknesses in our internal control over financial reporting identified below. To address the material weaknesses, management performed additional analyses and other procedures to determine whether the financial statements included herein fairly present our financial results. Subject to the limitations above, management believes that the consolidated financial statements and other financial information contained in this report, fairly present in all material respects our financial condition, results of operations, and cash flows for the periods presented.



### *Internal Control Over Financial Reporting.*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America, or GAAP. Our management does not expect that our disclosure controls and procedures or our internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control.

Two material weaknesses previously identified as of December 31, 2018, continued to exist as of September 30, 2019, which include (1) insufficient internal controls related to information technology general controls in the areas of user access and user provisioning, over certain systems that support the financial reporting process; and (2) ineffective controls related to the documentation and completeness of the Company's stock-based compensation expense.

#### *Changes to Internal Control over Financial Reporting*

There were no significant changes in the Company's internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

We have taken several steps to remediate the material weaknesses identified above. These steps include the following:

- *Stock-Based Compensation System* – The Company is in the process of implementing a systemic solution to our stock-based compensation accounting, including internal processes and an external compensation account management tool. The tool was launched during the first quarter of 2019 and we continue to run parallel tests, including data reconciliations. The system implementation and additional procedures enable the Company to properly document the stock-based compensation expense. The Company expects this issue to be remediated during 2019 after adequate test sampling to evaluate operating effectiveness.
- *IT Systems & Controls* – The Company has hired additional IT personnel and adopted access restrictions and protocols to prevent unauthorized access and unauthorized changes to data and records. We are evaluating these changes and whether they address the system control issues.

As we continue to evaluate and work to improve our internal control over financial reporting, management may determine to take additional measures to address the material weaknesses or determine to modify the remediation plan described above. Until the remediation steps set forth above are fully implemented and operating for a sufficient period of time, the material weakness described above will continue to exist.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

On June 26, 2018, a class action complaint alleging violations of the Federal securities laws was filed in the United States District Court, District of Utah, by Jose Moreno against the Company and two directors of the Company, Case No. 2:18-cv-00510-JNP (the “Moreno Complaint”). On July 6, 2018, a similar complaint was filed in the same court against the same defendants by Yedid Lawi, Case No. 2:18-cv-00541-PMW (the “Lawi Complaint”). Both the Moreno Complaint and Lawi Complaint allege that the defendants made or were responsible for, disseminating information to the public through reports filed with the Securities and Exchange Commission and other channels that contained material misstatements or omissions in violation of Sections 10 and 20(a) of the Exchange Act and Rule 10b-5 adopted thereunder. Specifically, both complaints allege that the defendants misrepresented the status of one of the Company’s patent applications while touting the unique nature of the Company’s technology and its effectiveness. Plaintiffs are seeking damages suffered by them and the class consisting of the persons who acquired the publicly-traded securities of the Company between March 31, 2017, and June 22, 2018. Plaintiffs have filed motions to consolidate and for appointment as lead plaintiff. On November 28, 2018, the Court consolidated the Moreno and Lawi cases under the caption In re PolarityTE, Inc. Securities Litigation (the “Consolidated Securities Litigation”), and requested the appointment of the plaintiff in Lawi as the lead plaintiff. On January 16, 2019, the Court granted the motion of Yedid Lawi for appointment as lead plaintiff, and on February 1, 2019, the Court granted the lead plaintiff’s motion for approval of lead counsel and liaison counsel. The Court ordered that the lead plaintiff file and serve a consolidated complaint no later than 60 days after February 1, 2019, the defendants shall have 60 days after filing and service of the consolidated complaint to answer or otherwise respond, and the lead plaintiff must file a motion for class certification within 90 days of service of the consolidated complaint. The Lead Plaintiff filed a consolidated complaint on April 2, 2019 and asserted essentially the same violations of Federal securities laws recited in the original complaints. The Company believes the allegations in the consolidated complaint are without merit, and intends to defend the litigation, vigorously. The Company filed a motion to dismiss the consolidated complaint on June 3, 2019. Plaintiffs’ opposition to the Company’s motion to dismiss was filed on August 2, 2019, and the Company filed a reply to the opposition on September 13, 2019. A hearing on the Company’s motion to dismiss is scheduled for November 19, 2019. At this early stage of the proceedings the Company is unable to make any prediction regarding the outcome of the litigation.

In the ordinary course of business, we may become involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements, regulatory compliance, and other matters. Except as noted above, at September 30, 2019, we were not party to any legal or arbitration proceedings that may have significant effects on our financial position or results of operations. We are not a party to any material proceedings in which any director, member of senior management or affiliate of ours is either a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

### Item 6. Exhibits

Except as otherwise noted, the following exhibits are included in this filing:

10.1	<a href="#">Settlement Terms Agreement dated August 21, 2019 between Denver Lough and PolarityTE, Inc.</a>
10.2	<a href="#">Change in Control Compensation Plan</a>
31.1	<a href="#">Certification Pursuant to Rule 13a-14(a)</a>
31.2	<a href="#">Certification Pursuant to Rule 13a-14(a)</a>
31.3	<a href="#">Certification Pursuant to Rule 13a-14(a)</a>
32.1	<a href="#">Certification Pursuant to Rule 13a-14(b) and Section 1350, Chapter 63 of Title 18, United States Code</a>
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.

**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/ Paul Mann*

\_\_\_\_\_  
Paul Mann  
Chief Financial Officer  
Duly Authorized Officer

Date: November 12, 2019



Parties: Dr. Denver Lough (“Lough”)  
PolarityTE, Inc. (“Polarity”)

1. Economic Terms.

~~\$1,000,000~~ \$1,500,000 (one million, five hundred thousand dollars) on October 1, 2019 and ~~\$1,000,000~~ \$1,500,000 (one million, five hundred thousand dollars) payable in equal monthly installments commencing on Nov 1, 2019, over 18 months and 200,000 restricted stock units vesting every month over 18 months

Process of registration of Lough’s existing shares to commence immediately upon request.

Lough will be treated like ~~all employees~~ senior executives in any options exchange.

2. Termination of Executive Employment Agreement between Lough and Polarity dated November 10, 2017 (“EEA”).

EEA is terminated effective immediately. Sections 6(B) on participation payments, 12 on confidentiality, 13 on non-competition and non-solicitation, and 15(a) on indemnification shall survive such termination.

### 3. Releases.

Lough releases all claims known and unknown against Polarity and its officers, directors, employees, and other affiliates as of ~~September~~ August 21, 2019. Polarity releases all claims known and unknown against Lough as of August 21, 2019.

### 4. Resignations

Lough resigns all offices with Polarity, including director, as of the start of the business day on August 26, 2019.

Steve Gorlin and David Seaburg will resign as directors as of the start of the business day on August 26, 2019.

Jon Mogford will resign as a director on or before July 31, 2020.

Replacement directors will be selected by the remaining directors, excluding Jon Mogford.

5. Voting Agreement.

Lough agrees that for the period that payments are made under paragraph 1, he will not vote his shares against any proposal or matter submitted to the shareholders for approval that is recommended by a majority of the board for approval of the shareholders, or vote his shares for any proposal or matter that a majority of the board recommends that the shareholders not approve, except to the extent that the action in question would disproportionately negatively effect Lough.

6. Lock Up. In connection with any future financing by Polarity conducted with or through an investment banking firm, Lough will sign and deliver any lock-up agreement requested by the investment banking firm that is the same lock-up agreement signed and delivered by the other directors of Polarity. There will otherwise be no restraint on Lough's ability to leverage, margin, or loan his shares.

7. Taxes. Lough shall pay all state and local taxes payable in respect of any payments under this Agreement made to him, and Polarity shall have no liability for any such taxes or liability under Section 409A of the Internal Revenue Code.

8. Under any shareholder rights plan Lough will not be subject to any triggering event that is different from its application to any other shareholder. To the extent that any additional shares are issued, Lough will receive equal rights on a pro-rata basis.

Date: August 21, 2019 By: /s/ Paul Mann  
Title: Chief Financial Officer  
PolarityTE, Inc.

Date: August 21, 2019 By: /s/ Denver M. Lough  
Denver M. Lough, MD, PHD





**POLARITYTE, INC.**  
**CHANGE IN CONTROL COMPENSATION PLAN**

**ARTICLE I - INTRODUCTION**

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

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

**ARTICLE II - ESTABLISHMENT OF THE POLICY**

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

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

**ARTICLE III - DEFINITIONS AND CONSTRUCTION**

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

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

(b) “Board” means the Board of Directors of the Company.

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

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

---

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

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

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

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

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

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

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

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

(h) "Executive" means any person who is the Company's Chief Operating Officer, President of Corporate Development, Chief Financial Officer, Chief Scientific Officer, Chief Translational Medicine Officer, General Counsel, Chief Intellectual Property Officer, or Chief Legal Officer.

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

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

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

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

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

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

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

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

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

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

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

(o) “Plan” means this Change in Control Compensation Plan.

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

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

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

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

#### Section 3.2 Status of Plan/Applicable Law.

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

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

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

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

#### **ARTICLE IV - ELIGIBILITY**

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

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

## ARTICLE V - SEVERANCE PAYMENTS

### Section 5.1 Right to Severance Payment

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

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

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

### Section 5.2 Amount of Severance Payment

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

(i) for any Participant who is designated as the Chief Operating Officer, President of Corporate Development, or Chief Financial Officer, the sum of (A) 1.5 multiplied by the greater of \$400,000 or Base Pay, and (B) 1.5 multiplied by the greater of \$400,000 or the target bonus established in an annual executive target bonus plan in effect on the Termination Date; and

(ii) for any other Participant, (A) 1.0 multiplied by the greater of \$350,000 or Base Pay, and (B) 1.0 multiplied by the greater of \$350,000 or the target bonus established in an annual executive target bonus plan in effect on the Termination Date; provided, however, that the amount of such cash payment determined pursuant to this Section 5.2(a) shall be reduced by an amount equal to the aggregate amount of any other cash payments in the nature of severance payments paid or payable by the Company or any Subsidiary pursuant to any agreement, policy, program, arrangement or requirement of statutory or common law (other than this Plan or cash payments received in lieu of stock incentives) from the Company.

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



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

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

#### **ARTICLE VI - OTHER RIGHTS AND BENEFITS NOT AFFECTED**

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

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

#### **ARTICLE VII - SUCCESSORS SECTION**

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

#### **ARTICLE VIII - DURATION, AMENDMENT AND TERMINATION**

##### Section 8.1 Duration/Termination.

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

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

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

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

## **ARTICLE IX - MISCELLANEOUS SECTION**

### **Section 9.1 Legal Fees and Expenses**

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

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

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

Section 9.3 Successors.

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

(b) The rights under this Plan are personal in nature and neither the Company nor any Participant shall, without the consent of the other, assign or transfer any rights or obligations hereunder except as expressly provided in Sections 5.3 and 7.1 hereof. Without limiting the generality of the foregoing, the Participant's right to receive a Severance Payment hereunder shall not be assignable or transferable, whether by pledge, creation of a security interest or otherwise, other than by a transfer by his or her will or by the laws of descent and distribution and, in the event of any attempted assignment or transfer contrary to this Section 9.3(b), the Company, shall have no liability to pay any amount so attempted to be assigned or transferred.

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

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

Adopted by Resolution of the Board of Directors on August 6, 2019.

ATTACHMENT A

**RELEASE**

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

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

[Without limiting the generality of Section 1, above, Executive acknowledges and agrees that he/she is waiving and releasing any rights he/she may have under the Age Discrimination in Employment Act of 1967, as amended (the "ADEA") (29 U.S. Code §621 et seq.), and that this waiver and release is knowing and voluntary. Executive and the Company agree that this waiver and release does not apply to any rights or claims that may arise under the ADEA after Executive has executed this Release. Nothing in this Release prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this Release under the ADEA, nor does it impose any condition precedent, penalties or costs for doing so, unless specifically authorized by federal law. Executive acknowledges that the consideration given for this Release under the Plan is in addition to anything of value to which he/she was already entitled. The Company advises Executive in this Release to consult with an attorney prior to executing this Release. Executive understands that insofar as this Release relates to Executive's rights, if any, under the ADEA, it shall not become effective or enforceable until seven days after he/she signs it. Executive acknowledges that he/she has been advised to consult with an attorney if he/she chooses before signing this Release. Executive understands that he/she has the right to revoke this Release, insofar as it extends to Executive's claims, if any, under the ADEA, by written notice of such to the Company within seven (7) calendar days following his/her signing this Release. Any such revocation must be in writing and hand-delivered to the Company or, if sent by mail, postmarked within the applicable revocation period, sent by certified mail, return receipt requested, and addressed to: PolarityTE, Inc., Attention: General Counsel, 123 N. Wright Brothers Drive, Salt Lake City, Utah, 84116.]<sup>1</sup>

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

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

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

---

<sup>1</sup> Retain this section if ADEA applicable to Executive.

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

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

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

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

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

EXECUTIVE

\_\_\_\_\_  
Print Name: \_\_\_\_\_

\_\_\_\_\_  
Date



## CERTIFICATION

I, Richard Hague, 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: November 12, 2019

/s/ Richard Hague

Richard Hague  
Chief Operating Officer

---





## CERTIFICATION

I, David Seaburg, 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: November 12, 2019

/s/ David Seaburg

David Seaburg  
President

---



## CERTIFICATION

I, Paul Mann, 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: November 12, 2019

*/s/ Paul Mann*

\_\_\_\_\_  
Paul Mann  
Chief Financial Officer

---



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

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

The Quarterly Report on Form 10-Q for the period ending September 30, 2019 (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.

Date: November 12, 2019

*/s/ Richard Hague*

Richard Hague  
Chief Operating Officer

*/s/ David Seaburg*

David Seaburg  
President

*/s/ Paul Mann*

Paul Mann  
Chief Financial Officer

---

