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 March 31, 2020

Commission File No. 000-51128

POLARITYTE, INC.
(Exact name of registrant as specified in its charter)

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

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
Preferred Stock Purchase Rights		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 [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes [X] No [ ]

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

Large accelerated filer	[ ]	Accelerated filer	[X]
Non-accelerated filer	[ ]	Smaller reporting company	[X]
		Emerging growth company	[ ]

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

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

As of May 7, 2020, there were 38,463,599 shares of the Registrant's common stock outstanding.

INDEX

PART I - FINANCIAL INFORMATION
Item 1. Financial Statements:

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

	March 31, 2020	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 38,517	$ 10,218
Short-term investments	997	19,022
Accounts receivable, net	1,186	1,731
Inventory	233	252
Prepaid expenses and other current assets	2,807	1,264
Total current assets	43,740	32,487
Property and equipment, net	15,022	14,911
Operating lease right-of-use assets	4,142	4,590
Intangible assets, net	683	731
Goodwill	278	278
Other assets	598	602
TOTAL ASSETS	$ 64,463	$ 53,599
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 8,026	$ 7,095
Other current liabilities	3,223	2,338
Current portion of long-term note payable	536	528
Deferred revenue	23	98
Total current liabilities	11,808	10,059
Common stock warrant liability	7,145	–
Operating lease liabilities	2,614	2,994
Other long-term liabilities	1,243	1,630
Total liabilities	22,810	14,683
Commitments and Contingencies (Note 12)		
STOCKHOLDERS' EQUITY		
Preferred stock - 25,000,000 shares authorized, 0 shares issued and outstanding at March 31, 2020 and December 31, 2019	–	–
Common stock – $.001 par value; 250,000,000 shares authorized; 38,393,289 and 27,374,653 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	38	27
Additional paid-in capital	490,009	474,174
Accumulated other comprehensive income	3	72
Accumulated deficit	(448,397)	(435,357)
Total stockholders' equity	41,653	38,916
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 64,463	$ 53,599

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 March 31,	
	2020	**2019**
Net revenues		
Products	$ 428	$ 297
Services	505	1,168
Total net revenues	933	1,465
Cost of sales		
Products	340	273
Services	176	503
Total costs of sales	516	776
Gross profit	417	689
Operating costs and expenses		
Research and development	3,373	5,352
General and administrative	11,057	17,195
Sales and marketing	3,694	3,953
Total operating costs and expenses	18,124	26,500
Operating loss	(17,707)	(25,811)
Other income (expense)		
Change in fair value of common stock warrant liability	4,532	–
Interest (expense) income, net	(12)	70
Other income, net	147	168
Net loss	$ (13,040)	$ (25,573)
Net loss per share, basic and diluted	$ (0.39)	$ (1.18)
Weighted average shares outstanding, basic and diluted	33,019,994	21,594,699

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 March 31,	
	2020	**2019**
Net loss	$ (13,040)	$ (25,573)
Other comprehensive income:		
Unrealized gain on available-for-sale securities	4	152
Reclassification of realized gains included in net loss	(73)	(135)
Comprehensive loss	$ (13,109)	$ (25,556)

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 Three Months Ended March 31, 2020					
	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Number	Amount	Capital	Income	Deficit	Equity
Balance - December 31, 2019	27,374,653	$ 27	$ 474,174	$ 72	$ (435,357)	$ 38,916
Issuance of common stock, net of issuance costs of $1.3 million	10,854,710	11	12,588	–	–	12,599
Stock-based compensation expense	–	–	3,221	–	–	3,221
Stock option exercises	10,000	–	31	–	–	31
Vesting of restricted stock units	158,513	–	–	–	–	–
Shares withheld for tax withholding	(4,587)	–	(5)	–	–	(5)
Other comprehensive loss	–	–	–	(69)	–	(69)
Net loss	–	–	–	–	(13,040)	(13,040)
Balance - March 31, 2020	38,393,289	$ 38	$ 490,009	$ 3	$ (448,397)	$ 41,653

	For the Three Months Ended March 31, 2019					
	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Number	Amount	Capital	Income	Deficit	Equity
Balance - December 31, 2018	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)
Balance - March 31, 2019	21,749,239	$ 22	$ 424,955	$ 53	$ (368,437)	$ 56,593

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)

	For the Three Months ended March 31,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (13,040)	$ (25,573)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation expense	3,221	10,289
Depreciation and amortization	752	676
Amortization of intangible assets	48	51
Amortization of debt discount	8	15
Change in fair value of common stock warrant liability	(4,532)	–
Change in fair value of contingent consideration	–	20
Other non-cash adjustments	(16)	(7)
Changes in operating assets and liabilities:		
Accounts receivable	545	(76)
Inventory	19	27
Prepaid expenses and other current assets	(1,543)	(412)
Operating lease right-of-use assets	448	355
Other assets	4	–
Accounts payable and accrued expenses	818	(1,331)
Other current liabilities	(61)	425
Deferred revenue	(75)	(80)
Operating lease liabilities	(450)	(343)
Other long-term liabilities	–	(4)
Net cash used in operating activities	(13,854)	(15,968)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(999)	(1,539)
Purchase of available-for-sale securities	(14,144)	(5,220)
Proceeds from maturities of available-for-sale securities	15,945	1,700
Proceeds from sale of available-for-sale securities	16,171	–
Net cash provided by (used in) investing activities	16,973	(5,059)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from the sale of common stock and warrants	24,276	–
Proceeds from stock options exercised	31	529
Cash paid for tax withholdings related to net share settlement	(2)	–
Payment of contingent consideration liability	–	(109)
Principal payments on financing leases	(123)	(118)
Proceeds from financing arrangements	1,053	–
Principal payments on financing arrangements	(55)	–
Net cash provided by financing activities	25,180	302
Net increase (decrease) in cash and cash equivalents	28,299	(20,725)
Cash and cash equivalents - beginning of period	10,218	55,673
Cash and cash equivalents - end of period	$ 38,517	$ 34,948
Non-cash investing and financing activities:		
Unpaid liability for acquisition of property and equipment	$ 137	$ 170
Reclassification of stock-based compensation expense that was previously classified as a liability to paid-in capital	**$** –	$ 38
Unpaid tax liability related to net share settlement	$ 3	$ 617
Allocation of proceeds from sale of common stock and warrants to warrant liability	$ 11,677	**$** –

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

1. PRINCIPAL BUSINESS ACTIVITY AND BASIS OF PRESENTATION

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

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, 2019 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 (U.S. GAAP) 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 year ended December 31, 2019 filed with the Securities and Exchange Commission on Form 10-K on March 12, 2020.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

Use of estimates. The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities or the disclosure of gain or loss contingencies at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Among the more significant estimates included in these financial statements is the extent of progress toward completion of contracts, stock-based compensation, valuation of common stock warrant liability, and the valuation allowances for deferred tax benefits. 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. In April 2020, the Company designated its Chief Executive Officer (CEO) to be its Chief Operating Decision Maker (CODM) and dissolved the function of the Office of the Chief Executive consisting of the President, Chief Operating Officer, and Chief Financial Officer which previously acted as its CODM. The CODM allocates resources to and assesses the performance of each operating segment using information about its revenue and operating income (loss).

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

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

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

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

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 (customers), primarily through direct sales representatives. Product revenues consist of a single performance obligation that the Company satisfies at a point in time. In general, the Company recognizes product revenue upon delivery to the customer.

In the contract services segment, the Company records service revenues from the sale of its contract research services, which includes delivery of preclinical studies and other research services to unrelated third parties. Service revenues generally consist of a single performance obligation that the Company satisfies over time using an input method based on costs incurred to date relative to the total costs expected to be required to satisfy the performance obligation. The Company believes that this method provides an appropriate measure of the transfer of services over the term of the performance obligation based on the remaining services needed to satisfy the obligation. This requires the Company to make reasonable estimates of the extent of progress toward completion of the contract. As a result, unbilled receivables and deferred revenue are recognized based on payment timing and work completed. Generally, a portion of the payment is due upfront and the remainder upon completion of the contract, with most contracts completing in less than a year. As of March 31, 2020 and December 31, 2019, the Company had unbilled receivables of $0.1 million and $0.1 million, and deferred revenue of $23,000 and $98,000, respectively. The unbilled receivables balance is included in accounts receivable. Revenue of $0.1 million was recognized during the three months ended March 31, 2020 that was included in the deferred revenue balance as of December 31, 2019.

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

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

Accruals for 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.

Common Stock Warrant Liability. The Company accounts for common stock warrants issued as freestanding instruments in accordance with applicable accounting guidance as either liabilities or as equity instruments depending on the specific terms of the warrant agreement. The Company's warrants under certain change of control situations, could require settlement in cash, which require the warrants to be recorded as liabilities. Warrants classified as liabilities are remeasured each period until settled or until classified as equity.

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

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

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

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.

Impairment of Long-Lived Assets. The Company reviews long-lived assets, including property and equipment, intangible assets and goodwill 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. There were no impairments of long-lived assets for any of the periods presented

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses (Topic 326)*, which requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost. This standard is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years with early adoption permitted. In November 2019, the FASB issued ASU No. 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates* , which defers the effective date of Topic 326. As a smaller reporting company, Topic 326 will now be effective for the Company beginning January 1, 2023. As such, the Company plans to adopt this ASU beginning January 1, 2023. The Company is currently evaluating the impact that the standard will have on its consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820), Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*. The ASU modifies the disclosure requirements for fair value measurements by removing, modifying or adding certain disclosures. The standard is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years with early adoption permitted. The Company adopted this standard on January 1, 2020. The adoption of this ASU did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

3. LIQUIDITY AND NEED FOR ADDITIONAL CAPITAL

The Company has experienced recurring losses and cash outflows from operating activities. As of March 31, 2020, the Company had an accumulated deficit of $448.4 million. As of March 31, 2020, the Company had cash and cash equivalents and short-term investments of $39.5 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.

On December 5, 2019, the Company entered into an Equity Purchase Agreement (the "Purchase Agreement"), with Keystone Capital Partners, LLC ("Keystone"), pursuant to which Keystone has agreed to purchase from the Company up to $25.0 million of shares of its common stock, subject to certain limitations including a minimum stock price of $2.00, at the direction of the Company from time to time during the 36-month term of the Purchase Agreement. Concurrently, the Company entered into a Registration Rights Agreement with Keystone, pursuant to which it agreed to register the sales of its common stock pursuant to the Purchase Agreement under the Company's existing shelf registration statement on Form S-3 or a new registration statement. On December 19, 2019, the Company sold 54,090 shares under the Purchase Agreement at a purchase price of $2.31 per share, for total proceeds of $0.1 million. During the three months ended March 31, 2020, the Company completed four additional sales of common stock to Keystone under the Purchase Agreement for a total of 216,412 shares generating total gross proceeds of $0.6 million.

On February 14, 2020, the Company completed an underwritten offering of 10,638,298 shares of its common stock and warrants to purchase 10,638,298 shares of common stock. Each common share and warrant were sold together for a combined public purchase price of $2.35 before underwriting discount and commission. The exercise price of each warrant is $2.80 per share, the warrants were exercisable immediately, and they will expire February 12, 2027. The net proceeds to the Company from the offering were $22.5 million, after offering expenses payable by the Company. In connection with this agreement, the Company agreed not to sell any additional shares under the Keystone Purchase Agreement for a period of 90 days after the closing date of the offering.

Based upon the current status of our product development and commercialization plans, the Company believes that its existing cash and cash equivalents, with planned operating cost reductions, and proceeds from the Loan, will be adequate to satisfy its capital and operating needs for at least the next 12 months from the date of filing. As noted in our April 21, 2020 press release, we have already taken action to reduce future cash burn by reducing payroll expense, adopting a salary and wage reduction, and reducing discretionary spending across the organization to minimal levels. As discussed in our April 30, 2020 press release updating corporate strategy and regulatory pathway for SkinTE, we are substantially reducing commercial operations and other functions to further significantly decrease cash burn. The Company believes it may need additional financing to continue clinical deployment and commercialization of SkinTE and development of its other product candidates. The Company will continue to pursue fundraising opportunities when available, but such financing may not be available in the future on favorable terms, if at all. If adequate financing is not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of its product development programs, or be unable to continue operations over a longer term. The Company plans to meet its capital requirements primarily through issuances of equity securities, debt financing, revenue from product and services sales or strategic partnership arrangements. Failure to generate cash from revenues, 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.
- Level 2: Quoted prices for similar instruments that are directly or indirectly observable in the market.
- Level 3: Significant unobservable inputs supported by little or no market activity. Financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, for which determination of fair value requires significant judgment or estimation.

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

The following table sets forth the fair value of the Company's financial assets and liabilities measured on a recurring basis by level within the fair value hierarchy (in thousands):

	March 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 19,065	$ –	$ –	$ 19,065
Commercial paper	–	747	–	747
Corporate debt securities	–	997	–	997
Total	$ 19,065	$ 1,744	$ –	$ 20,809
Liabilities:				
Common stock warrant liability	$ –	$ –	$ 7,145	$ 7,145
Total	$ –	$ –	$ 7,145	$ 7,145

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 2,019	$ –	$ –	$ 2,019
Commercial paper	–	11,064	–	11,064
Corporate debt securities	–	8,982	–	8,982
U.S. government debt securities	–	3,770	–	3,770
Total	$ 2,019	$ 23,816	$ –	$ 25,835
Liabilities:				
Contingent consideration	$ –	$ –	$ 31	$ 31
Total	$ –	$ –	$ 31	$ 31

The fair value of the common stock warrant liability is estimated using a Monte Carlo simulation model, which uses certain assumptions related to risk-free interest rates, expected volatility, and expected term. The fair value of the warrant liability was $11.7 million upon the issuance date of February 14, 2020 and $7.1 million as of March 31, 2020.

The following assumptions were used in estimating the fair value of the warrant liability as of March 31, 2020 and upon the issuance date of February 14, 2020:

	March 31, 2020	February 14, 2020
Stock price	$ 1.08	$ 1.69
Exercise price	$ 2.80	$ 2.80
Risk-free rate	0.54%	1.51%
Volatility	94.21%	93.40%
Term	6.87	6.99

The contingent consideration related to the IBEX acquisition of $31,000 outstanding at December 31, 2019, was paid during the three months ended March 31, 2020. As of March 31, 2020, the obligation related to the contingent consideration was fully satisfied.

5. CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

Cash equivalents and short-term investments consisted of the following (in thousands):

	March 31, 2020			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Market Value
Cash equivalents:				
Money market funds	$ 19,065	$ –	$ –	$ 19,065
Commercial paper	747	–	–	747
Total cash equivalents (1)	19,812	–	–	19,812
Short-term investments:				
Corporate debt securities	994	3	–	997
Total short-term investments	994	3	–	997
Total	$ 20,806	$ 3	$ –	$ 20,809

(1) Included in cash and cash equivalents in the Company's consolidated balance sheet as of March 31, 2020 in addition to $18.7 million of cash.

	December 31, 2019			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Market Value
Cash equivalents:				
Money market funds	$ 2,019	$ –	$ –	$ 2,019
Commercial paper	1,020	4	–	1,024
U.S. government debt securities	3,761	9	–	3,770
Total cash equivalents (1)	6,800	13	–	6,813
Short-term investments:				
Commercial paper	9,986	54	–	10,040
Corporate debt securities	8,977	5	–	8,982
Total short-term investments	18,963	59	–	19,022
Total	$ 25,763	$ 72	$ –	$ 25,835

(1) Included in cash and cash equivalents in the Company's consolidated balance sheet as of December 31, 2019 in addition to $3.4 million of cash.

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

6. PROPERTY AND EQUIPMENT, NET

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

	March 31, 2020	December 31, 2019
Machinery and equipment	$ 12,089	$ 12,083
Land and buildings	2,000	2,000
Computers and software	1,276	1,189
Leasehold improvements	2,335	2,282
Construction in progress	2,323	1,606
Furniture and equipment	470	470
Total property and equipment, gross	20,493	19,630
Accumulated depreciation and amortization	(5,471)	(4,719)
Total property and equipment, net	$ 15,022	$ 14,911

Depreciation and amortization expense for property and equipment, including assets acquired under financing leases was as follows (in thousands):

	For the Three Months Ended March 31,	
	2020	2019
General and administrative expense	$ 392	$ 357
Research and development expense	360	319
Total depreciation and amortization expense	$ 752	$ 676

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.

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

	Operating leases	Finance leases
2020 (excluding the three months ended March 31, 2020)	$ 1,555	$ 494
2021	1,730	656
2022	1,345	405
2023	132	336
2024	87	42
Total lease payments	4,849	1,933
Less imputed interest	(559)	(281)
Total lease liabilities	$ 4,290	$ 1,652

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

Finance leases

	March 31, 2020	December 31, 2019
Finance lease right-of-use assets included within property and equipment, net	$ 2,005	$ 2,177
Current finance lease liabilities included within other current liabilities	$ 520	$ 508
Non-current finance lease liabilities included within other long-term liabilities	1,132	1,267
Total finance lease liabilities	$ 1,652	$ 1,775

Operating leases

	March 31, 2020	December 31, 2019
Current operating lease liabilities included within other current liabilities	$ 1,676	$ 1,746
Operating lease liabilities – non current	2,614	2,994
Total operating lease liabilities	$ 4,290	$ 4,740

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

	For the Three Months Ended March 31,	
	2020	2019
Operating lease costs included within operating costs and expenses	$ 556	$ 482
Finance lease costs:		
Amortization of right-of-use assets	$ 175	$ 138
Interest on lease liabilities	43	23
Total	$ 218	$ 161

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

	For the Three Months Ended March 31,	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash out flows from operating leases	$ 558	$ 470
Operating cash out flows from finance leases	43	23
Financing cash out flows from finance leases	123	118
Lease liabilities arising from obtaining right-of-use assets:		
Finance leases	$ –	$ 1,824
Lease payments made in prior period reclassified to property and equipment	–	535
Operating leases	–	9

As of March 31, 2020 and December 31, 2019, the weighted average remaining lease term for operating leases was 2.6 and 2.8 years, respectively, and the weighted average discount rate used for operating leases was 9.84% and 9.83%, respectively. As of March 31, 2020 and December 31, 2019, the weighted average remaining lease term for finance leases was 3.3 and 3.5 years, respectively, and the weighted average discount rate used for finance leases was 9.77%.

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):

	March 31, 2020	December 31, 2019
Accounts payable	$ 2,059	$ 1,689
Salaries and other compensation	1,437	1,462
Legal and accounting	1,365	1,404
Accrued severance	1,843	1,053
Benefit plan accrual	448	557
Other	874	930
Total accounts payable and accrued expenses	$ 8,026	$ 7,095

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

Other current liabilities are comprised of the current portion of operating lease liabilities and finance lease liabilities, and short-term debt. The short-term debt had a balance of $1.0 million as of March 31, 2020, while the other components are disclosed in the footnotes above. The short-term debt balance is related to two financing arrangements entered into during the three months ended March 31, 2020 to fund an insurance contract. Under the financing arrangements, the Company borrowed $0.8 million and $0.2 million. The amounts will be repaid in nine equal installments, with an interest rate of 4.25% and 6.35%, respectively.

9. STOCK-BASED COMPENSATION

2020, 2019 and 2017 Equity Incentive Plans

2020 Plan

On October 25, 2019, the Company's Board of Directors (the "Board") approved the Company's 2020 Stock Option and Incentive Plan (the "2020 Plan"). The 2020 Plan became effective on December 19, 2019, the date approved by the stockholders. The 2020 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights, unrestricted stock awards, dividend equivalent rights, and cash-based awards to the Company's employees, officers, directors and consultants. The Compensation Committee of the Board will administer the 2020 Plan, including determining which eligible participants will receive awards, the number of shares of common stock subject to the awards and the terms and conditions of such awards. Up to 3,000,000 shares of common stock are issuable pursuant to awards under the 2020 Plan. No grants of awards may be made under the 2020 Plan after the later of December 19, 2029, or the tenth anniversary of the latest material amendment of the 2020 Plan and no grants of incentive stock options may be made after October 25, 2029. As of March 31, 2020, the Company had 3,000,000 shares available for future issuances under the 2020 Plan.

2019 Plan

On October 5, 2018, the Company's Board approved the Company's 2019 Equity Incentive Plan (the "2019 Plan"). The 2019 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights and other types of stock-based awards to the Company's employees, officers, directors and consultants. The Compensation Committee of the Board will administer the 2019 Plan, including determining which eligible participants will receive awards, the number of shares of common stock subject to the awards and the terms and conditions of such awards. Up to 3,000,000 shares of common stock are issuable pursuant to awards under the 2019 Plan. Unless earlier terminated by the Board, the 2019 Plan shall terminate at the close of business on October 5, 2028. As of March 31, 2020, the Company had 115,284 shares available for future issuances under the 2019 Plan.

2017 Plan

On December 1, 2016, the Company's Board approved the Company's 2017 Equity Incentive Plan (the "2017 Plan"). The purpose of the 2017 Plan is to promote the success of the Company and to increase stockholder value by providing an additional means through the grant of awards to attract, motivate, retain and reward selected employees, consultants and other eligible persons. The 2017 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights and other types of stock-based awards to the Company's employees, officers, directors and consultants. The Compensation Committee of the Board will administer the 2017 Plan, including determining which eligible participants will receive awards, the number of shares of common stock subject to the awards and the terms and conditions of such awards. Up to 7,300,000 shares of common stock are issuable pursuant to awards under the 2017 Plan. Unless earlier terminated by the Board, the 2017 Plan shall terminate at the close of business on December 1, 2026. As of March 31, 2020, the Company had 2,230,045 shares available for future issuances under the 2017 Plan.

A summary of the Company's employee and non-employee stock option activity for the three months ended March 31, 2020 is presented below:

	Number of Shares		Weighted-Average Exercise Price
Outstanding – December 31, 2019	4,529,988	$	15.26
Granted	117,632	$	2.54
Exercised	(10,000)	$	3.12
Forfeited	(289,061)	$	17.13
Outstanding – March 31, 2020	4,348,559	$	14.80
Options exercisable, March 31, 2020	3,584,300	$	14.84

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.

Stock-Based Compensation Expense

The stock-based compensation expense related to stock options, restricted stock awards, and the employee stock purchase plan was as follows (in thousands):

	For the Three Months Ended March 31	
	2020	2019
General and administrative expense	$ 3,076	$ 9,037
Research and development expense	(36)	1,084
Sales and marketing expense	181	168
Total stock-based compensation expense	$ 3,221	$ 10,289

Restricted Stock

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

	Number of Shares
Unvested - December 31, 2019	1,843,001
Granted	188,944
Vested (1)	(452,067)
Forfeited	(5,000)
Unvested – March 31, 2020	1,574,878

(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.

10. Common Stock Warrants

On February 14, 2020, the Company completed an underwritten offering of 10,638,298 shares of its common stock and warrants to purchase 10,638,298 shares of common stock. Each common share and warrant were sold together for a combined public purchase price of $2.35 before underwriting discount and commission. The exercise price of each warrant is $2.80 per share, the warrants were exercisable immediately, and they will expire February 12, 2027. As the warrants could require cash settlement in certain scenarios, the warrants were classified as a liability and are recorded at an estimated fair value using a Monte Carlo simulation model. The total proceeds from the offering were allocated first to the warrant liability based on the estimated fair value with the residual allocated to the common shares. Issuance costs including underwriter commissions and fees paid to third parties were allocated between the warrant liability and common shares on a pro rata basis. The amount allocated to the warrant liability was expensed and the amount allocated to the common shares was recorded as a reduction to additional paid-in-capital. As of March 31, 2020, none of the warrants had been exercised.

The change in fair value of the common stock warrant liability is presented in the following table and is reported as a change in fair value of common stock warrant liability in the statements of operations (in thousands):

	March 31, 2020
Beginning balance	$ –
Initial value of common stock warrant liability	11,677
Change in fair value of common stock warrant liability	(4,532)
Ending balance	$ 7,145

11. LOSS PER SHARE

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

	As of March 31,	
	2020	**2019**
Stock options	4,348,559	6,576,816
Restricted stock	1,574,878	516,875
Common stock warrants	10,638,298	–
Shares committed under ESPP	54,632	–

12. 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 also ordered that the lead plaintiff file and serve a consolidated complaint no later than 60 days after February 1, 2019. 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 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 was held on November 19, 2019; no order has been issued to date. At this early stage of the proceedings the Company is unable to make any prediction regarding the outcome of the litigation.

In November 2018, a shareholder derivative lawsuit was filed in the United States District Court, District of Utah, with the caption *Monther v. Lough, et al.*, case no. 2:18-cv-00791-TC, alleging violations of the Exchange Act, breach of fiduciary duty, and unjust enrichment on the part of certain officers and directors based on the facts and circumstances recited in the Consolidated Securities Litigation. On November 26, 2018, the court issued an order staying all proceedings until after the disposition of motions to dismiss the Consolidated Securities Litigation.

Other Matters

In the ordinary course of business, the Company may become involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements, employment, regulatory compliance, and other matters. Except as noted above, at March 31, 2020, the Company was not party to any legal or arbitration proceedings that may have material effects on its financial position or results of operations. No governmental proceedings are pending or, to the Company's knowledge, contemplated against the Company. The Company is not a party to any material proceedings in which any director, member of senior management or affiliate of the Company is either a party adverse to the Company or its subsidiaries or has a material interest adverse to the Company or its subsidiaries.

Commitments

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

13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

On August 21, 2019, the Company and Dr. Denver Lough, a principal shareholder and former officer and director, signed a settlement terms agreement that provides, in part, that the Company pay to Dr. Lough $1,500,000 in cash on October 1, 2019 and an additional $1,500,000 in cash in equal monthly installments beginning November 1, 2019 and ending April 1, 2021. In addition, the Company agreed to award to Dr. Lough 200,000 restricted stock units that vest in 18 equal monthly installments beginning October 1, 2019. The fair value of the restricted stock units was $0.8 million. The Company expensed the cash portion and equity portion of these awards upon Dr. Lough's termination. As of March 31, 2020, the Company has recorded a liability of $1.0 million related to future cash payments under the agreement.

In October 2018, the Company entered into an office lease covering approximately 7,250 square feet of rental space in the building located at 40 West 57th Street in New York City. The lease is for a term of three years. The annual lease rate is $60 per square foot. Initially the Company occupied and paid 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.

During 2019, the Company increased the space leased from 3,275 square feet to 6,232 square feet. The Company is using 1,648 square feet, and Cohen LLC is using approximately 4,584 square feet as of March 31, 2020. The monthly lease payment for 6,232 square feet is $31,160. Of this amount $22,920 is charged pro rata to Cohen LLC based on square footage occupied. Additional lease charges for operating expenses and taxes are also charged 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 $51,000 of sublease income related to this agreement for the three months ended March 31, 2020 and 2019, respectively. The sublease income is included in other income, net in the statement of operations. As of March 31, 2020 and December 31, 2019, there were no amounts due from the related party under this agreement.

14. SEGMENT REPORTING

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

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

	For the Three Months Ended March 31,	
	2020	**2019**
Net revenues:		
Reportable segments:		
Regenerative medicine	$ 428	$ 297
Contract services	505	1,168
Total net revenues	$ 933	$ 1,465
Net loss:		
Reportable segments:		
Regenerative medicine	$ (12,703)	$ (25,209)
Contract services	(337)	(364)
Total net loss	$ (13,040)	$ (25,573)

15. SUBSEQUENT EVENTS

On April 12, 2020, our subsidiary PolarityTE MD, Inc. (the "Borrower") entered into a promissory note evidencing an unsecured loan in the amount of $3,576,145 made to it under the Paycheck Protection Program (the "Loan"). The Paycheck Protection Program (or "PPP") was established under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and is administered by the U.S. Small Business Administration. The Loan to the Borrower was made through KeyBank, N.A., a national banking association (the "Lender"). The interest rate on the Loan is 1.00%. Beginning seven months from the date of the Loan the Borrower is required to make 24 monthly payments of principal and interest in the amount of $150,563. The promissory note evidencing the Loan contains customary events of default relating to, among other things, payment defaults, making materially false and misleading representations to the SBA or Lender, or breaching the terms of the Loan documents. The occurrence of an event of default may result in the repayment of all amounts outstanding, collection of all amounts owing from the Borrower, or filing suit and obtaining judgment against the Borrower. Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of a loan granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for payment of payroll costs and any payments of mortgage interest, rent, and utilities. No assurance is provided that the Borrower will obtain forgiveness of the Loan in whole or in part.

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

The discussion and analysis below includes certain forward-looking statements that are subject to risks, uncertainties and other factors, as described in "Risk Factors" in our Annual Report on Form 10-K and this report, that could cause our actual growth, results of operations, performance, financial position and business prospects and opportunities for this fiscal year and periods that follow to differ materially from those expressed in or implied by those forward-looking statements. Readers are cautioned that forward-looking statements contained in this Quarterly Report on Form 10-Q should be read in conjunction with our disclosure under the heading "Disclosure Regarding Forward-Looking Statements" below.

Overview

We are a commercial-stage biotechnology and regenerative biomaterials company focused on transforming the lives of patients by discovering, designing and developing regenerative tissue products and biomaterials for the fields of medicine, biomedical engineering and material sciences. Historically, we have operated two segments: the regenerative medicine business segment and the contract research segment.

Segment Reporting

The regenerative medicine business segment is engaged in the commercialization of SkinTE, our first commercial product, via a sales team, the pursuit of clinical studies of SkinTE, and working on the development of Skin TE Cryo (cryopreservation of SkinTE for multiple deployments on a single patient), SkinTE POC (point-of-care device for on-site SkinTE processing and deployment), and PTE 11000 (allogenic, biologically active dressing for use in wound care). Our commercial and development activity in the regenerative medicine business segment includes the maintenance and operation of manufacturing facilities, sales and marketing, and research and development.

The contract services segment operates a preclinical research and veterinary sciences business through our subsidiary, Ibex Preclinical Research, Inc. We also offer research services to unrelated third parties on a contract basis through our subsidiary, Arches Research, Inc.

Change in Corporate Strategy

We recently announced a change in our strategic focus and a planned change in the regulatory pathway for SkinTE. The change in strategy is the result of a combination of the following unexpected events.

FDA Developments

Following informal, voluntary discussions between us and the United States Food and Drug Administration (FDA), and preliminary views expressed by FDA received on April 21, 2020 regarding the regulatory pathway for SkinTE, the Company believes that it is prudent to submit an investigational new drug application (IND) and thereafter a biologics license application (BLA) for SkinTE. We are in the process of arranging meetings with FDA to determine the most appropriate development plan for a BLA submission. Since 2018 we have been actively engaged in a clinical development program, which includes a completed SkinTE study in burn wounds, ongoing randomized controlled trials (RCTs) in repairing diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs), and outcomes data from many of the approximately 700 SkinTE clinical cases. We intend to submit these data to FDA as potential candidates for inclusion in a clinical data package to support a BLA.

FDA has not asked us to stop marketing SkinTE pending submission or approval of a BLA. We plan to discuss with FDA the possibility of continued marketing of SkinTE as a 361 HCT/P on a limited basis at a future meeting, both until November 2020, which marks the end of a 36-month period of enforcement discretion that the Agency announced in final Guidance issued in November 2017 that it would generally observe unless there are reported or potential significant safety concerns, and beyond November 2020. It is not customary for the FDA to allow wide-spread commercial sales of a product subject to a pending BLA.

COVID-19 Pandemic

In December 2019, there was an outbreak of a new strain of coronavirus ("COVID-19"). In March 2020, the World Health Organization declared COVID-19 a pandemic. Rapid growth of the pandemic soon followed in the United States. Throughout the country, healthcare assets in terms of facilities and providers have been marshalled and dedicated to the care and treatment of COVID-19 patients while still trying to meet the acute and traumatic care needs of the general population. Consequently, medical care and procedures that are considered "elective" have been put on hold in many regions across the country. Many of the initial economic effects in the healthcare industry of the early stages of the COVID-19 outbreak in the United States and the shift in healthcare resources occurred during the last three weeks of the quarter ended March 31, 2020. The number of paid SkinTE cases in the first quarter of 2020 was 81 compared to 89 paid cases in the fourth quarter of 2019. The number of paid cases were impacted during the last three weeks of March, and we observed that some SkinTE procedures planned for April were postponed, cancelled, or not scheduled as a direct result of the COVID-19 pandemic. The impact is most evident in chronic wounds without amputation risk. The Company anticipates continued postponement of elective procedures through the second quarter and it is not possible to predict the impact of a second wave of COVID-19 that might occur in the fall or winter.

Moving Forward

Given the Company's recent decision to change the regulatory pathway for SkinTE with the FDA, and the headwinds associated with the COVID-19 pandemic, management has determined the best use of the Company's capital resources going forward is to focus on the preparation and prosecution of an IND and then a BLA with the FDA. We believe a BLA will enhance the value of SkinTE as a product and increase the likelihood of achieving widespread commercial adoption. We believe this pathway will align more clearly with our goal of delivering to healthcare providers additional data to establish SkinTE as the standard of care for chronic and traumatic wounds. In connection with pursuing this strategy, over the next several months we will substantially decrease commercial operations and other functions to reduce historical monthly cash burn and redirect our capital resources to advancing our IND and BLA submissions.

Revenue Recognition

In the regenerative medicine products segment, we record product revenues primarily from the sale of its regenerative tissue products. We sell our products to healthcare providers, primarily through direct sales representatives. Product revenues consist of a single performance obligation that we satisfy at a point in time. In general, we recognize product revenue upon delivery to the customer. In the contract services segment, we earn 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 we satisfy 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.

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, clinical trial costs, and other overhead charges.

General and Administrative Expenses

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

Sales and Marketing Expenses

Sales and marketing expenses primarily represent employee related costs, including stock compensation for sales and marketing executives and staff, marketing and advertising expenses, trade shows and other promotional costs, and other related charges.

Results of Operations

Comparison of the three months ended March 31, 2020 compared to the three months ended March 31, 2019.

(in thousands)	For the Three Months Ended		Increase (Decrease)	
	March 31, 2020	March 31, 2019	Amount	%
	(Unaudited)			
Net revenues				
Products	$ 428	$ 297	$ 131	44%
Services	505	1,168	(663)	(57)%
Total net revenues	933	1,465	(532)	(36)%
Cost of sales				
Products	340	273	67	25%
Services	176	503	(327)	(65)%
Total cost of sales	516	776	(260)	(34)%
Gross profit	417	689	(272)	(39)%
Operating costs and expenses				
Research and development	3,373	5,352	(1,979)	(37)%
General and administrative	11,057	17,195	(6,138)	(36)%
Sales and marketing	3,694	3,953	(259)	(7)%
Total operating costs and expenses	18,124	26,500	(8,376)	(32)%
Operating loss	(17,707)	(25,811)	8,104	31%
Other income (expense)				
Change in fair value of common stock warrant liability	4,532	–	4,532	*
Interest income, net	(12)	70	(82)	(117)%
Other income, net	147	168	(21)	(13)%
Net loss	$ (13,040)	$ (25,573)	$ 12,533	49%

Net Revenues

For the three-month period ended March 31, 2020, we recorded net revenues of $0.93 million, which represents a decrease of $0.53 million or 36% from the $1.47 million of net revenues recorded for the three months ended March, 31, 2019. The $0.53 million decrease in net revenues was due to decreased revenue in our contract services operating segment from lower demand in the first quarter of 2020, which was partially offset by an increase in product revenue.

Gross Profit

Cost of sales for the product segment as a percentage of net revenues was 19% in the first quarter of 2019 compared to 36% for the first quarter of 2020. The increase is driven by a higher percentage of variable cost per unit due to smaller case sizes. Cost of sales for the services segment as a percentage of net revenues was 34% in the first quarter of 2019 compared to 19% for the first quarter of 2020, which we attribute to variations in service specific materials requirements for performing services in the first quarter of 2020 compared to the same quarter in 2019. As a result of the changes in net revenues and cost of sales in both segments, the combined effect is that gross profit decreased as a percentage in line with net revenues period over period from $0.69 million for the three-month period ended March 31, 2019 to $0.42 million for the three-month period ended March 31, 2020, or a decrease in gross profit of 39%.

Research and Development

For the three-month period ended March 31, 2020, we recorded research and development expenses totaling $3.37 million, which represents a decrease of $1.98 million, or 37%, from $5.35 million of research and development expenses for the three months ended March 31, 2019. There was a reduction in staff in research and development that reduced compensation and benefits costs by $.72 million and stock compensation expense decreased $1.12 million.

General and Administrative Expenses

General and administrative expenses totaled $11.06 million for the three-month period ended March 31, 2020, which represents a decrease of $6.14 million as compared to $17.20 million of general and administrative expenses incurred during the three months ended March 31, 2019. The primary driver for this decrease is a $5.96 million reduction in stock compensation expense in the first quarter of 2020 compared to the first quarter of 2019.

Sales and Marketing

Sales and marketing expenses totaled $3.69 million for the three-month period ended March 31, 2020, compared to $3.95 million of sales and marketing expenses incurred during the three months ended March 31, 2019, which is roughly equivalent and consistent with the Company's focus on commercialization of SkinTE in both periods. The service segment does not have a meaningful sales and marketing component to its business.

Liquidity and Capital Resources

As of March 31, 2020, our cash and cash equivalents and short-term investments totaled $39.51 million and our working capital was approximately $31.93 million, compared to cash and cash equivalents and short-term investments of $29.24 million and our working capital of approximately $22.43 million at December 31, 2019. Our accumulated deficit at March 31, 2020, was approximately $448.40 million.

On April 12, 2020, our subsidiary PolarityTE MD, Inc. (the "Borrower") entered into a promissory note evidencing an unsecured loan in the amount of $3,576,145 made to us under the Paycheck Protection Program (the "Loan"). The Paycheck Protection Program (or "PPP") was established under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and is administered by the U.S. Small Business Administration. The Loan to the Borrower was made through KeyBank, N.A., a national banking association (the "Lender"). The interest rate on the Loan is 1.00%. Beginning seven months from the date of the Loan the Borrower is required to make 24 monthly payments of principal and interest in the amount of $150,563. The promissory note evidencing the Loan contains customary events of default relating to, among other things, payment defaults, making materially false and misleading representations to the SBA or Lender, or breaching the terms of the Loan documents. The occurrence of an event of default may result in the repayment of all amounts outstanding, collection of all amounts owing from the Borrower, or filing suit and obtaining judgment against the Borrower. Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of a loan granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for payment of payroll costs and any payments of mortgage interest, rent, and utilities. No assurance is provided that the Borrower will obtain forgiveness of the Loan in whole or in part.

On February 14, 2020, we completed an underwritten offering of 10,638,298 shares of our common stock and warrants to purchase 10,638,298 shares of common stock. Each common share and warrant were sold together for a combined public purchase price of $2.35 before underwriting discount and commission. Each warrant has an exercise price of $2.80 per share, was exercisable immediately, and will expire February 12, 2027. The net proceeds to the Company from the offering were $22.5 million, after offering expenses payable by the Company. In connection with this offering, the Company agreed not to sell any additional shares under the Keystone Purchase Agreement described below for a period of 90 days after the closing date of the offering.

We are party to an Equity Purchase Agreement dated as of December 5, 2019 (the "Purchase Agreement"), with Keystone Capital Partners, LLC ("Keystone"), pursuant to which Keystone has agreed to purchase from us up to $25.0 million of shares of our common stock, subject to certain limitations including a minimum purchase price of $2.00 per share, at our direction from time to time during the 36-month term of the Purchase Agreement. Concurrently, we entered into a Registration Rights Agreement with Keystone, pursuant to which we agreed to register the sales of our common stock pursuant to the Purchase Agreement under our existing shelf registration statement on Form S-3 or a new registration statement. During the period from the date of the Purchase Agreement to the date of this filing, we have sold 270,502 shares of our common stock under the Purchase Agreement generating total gross proceeds of $725,000 and have up to $24,275,000 available for future sale under the Purchase Agreement. In connection with the underwritten offering described in the preceding paragraph, we agreed not to sell any additional shares under the Purchase Agreement for a period of 90 days after the closing date of the offering.

Based upon the current status of our product development plans, we believe that our existing cash and cash equivalents, with planned operating cost reductions, will be adequate to satisfy our capital and operating needs for at least the next 12 months from the date of filing. This conclusion is based on our current capital resources and plans for implementing operating cost reductions. We believe we may need additional financing to continue clinical trials for SkinTE and development of our other product candidates. 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, we may be required to delay, reduce the scope of, or eliminate one or more of our product development programs or be unable to continue operations over a longer term. We plan to meet our future capital requirements primarily through issuances of equity securities, debt financing, or strategic partnership arrangements. Failure to generate revenue or raise additional capital would adversely affect our ability to achieve our intended business objectives

Our actual capital requirements will depend on many factors, including the cost and timing of pursuing a biologics license application for SkinTE we intend to file with FDA; 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 for our product candidates. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. The foregoing factors, along with the other factors described in the section, Item 1A, "Risk Factors" in Part II of this Report on Form 10-Q will impact our future capital requirements and the adequacy of our available funds. If we are required to raise additional funds, any additional equity financing may be highly dilutive, or otherwise disadvantageous, to existing stockholders, and debt financing, if available, may involve restrictive covenants. If we elect to pursue collaborative arrangements, the terms of such arrangements may require us to relinquish rights to certain of our technologies, products or marketing territories. Our failure to raise additional capital when needed, and on acceptable terms, would require us to reduce our operating expenses and would limit our ability to 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.

The following table sets forth the primary sources and uses of cash for each period indicated:

	Three Months Ended	
(in thousands)	**March 31, 2020**	**March 31, 2019**
Net cash provided by (used in)		
Operating activities	$ (13,854)	$ (15,968)
Investing activities	16,973	(5,059)
Financing activities	25,180	302
Net increase/(decrease) in cash and cash equivalents	$ 28,299	$ (20,725)

Cash used in operating activities

During the three-month period ended March 31, 2020, net cash used in operating activities was $13.85 million, which included $1.16 million of issuance fees related to the February raise. The cash used in operating activities was due to a net loss of $13.04 million adjusted by $4.53 million due to remeasurement of the warrant liability arising from the underwritten offering of common stock and warrants in February 2020, which was offset by the non-cash expenses of $3.22 million for stock compensation expense.

During the three-month period ended March 31, 2019, net cash used in operating activities was $15.97 million, which was due to a net loss of $25.57 million offset primarily by the non-cash expenses of $10.29 million for stock compensation expense

Cash provided by (used in) investing activities

During the three-month period ended March 31, 2020, net cash provided by investing activities was $16.97 million, which was due primarily to proceeds from the sale and maturities of available for sale securities.

During the three-month period ended March 31, 2019, net cash used in investing activities was $5.06 million, which was due primarily due to purchases of available for sale securities.

Cash provided by financing activities

During the three-month period ended March 31, 2020, net cash provided by financing activities was $25.18 million due to proceeds from financing arrangements and net proceeds received from sale of common stock and warrants.

During the three-month period ended March 31, 2019, net cash provided by financing activities was $0.30 million primarily from proceeds received from stock option exercises of $0.53 million offset by payment of contingent liabilities of $0.11 million and principal payments on financing leases of $0.12 million.

Critical Accounting Policies and Estimates

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

Our discussion and analysis of the financial condition and results of operations is based upon our condensed 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 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.

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 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 consists of a single performance obligation that the Company satisfies at a point in time. In general, the Company recognizes product revenue upon delivery to the customer.

In the contract services segment, the Company records service revenues from the sale of its contract research services, which includes delivery of preclinical studies and other research services to unrelated third parties. Service revenues generally consist of a single performance obligation that the Company satisfies over time using an input method based on costs incurred to date relative to the total costs expected to be required to satisfy the performance obligation. The Company believes that this method provides a faithful depiction of the transfer of services over the term of the performance obligation based on the remaining services needed to satisfy the obligation. This requires the Company to make reasonable estimates of the extent of progress toward completion of the contract. As a result, unbilled receivables and deferred revenue are recognized based on payment timing and work completed. Generally, a portion of the payment is due upfront and the remainder upon completion of the contract, with most contracts completing in less than a year.

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

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

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.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, intangible assets and goodwill 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. There were no impairments of long-lived assets for any of the periods presented.

Common Stock and Warrant Transactions

The Company issued units consisting of common stock and warrants and subsequently remeasured those warrants at fair value. Determining the fair value of the securities in these transactions requires significant judgment, including adjustments to quoted share prices and expected stock volatility. Such estimates may significantly impact our results of operations and losses applicable to common stockholders.

Disclosure Regarding Forward-Looking Statements

Statements that are not historical facts contained in or incorporated by reference into this Quarterly Report on Form 10-Q are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements involve risks and uncertainties that could cause actual results to differ from projected results. The words "anticipate," "goal," "seek," "project," "strategy," "future," "likely," "may," "should," "will," "believe," "estimate," "expect," "plan," "intend" and similar expressions and references to future periods, as they relate to us, are intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are subject to certain risks, uncertainties and assumptions. We cannot assure you that any of our expectations will be realized. Forward-looking statements include, among others, statements we make regarding:

- the timing or success of obtaining regulatory licenses or approvals for marketing our products;
- the initiation, timing, progress, and results of our research and development programs;
- the initiation, timing, progress, and results of our clinical trials;
- the timing for the healthcare industry to resume performing elective procedures that may impact the timing and cost of clinical trials;
- the impact of new accounting pronouncements;
- size and growth of our target markets;
- sufficiency of our working capital to fund our operations for the next 12 months;
- infrastructure required to support operations in future periods, including the expected costs thereof;
- estimates associated with revenue recognition, asset impairments, and cash flows;
- variance in our estimates of future operating costs;
- future vesting and forfeitures of compensatory equity awards;
- the effectiveness of our disclosure controls and our internal control over financial reporting; and
- our plans to remediate material weaknesses in our internal control over financial reporting.

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

- the ability to comply with regulations applicable to the manufacture, marketing, sale and distribution of our products;
- the ability to gain adoption by healthcare providers of our products for patient care;
- the ability to manufacture product to meet demand;
- the acceptance and level of reimbursement to healthcare providers for application of our products by public and private payors;

- the scope of protection we can establish and maintain for intellectual property rights covering our product candidates and technology;
- developments relating to our competitors and industry;
- the development of new therapies or new discoveries that render our products obsolete;
- outbreaks of disease, including the COVID-19 pandemic, and related stay-at-home orders, quarantine policies and restrictions on travel, trade and business operations;
- political and economic instability, whether resulting from natural disasters, wars, terrorism, pandemics or other sources;
- decisions made by healthcare providers regarding elective procedures and use of facilities and resources when there is a major outbreak of life-threatening infectious disease, such as COVID-19;
- the ability to pursue sales activity in the healthcare industry when there is a major outbreak of life-threatening infectious disease, such as COVID-19;
- the ability to manufacture and deliver our products if employees are quarantined due to the impact of the COVID-19;
- the ability to find and retain skilled personnel;
- the need for, and ability to obtain, additional financing in the future;
- general economic conditions;
- inaccuracies in estimates of our expenses, future revenues, and capital requirements;
- future accounting pronouncements;
- unauthorized access to confidential information and data on our information technology systems and security and data breaches; and
- factors described under "Risk Factors" in our 2019 Annual Report on Form 10-K and under Item 1A of this Quarterly Report on Form 10-Q.

We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are expressly qualified by these cautionary statements.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

Not applicable.

Item 4. Controls and Procedures

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 March 31, 2020, our principal executive and financial officers concluded that, as of such date, our disclosure controls and procedures were not effective due to the material weakness in our internal control over financial reporting identified below. To address the material weakness, 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.

The material weakness previously identified as of December 31, 2019, continued to exist as of March 31, 2020. In 2019, we failed to execute controls relating to reconciliation procedures. In addition, we did not have a sufficient level of precision in our review procedures to detect potentially material errors in accrual and related accounts.

In the first quarter of 2020 management implemented a systemic tool to enhance the reconciliation and review procedures identified in the material weakness above. The tool has not been in operation for a sufficient period of time required for remediation. There were no other 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.

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 weakness. 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 1A. Risk Factors

You should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, which could materially affect our business, financial position, or future results of operations. The risks described in that Annual Report are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial position, or future results of operations. The risk factors set forth below update, and should be read together with, the risk factors described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019.

Risks Related to Our Business

Public health crises, or the perception of their effects, have had and could continue to have a material adverse effect on our business and results of operations.

We could be negatively impacted by the widespread outbreak of an illness or any other communicable disease, such as the COVID-19 pandemic, or any other public health crisis that results in economic and healthcare industry disruptions. The COVID-19 pandemic has negatively impacted the global economy, disrupted supply chains and workforce participation due to "shelter-in-place" restrictions by various governments, and created significant volatility and disruption of financial markets. To date, COVID-19 has had, and may continue to have, an adverse impact on our product sales and commercial operations. We have experienced and may continue to experience significant and unpredictable reductions in the demand for our product as healthcare customers devote medical resources and priorities to the treatment of COVID-19. Our customers may delay their customary purchasing and contracting practices during the healthcare crisis, which could contribute to the reduction in demand for our product. In addition, the American College of Surgeons, U.S. surgeon general, and other public health bodies have recommended delaying elective surgeries during the COVID-19 pandemic, and surgeons and medical societies are evaluating the risks of minimally invasive surgeries in the presence of infectious diseases, which we expect will continue to negatively impact the sale of our product.

The extent of the impact of the COVID-19 pandemic on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected time frame, will depend on future developments, including the duration and spread of the pandemic and the effect on healthcare providers and the healthcare industry; our ability to travel, distribute, and deploy SkinTE, as well as reduction in access to our customers due to stay-at-home orders, quarantine policies and restrictions on travel, trade, and business operations. These unprecedented measures to slow the spread of the virus taken by local governments and health care authorities, including the deferral of elective medical procedures and social distancing measures, will adversely affect our operations and financial results.

In addition, the COVID-19 pandemic has adversely affected, and may continue to adversely affect, the economies and financial markets of many countries, which may result in a period of regional, national, and global economic slowdown or regional, national, or global recessions that could affect decisions on healthcare spending, adversely affect the healthcare industry, and adversely affect access to capital. COVID-19 and the current financial, economic, and capital markets environment, and future developments in these and other areas present material uncertainty and risk with respect to our performance, financial condition, volume of business, results of operations, and cash flows. Due to the uncertain scope and duration of the pandemic and uncertain timing of national recovery and economic normalization, we are unable to estimate the impact on our operations and financial condition.

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

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

No assurance is provided that the Borrower will elect to pursue forgiveness of all or a portion of the Loan or be eligible for and obtain forgiveness of all or a portion of the Loan. If the Borrower elects not to pursue or is unable to qualify for or obtain forgiveness of all or a portion of the Loan, our liquidity could be reduced and our business, financial condition and results of operations may be adversely affected.

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

Subsequent to the Borrower's application for the loan, SBA issued various interpretive guidelines in connection with the PPP, including guidance on how SBA interprets certain of the certification requirements. One of the interpretations appears to be in response to various press reports that well-established or well capitalized private and public companies were able to secure PPP loans that were meant for smaller companies. SBA's interpretive guidelines published on April 23, 2020 set forth that public companies with substantial market value and access to capital markets would likely not qualify to participate in the PPP and SBA advised any such public company to be prepared to provide the basis for the certifications upon SBA request. Subsequently, on April 28, 2020 the Secretary of the Treasury and SBA announced that the government will conduct a full audit of all PPP loans of more than $2 million for which the borrower applies for forgiveness. As the Borrower expects it will be audited or reviewed by SBA or the U.S. Department of the Treasury if it files an application for forgiveness, and, whether or not it elects to seek forgiveness of all or part of the loan, it could be subject to investigation, audit or other review by governmental agencies or claims by third parties, with respect to whether it qualified for an SBA loan, or whether the certifications it made to obtain the Loan are accurate, or other matters. There is a risk that any such audit, review, investigation or claim could result in the diversion of our management's time and attention, the need to incur significant legal expenses and the possibility that we will sustain reputational injury. If the Borrower were to be audited, investigated, reviewed or subject to suit and if there is any adverse finding in such audit, investigation, review or suit or if the Borrower were alleged, or determined, not to qualify for the Loan or alleged, or found, to have made false certifications in connection with the Loan, the Borrower could be required to return the full amount of the Loan, which would reduce its liquidity, and would subject it to fines and penalties, and exclusion from government contracts. In particular, the Borrower may become subject to actions under the federal False Claims Act, or the FCA, including its qui tam provisions, which, among other things, prohibits persons from knowingly filing, or knowingly causing to be filed, a false statement, or knowingly using a false statement, to obtain payment from the federal government. Violations of the FCA are subject to treble damages and penalties. In the case of an SBA loan, the government could allege that single damages are the amount of the loan and interest thereon (or more), which under the FCA could then be trebled. Substantial penalties must also be imposed for each submitted false statement when a defendant loses an FCA trial. FCA cases may be initiated by the U.S. Department of Justice or by private persons or entities, often called "whistleblowers," who bring the action on behalf of the United States. The Borrower may also face enforcement arising under other federal statutes, including criminal laws, and administrative actions and investigations initiated by SBA or other governmental entities. Furthermore, if the Borrower is identified as an entity that the media, government officials or others seek to portray as a business that should not have availed itself of PPP funding, the Borrower may face negative publicity, which could have a materially adverse impact on its business and operations and on our business and operations as its parent.

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

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

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

When SkinTE was registered and listed with the FDA, we believed SkinTE was appropriately regulated solely under Section 361 of the Public Health Service Act and Part 1271 of Title 21 of the Code of Federal Regulations (i.e., as a so-called "361 HCT/P") and that, as a result, no premarket review or approval by the FDA was required. We still believe that SkinTE is appropriately regulated as a 361 HCT/P. However, following informal, voluntary discussions between FDA and the Company, and preliminary views expressed by FDA received on April 21, 2020, we believe that the FDA may disagree with our interpretation if we sought a formal designation of SkinTE's regulatory classification, and that it therefore is prudent to pursue a strategy to file an investigational new drug application ("IND") and thereafter a biologics license application ("BLA") for SkinTE. While we could pursue a formal designation, and we could potentially challenge FDA's formal designation administratively or in court if we disagreed with their interpretation of the regulations, that would be a lengthy and costly process that would put us in a highly adversarial position vis-à-vis the FDA. Moreover, courts give deference to administrative agencies' interpretations of governing regulations, and an adverse formal decision from either FDA or a federal court, or both, could have significant negative consequences on our ability to continue our collaborative relationship with the FDA.

FDA has not asked us to stop marketing SkinTE at this time, but we could be required to withdraw SkinTE from the market until the required clinical trials are complete and the applicable premarket regulatory clearances or approvals are obtained. Manufacturers of new drugs, biologics, and some medical devices must complete extensive clinical trials, which must be conducted pursuant to an effective IND or investigational device exemption (IDE). In addition, the FDA must review and approve a BLA or new drug application before a new drug or biologic may be marketed and must approve or clear most medical devices prior to marketing.

The preliminary assessment by the FDA that SkinTE appears to be a biological product that would be regulated under Section 351 of the Public Health Service Act will negatively impact our commercialization of the product and substantially increase the cost to us of regulatory compliance, all of which could adversely affect our results of operations and financial condition. This same risk applies to any other product we may develop that we believe should be regulated as a 361 HCT/P but where the FDA may disagree with our interpretation of the applicable regulations.

Some of the future new products and enhancements of existing products that we expect to develop and market may not be 361 HCT/Ps, and may require premarket approval or clearance from the FDA. As a result, those product candidates would be subject to additional regulatory requirements, including premarket approval or clearance. There can be no assurance, however, that approval or clearance will be granted with respect to SkinTE, any such products, or enhancements of existing products. Such products or enhancements may encounter significant delays during FDA's premarket review process that would adversely affect our ability to market such products or enhancements.

Even if premarket approval or clearance are obtained from the FDA, the approvals or clearances may contain substantial limitations on the indicated uses of such products and other uses may be prohibited. Product approvals by the FDA can also be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval. Furthermore, the FDA could limit or prevent the distribution of products, and the FDA has the power to require the recall of such products. FDA regulations depend heavily on administrative interpretation, and there can be no assurance that future interpretations made by the FDA or other regulatory bodies will not adversely affect our operations. In addition, regulatory clearance or approval is subject to continuing compliance with regulatory standards, including the FDA's current good manufacturing practice (cGMP) or quality system regulations and adverse event reporting regulations, and additional clearance, approval, or regulatory reporting may be needed for changes made to products following their initial clearance or approval.

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

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

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

Our failure to comply with the regulatory guidelines set forth by the FDA with respect to our product candidates could delay or prevent the completion of market entry, clinical trials, the approval or registration of any product candidates, or the commercialization of our product candidates.

We are subject to regulation and inspection by the FDA for cGTP compliance with respect to our 361 HCT/P products, and we will need to transition to cGMP manufacturing for SkinTE as we pursue a BLA. To the extent that products we develop are not regulated as 361 HCT/Ps, in addition to cGTP, we will be subject to regulation under cGMP as well as to FDA premarket approval or clearance requirements. Complying with cGTP and cGMP requires that we expend time, money, and effort in production, recordkeeping, and quality control to assure that the product meets applicable specifications and other requirements. For any products for which we are required to obtain FDA premarket approval, we must also pass a pre-approval inspection prior to FDA approval or clearance. Failure to pass a pre-approval inspection may significantly delay FDA approval of our product candidates. If we fail to comply with these requirements, we would be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our product candidates. As a result, our business, financial condition, and results of operations may be materially harmed.

The manufacture of cell and tissue-based therapy products, such as our product candidates, is highly complex and is characterized by inherent risks and challenges such as autologous raw material inconsistencies, logistical challenges, significant quality control and assurance requirements, manufacturing complexity, and significant manual processing. Unlike products that rely on chemicals for efficacy, such as most pharmaceuticals, cell and tissue-based therapy products are difficult to characterize due to the inherent variability of biological input materials.

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

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

Even if we are permitted to continue marketing SkinTE for some period of time before making a submission to the FDA for premarket approval, we still must generate adequate substantiation for claims we make in our marketing materials. Both the Federal Trade Commission ("FTC") and the states retain jurisdiction over the marketing of 361 HCT/Ps (and other) products in commerce and require a reasonable basis for claims made in marketing materials, and FDA has similar requirements for the labeling and promotion of HCT/Ps that are also considered drugs, biologics, or medical devices. Through clinical use, case studies, clinical studies, as well as other endeavors, we intend to generate such adequate substantiation for any claims we make about our products. If, however, after we commence marketing of any of our products, including SkinTE, the FTC, FDA or one or more states conclude that we lack adequate substantiation for our claims, we may be subject to significant penalties, or may be forced to alter our marketing approach in one or more jurisdictions. Any of this could materially harm our business.

Even if any of our products meet the criteria for a 361 HCT/P, they will be subject to ongoing regulation. We could be subject to significant penalties if we fail to comply with these requirements, which would adversely affect our results of operations.

If one or more of our products meets the criteria for a 361 HCT/P or we are able to continue marketing SkinTE before receiving BLA approval, we would still be subject to numerous post-market requirements, including those related to registration and listing, record keeping, labeling, cGTP, donor eligibility, deviation and adverse event reporting, and other activities. HCT/Ps that do not meet the definition of a 361 HCT/P are also subject to these or additional obligations. If we fail to comply with these requirements, we could be subject to, without limitation, warning letters, product seizures, injunctions, or civil and criminal penalties. We have established our own processing facility, which we believe is cGTP compliant. Any failure by us to maintain cGTP compliance would require remedial actions, which could potentially include actions such as delays in distribution and sales of our product, as well as enforcement actions.

Clinical trials can be long and expensive, and results are ultimately uncertain, which could jeopardize PolarityTE's ability to obtain regulatory approval for its SkinTE product.

PolarityTE will likely be required to perform one or more clinical trials for SkinTE under FDA's statutory requirements to obtain approval of a BLA for the product. Clinical trials can be expensive, can take several years to execute, and are subject to factors within and outside of PolarityTE's control. The outcomes of clinical trials are uncertain. PolarityTE has not yet submitted an IND to FDA to conduct clinical trials to support a BLA for SkinTE. PolarityTE has two ongoing randomized controlled clinical trials—one in diabetic foot ulcers (DFUs) and one in venous leg ulcers (VLUs)—that were being conducted with SkinTE as a 361 HCT/P. While those trials are being conducted pursuant to protocols approved by an institutional review board (IRB), we do not know whether data from those trials or other clinical investigations previously conducted with SkinTE will be able to be used as part of a clinical data package for a SkinTE BLA submission.

PolarityTE will likely need to ensure compliance with applicable regulations for a BLA submission by transitioning its quality system to 21 CFR Parts 210/211 and 600-610 regulations with the FDA. Final determination of regulatory compliance with 21 CFR Parts 210/211 and 600-610 would be made during FDA's pre-license inspection as part of the BLA review. If the FDA is unable to agree with PolarityTE, or PolarityTE is unable to meet the standards required of it by the FDA, regarding preclinical studies, clinical studies and chemistry, manufacturing and controls, the approval of any BLA would not occur or would be delayed.

The results of non-clinical studies do not necessarily predict future clinical trial results and predecessor clinical trial results may not be repeated in subsequent clinical trials. Additionally, the FDA may disagree with PolarityTE's interpretation of the data from its non-clinical studies and clinical trials, and may require the company to pursue additional non-clinical studies or clinical trials, or not approve any BLA that PolarityTE may submit. If PolarityTE is unable to demonstrate the safety and efficacy of its product through its clinical trials, it will be unable to obtain regulatory approval to market SkinTE as a licensed biologic.

PolarityTE will rely on third parties to conduct its clinical trial and they may not perform as contractually required or expected.

PolarityTE may rely on third parties, such as contract research organizations ("CROs"), medical institutions, clinical investigators and contract laboratories to conduct its clinical trials and potentially certain nonclinical studies to support a BLA for SkinTE. PolarityTE and its CROs are also required to comply with all applicable regulations governing nonclinical and clinical research, including good laboratory practice ("GLP") and good clinical practice ("GCP"). The FDA enforces these regulations through periodic inspections of trial sponsors, principal investigators, CROs and trial sites. If PolarityTE or its CROs fail to comply with applicable FDA regulations, the data generated in clinical trials may be deemed unreliable and the FDA may require PolarityTE to perform additional clinical trials before approving its applications. PolarityTE cannot be certain that, upon inspection, the FDA and similar foreign regulatory authorities will determine that PolarityTE's clinical trials comply or complied with clinical trial regulations, including GCP. In addition, PolarityTE's clinical trials in support of a BLA may need to be conducted with product produced under applicable cGMP regulations. Failure to comply with the clinical trial regulations may require PolarityTE to repeat clinical trials, which would delay the regulatory approval process. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to PolarityTE's clinical protocols or regulatory requirements or for other reasons, PolarityTE's non-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and it would not be able to obtain regulatory approval for its products on a timely basis, if at all, and its business, results of operations, financial condition and growth prospects would be adversely affected. Furthermore, PolarityTE's third party clinical trial investigators may be delayed in conducting its clinical trials for reasons outside of their control.

Item 6. Exhibits

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

4.1	Form of Common Stock Warrant Certificate (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K filed on February 14, 2020)
4.2	Form of Warrant Agency Agreement (incorporated by reference to Exhibit 4.2 to our Current Report on Form 8-K filed on February 14, 2020)
10.1	Form of Indemnification Agreement (incorporated by reference to Exhibit 4.2 to our Current Report on Form 8-K filed on March 25, 2020)
10.2	Separation, Transition and Release of Claims Agreement dated March 31, 2020 (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on April 1, 2020)
10.3	Note and Loan Agreement dated April 12, 2020, between PolarityTE MD, Inc., and KeyBank National Association (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on April 15, 2020)
31.1	Certification Pursuant to Rule 13a-14(a)
31.2	Certification Pursuant to Rule 13a-14(a).
32.1	Certification Pursuant to Rule 13a-14(b) and Section 1350, Chapter 63 of Title 18, United States Code
101.INS	XBRL Instance Document.
101.SCH	XBRL 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.

Date: May 11, 2020

/s/ David Seaburg
David Seaburg
Chief Executive Officer
Duly Authorized Officer

Date: May 11, 2020

/s/ Jacob Patterson
Jacob Patterson
Interim Chief Financial Officer
Chief Accounting Officer

EXHIBIT 31.1

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: May 11, 2020

/s/ David Seaburg
David Seaburg
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Jacob Patterson, 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: May 11, 2020

/s/ Jacob Patterson
Jacob Patterson
Interim Chief Financial Officer

EXHIBIT 32.1

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

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

The Quarterly Report on Form 10-Q for the period ending March 31, 2020 (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: May 11, 2020

/s/ David Seaburg
David Seaburg
Chief Executive Officer

/s/ Jacob Patterson
Jacob Patterson
Interim Chief Financial Officer