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 June 30, 2020

Commission File No. 001-32404

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

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

1960 S. 4250 West, Salt Lake City, UT 84104
(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 ☒ No ☐

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

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

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

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

As of August 3, 2020, there were 38,740,704 shares of the Registrant's common stock outstanding.

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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)

	June 30, 2020	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 30,504	$ 10,218
Short-term investments	–	19,022
Accounts receivable, net	2,115	1,731
Inventory	281	252
Prepaid expenses and other current assets	2,453	1,264
Total current assets	35,353	32,487
Property and equipment, net	12,729	14,911
Operating lease right-of-use assets	3,559	4,590
Intangible assets, net	636	731
Goodwill	278	278
Other assets	599	602
TOTAL ASSETS	$ 53,154	$ 53,599
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 5,050	$ 7,095
Other current liabilities	2,644	2,338
Current portion of long-term notes payable	1,436	528
Deferred revenue	97	98
Total current liabilities	9,227	10,059
Common stock warrant liability	8,736	–
Operating lease liabilities	2,192	2,994
Other long-term liabilities	1,022	1,630
Long-term notes payable	2,410	–
Total liabilities	23,587	14,683
Commitments and Contingencies (Note 14)		
STOCKHOLDERS' EQUITY		
Preferred stock -25,000,000 shares authorized, 0 shares issued and outstanding at June 30, 2020 and December 31, 2019	–	–
Common stock – $.001 par value; 250,000,000 shares authorized; 38,496,910 and 27,374,653 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	38	27
Additional paid-in capital	490,603	474,174
Accumulated other comprehensive income	–	72
Accumulated deficit	(461,074)	(435,357)
Total stockholders' equity	29,567	38,916
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 53,154	$ 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 June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Net revenues				
Products	$ 944	$ 504	$ 1,372	$ 801
Services	1,322	822	1,827	1,990
Total net revenues	2,266	1,326	3,199	2,791
Cost of sales				
Products	275	342	615	615
Services	607	254	783	757
Total cost of sales	882	596	1,398	1,372
Gross profit	1,384	730	1,801	1,419
Operating costs and expenses				
Research and development	3,164	4,764	6,537	10,116
General and administrative	5,211	15,060	15,816	32,255
Sales and marketing	2,024	3,981	5,718	7,934
Restructuring and other charges	2,084	–	2,536	–
Total operating costs and expenses	12,483	23,805	30,607	50,305
Operating loss	(11,099)	(23,075)	(28,806)	(48,886)
Other income (expenses)				
Change in fair value of common stock warrant liability	(1,591)	–	2,941	–
Interest (expense) income, net	(65)	29	(77)	99
Other income, net	78	254	225	422
Net loss	$ (12,677)	$ (22,792)	$ (25,717)	$ (48,365)
Net loss per share, basic and diluted	$ (0.33)	$ (0.92)	$ (0.72)	$ (2.09)
Weighted average shares outstanding, basic and diluted	38,428,289	24,768,453	35,724,141	23,190,343

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 June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Net loss	$ (12,677)	$ (22,792)	$ (25,717)	$ (48,365)
Other comprehensive income/(loss):				
Unrealized gain on available-for-sale securities	7	160	11	312
Reclassification of realized gains included in net loss	(10)	(134)	(83)	(269)
Comprehensive loss	$ (12,680)	$ (22,766)	$ (25,789)	$ (48,322)

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 and Six Months Ended June 30, 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
Stock-based compensation expense	–	–	563	–	–	563
Purchase of ESPP shares	38,293	–	40	–	–	40
Vesting of restricted stock units	119,132	–	–	–	–	–
Shares withheld for tax withholding	(6,918)	–	(9)	–	–	(9)
Forfeiture of restricted stock awards	(46,886)	–	–	–	–	–
Other comprehensive loss	–	–	–	(3)	–	(3)
Net loss	–	–	–	–	(12,677)	(12,677)
Balance – June 30, 2020	38,496,910	$ 38	$ 490,603	$ –	$ (461,074)	$ 29,567

	For the Three and Six Months Ended June 30, 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
Proceeds received from issuance of common stock, net of issuance costs of $1,146	3,418,918	3	27,945	–	–	27,948
Stock-based compensation expense	–	–	8,618	–	–	8,618
Stock option exercises	9,167	–	–	–	–	–
Shares issued under the ESPP	7,260	–	35	–	–	35
Vesting of restricted stock units	51,440	–	–	–	–	–
Shares withheld for tax withholding	(17,418)	–	(62)	–	–	(62)
Other comprehensive income	–	–	–	26	–	26
Net loss	–	–	–	–	(22,792)	(22,792)
Balance – June 30, 2019	25,218,606	$ 25	$ 461,491	$ 79	$ (391,229)	$ 70,366

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 Six Months Ended June 30,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (25,717)	$ (48,365)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation expense	3,784	18,907
Depreciation and amortization	1,549	1,446
Amortization of intangible assets	95	99
Amortization of debt discount	13	28
Change in fair value of common stock warrant liability	(2,941)	–
Change in fair value of contingent consideration	–	(48)
Loss on abandonment of property and equipment	1,529	
Other non-cash adjustments	(21)	30
Changes in operating assets and liabilities:		
Accounts receivable	(384)	(624)
Inventory	(29)	(26)
Prepaid expenses and other current assets	(1,189)	(486)
Operating lease right-of-use assets	899	791
Other assets	3	25
Accounts payable and accrued expenses	(2,109)	(17)
Other current liabilities	9	367
Deferred revenue	(1)	(126)
Operating lease liabilities	(903)	(670)
Other long-term liabilities	–	(120)
Net cash used in operating activities	(25,413)	(28,789)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(1,170)	(2,110)
Purchase of available-for-sale securities	(14,144)	(15,445)
Proceeds from maturities of available-for-sale securities	16,945	9,278
Proceeds from sale of available-for-sale securities	16,171	–
Net cash provided by (used in) investing activities	17,802	(8,277)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from the sale of common stock and warrants	24,276	27,948
Proceeds from stock options exercised	31	529
Proceeds from ESPP purchase	40	35
Cash paid for tax withholdings related to net share settlement	(6)	(636)
Payment of contingent consideration liability	–	(109)
Principal payments on financing leases	(243)	(225)
Proceeds from term note payable and financing arrangements	4,629	–
Principal payments on term note payable and financing arrangements	(830)	(262)
Net cash provided by financing activities	27,897	27,280
Net increase (decrease) in cash and cash equivalents	20,286	(9,786)
Cash and cash equivalents - beginning of period	10,218	55,673
Cash and cash equivalents - end of period	$ 30,504	$ 45,887
Non-cash investing and financing activities:		
Unpaid liability for acquisition of property and equipment	$ –	$ 63
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	$ 7	$ 43
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. (together with its 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. LIQUIDITY AND NEED FOR ADDITIONAL CAPITAL

The Company has experienced recurring losses and cash outflows from operating activities. As of June 30, 2020, the Company had an accumulated deficit of $161.1 million. As of June 30, 2020, the Company had cash and cash equivalents of $30.5 million. The Company has been funded historically through sales of equity and debt.

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.

The Company entered into a promissory note for $3.6 million under the Paycheck Protection Program on April 12, 2020. Additional details are available in note 12.

The Company does not expect existing cash as of June 30, 2020 to be sufficient to fund the Company's operations for at least twelve months from the date of filing. These financial statements have been prepared on a going concern basis, which assumes the Company will continue to realize its assets and settle its liabilities in the normal course of business. The Company has incurred recurring losses and negative cash flows, has not yet generated material revenue from operations, and will require additional funds to maintain its operations. These factors raise substantial doubt regarding the Company's ability to continue as a going concern within one year after these condensed consolidated financial statements are issued.

In the second quarter of 2020 the Company took steps to reduce cash burn by reducing payroll expense, adopting a salary and wage reduction, and reducing discretionary spending across the organization to minimal levels. The Company will seek additional capital through equity offerings or debt financing. However, such financing may not be available in the future on favorable terms, if at all. 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.

3. 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.

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.

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.

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

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 of 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.

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.

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.

During the three months ended June 30, 2020, the Company transferred all available-for-sale securities to cash accounts.

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):

	June 30, 2020			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Common stock warrant liability	$ –	$ –	$ 8,736	$ 8,736
Total	$ –	$ –	$ 8,736	$ 8,736

	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 $8.7 million as of June 30, 2020.

The following assumptions were used in estimating the fair value of the warrant liability as of June 30, 2020 and upon the issuance date of February 14, 2020:

	June 30, 2020	February 14, 2020
Stock price	$ 1.24	$ 1.69
Exercise price	$ 2.80	$ 2.80
Risk-free rate	0.45%	1.51%
Volatility	97.5%	93.40%
Term	6.62	6.99

The contingent consideration related to the IBEX acquisition of $31,000 outstanding at December 31, 2019, was paid during the six months ended June 30, 2020. As of June 30, 2020, the obligation related to the contingent consideration was fully satisfied.

5. CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS

During the three months ended June 30, 2020, the Company transferred all available-for-sale securities to cash accounts.

Cash equivalents and short-term investments consisted of the following as of December 31, 2019 (in thousands):

	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.

For the six months ended June 30, 2020 and 2019, the Company recognized net realized gains on available-for-sale securities of $0.1 million and $0.3 million, respectively.

6. PROPERTY AND EQUIPMENT, NET

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

	June 30, 2020	December 31, 2019
Machinery and equipment	$ 12,198	$ 12,083
Land and buildings	2,000	2,000
Computers and software	1,255	1,189
Leasehold improvements	3,044	2,282
Construction in progress	179	1,606
Furniture and equipment	233	470
Total property and equipment, gross	18,909	19,630
Accumulated depreciation and amortization	(6,180)	(4,719)
Total property and equipment, net	$ 12,729	$ 14,911

The Company abandoned $1.5 million of construction in progress and other equipment during the period ended June 30, 2020. See note 13.

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
General and administrative expense	$ 408	$ 407	$ 800	$ 764
Research and development expense	389	363	749	682
Total depreciation and amortization expense	$ 797	$ 770	$ 1,549	$ 1,446

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 June 30, 2020, the maturities of our operating and finance lease liabilities were as follows (in thousands):

	Operating leases	Finance leases
2020 (excluding the six months ended June 30, 2020)	$ 948	$ 335
2021	1,646	656
2022	1,345	405
2023	132	336
2024	87	42
Total lease payments	4,158	1,774
Less imputed interest	(452)	(242)
Total lease liabilities	$ 3,706	$ 1,532

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

Finance leases

	June 30, 2020	December 31, 2019
Finance lease right-of-use assets included within property and equipment, net	$ 1,631	$ 2,177
Current finance lease liabilities included within other current liabilities	$ 532	$ 508
Non-current finance lease liabilities included within other long-term liabilities	1,000	1,267
Total finance lease liabilities	$ 1,532	$ 1,775

Operating leases

	June 30, 2020	December 31, 2019
Current operating lease liabilities included within other current liabilities	$ 1,514	$ 1,746
Operating lease liabilities – non current	2,192	2,994
Total operating lease liabilities	$ 3,706	$ 4,740

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Operating lease costs included within operating costs and expenses	$ 548	$ 546	$ 1,104	$ 1,061
Finance lease costs:				
Amortization of right-of-use assets	$ 174	$ 170	$ 349	$ 309
Interest on lease liabilities	39	44	82	67
Total	$ 213	$ 214	$ 431	$ 376

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

	For the Six Months Ended June 30,	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash out flows from operating leases	$ 1,108	$ 941
Operating cash out flows from finance leases	$ 82	$ 67
Financing cash out flows from finance leases	$ 243	$ 225
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
Remeasurement of finance lease liability due to lease modification	$ –	$ (22)
Operating leases	$ –	$ 939
Remeasurement of operating lease liability due to lease modification	$ 131	$ –

As of June 30, 2020 and December 31, 2019, the weighted average remaining lease term for operating leases was 2.5 and 2.8 years, respectively, and the weighted average discount rate used for operating leases was 9.76% and 9.83%, respectively. As of June 30, 2020 and December 31, 2019, the weighted average remaining lease term for finance leases was 3.0 and 3.5 years, respectively, and the weighted average discount rate used for finance leases was 9.77% for both periods. In May 2020, the Company reduced office space related to one of its existing lease agreements resulting in lower monthly payments.

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):

	June 30, 2020	December 31, 2019
Accounts payable	$ 423	$ 1,689
Salaries and other compensation	1,815	1,462
Legal and accounting	426	1,404
Accrued severance	1,217	1,053
Benefit plan accrual	560	557
Other	609	930
Total accounts payable and accrued expenses	$ 5,050	$ 7,095

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 $0.6 million as of June 30, 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 six months ended June 30, 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 monthly 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 June 30, 2020, the Company had 18,000 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 June 30, 2020, the Company had 257,570 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 June 30, 2020, the Company had 1,177,365 shares available for future issuances under the 2017 Plan.

A summary of the Company's employee and non-employee stock option activity for the six months ended June 30, 2020 is presented below:

	Number of Shares	Weighted-Average Exercise Price
Outstanding – December 31, 2019	4,529,988	$ 15.26
Granted	1,458,026	$ 1.19
Exercised	(10,000)	$ 3.12
Forfeited	(867,432)	$ 11.78
Outstanding – June 30, 2020	5,110,582	$ 11.84
Options exercisable, June 30, 2020	3,603,571	$ 14.87

Employee Stock Purchase Plan (ESPP)

In May 2018, the Company adopted the Employee Stock Purchase Plan ("ESPP"). The Company has initially reserved500,000 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.

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	3,401,036
Vested (1)	(832,910)
Forfeited	(79,803)
Unvested – June 30, 2020	4,331,324

(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.

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 June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
General and administrative expense	$ 143	$ 6,892	$ 3,220	$ 15,929
Research and development expense	404	1,481	367	2,565
Sales and marketing expense	16	245	197	413
Total stock-based compensation expense	$ 563	$ 8,618	$ 3,784	$ 18,907

10. COMMON STOCK WARRANTS

On February 14, 2020, the Company completed an underwritten offering of10,638,298 shares of its common stock and warrants to purchase10,638,298 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 expireFebruary 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. As of June 30, 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):

	June 30, 2020
Beginning balance	$ –
Initial value of common stock warrant liability	11,677
Change in fair value of common stock warrant liability	(2,941)
Ending balance	$ 8,736

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 June 30,	
	2020	2019
Stock options	5,110,582	6,604,461
Restricted stock	4,331,324	493,447
Common stock warrants	10,638,298	–

12. DEBT

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 make24 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 Company will obtain forgiveness of the Loan in whole or in part.

13. RESTRUCTURING

In the first half of 2020, management approved several actions as part of a restructuring plan designed to improve operational efficiency and financial results. Management approved a reduction in force which affected 40 of the 126 employees in the regenerative medicine business segment, or approximately 31.7% of that workforce. The Company did not make any change in the workforce of its contract services segment. The Company recognized $0.6 and $1.0 million of expense related to employee severance and benefit arrangements for the three and six-month periods ended June 30, 2020, respectively. It is expected that the full amount will be paid by the end of 2020. Management also recorded $1.5 million of asset abandonments within the Company's regenerative medicine business segment for both the three and six-month periods ended June 30, 2020.

14. COMMITMENTS AND CONTINGENCIES

Contingencies

On June 26, 2018, a class action complaint alleging violations of the Federal securities laws was filed in the United States District Court, District of Utah, by Jose Moreno against the Company and two directors of the Company, Case No. 2:18-cv-00510-JNP (the "Moreno Complaint"). On July 6, 2018, a similar complaint was filed in the same court against the same defendants by Yedid Lawi, Case No. 2:18-cv-00541-PMW (the "Lawi Complaint"). Both the Moreno Complaint and Lawi Complaint allege that the defendants made or were responsible for, disseminating information to the public through reports filed with the Securities and Exchange Commission and other channels that contained material misstatements or omissions in violation of Sections 10 and 20(a) of the Exchange Act and Rule 10b-5 adopted thereunder. Specifically, both complaints allege that the defendants misrepresented the status of one of the Company's patent applications while touting the unique nature of the Company's technology and its effectiveness. Plaintiffs are seeking damages suffered by them and the class consisting of the persons who acquired the publicly-traded securities of the Company between March 31, 2017, and June 22, 2018. Plaintiffs have filed motions to consolidate and for appointment as lead plaintiff. On November 28, 2018, the Court consolidated the *Moreno* and *Lawi* cases under the caption *In re PolarityTE, Inc. Securities Litigation* (the "Consolidated Securities Litigation"), and requested the appointment of the plaintiff in *Lawi* as the lead plaintiff. On January 16, 2019, the Court granted the motion of Yedid Lawi for appointment as lead plaintiff, and on February 1, 2019, the Court granted the lead plaintiff's motion for approval of lead counsel and liaison counsel. The Court 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, as of June 30, 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.

15. 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 June 30, 2020, the Company has recorded a liability of $0.8 million related to future cash payments under the agreement.

In October 2018, the Company entered into an office lease covering approximately7,250 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 from 3,275 square feet to6,232 square feet. In May 2020, the Company reduced the space from 6,232 to 4,554. The Company is using 1,099 square feet, and Cohen LLC is using approximately 3,455 square feet as of June 30, 2020. The monthly lease payment for 4,554 square feet is $22,771. Of this amount $17,277 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. If the space becomes 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 sublease income related to this agreement of $63,000 and $51,000 for the three months ended June 30, 2020 and 2019, respectively, and$132,000 and $126,000 for the six months ended June 30, 2020 and 2019, respectively. The sublease income is included in other income, net in the statement of operations. As of June 30, 2020 and December 31, 2019, there were no amounts due from the related party under this agreement.

16. SEGMENT REPORTING

Reportable segments are presented in a manner consistent with the internal reporting provided to the chief operating decision maker (CODM). 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 segment using information about its revenue and operating income (loss). These measures are presented in the following tables (in thousands). Asset information by segment is not presented, as this measure is not used by the CODM to assess the segment's performance.

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Net revenues by segment:				
Regenerative medicine	$ 944	$ 504	$ 1,372	$ 801
Contract services	1,322	822	1,827	1,990
Total net revenues	$ 2,266	$ 1,326	$ 3,199	$ 2,791
Net loss by segment:				
Regenerative medicine	$ (12,567)	$ (22,572)	$ (25,270)	$ (47,781)
Contract services	(110)	(220)	(447)	(584)
Total net loss	$ (12,677)	$ (22,792)	$ (25,717)	$ (48,365)

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 product segment and the contract services segment.

Segment Reporting

Regenerative Medicine Product Segment

The regenerative medicine product segment is engaged in the development of SkinTE, our first commercial product, and also the development of SkinTE POC (point-of-care device for on-site SkinTE processing and deployment), Skin TE Cryo (cryopreservation of SkinTE for multiple deployments on a single patient), and PTE 11000 (allogeneic, biologically active dressing for use in wound care).

SkinTE was registered and listed with the United States Food and Drug Administration (FDA) in August 2017 based on our determination that SkinTE is 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 is required. We proceeded to develop sales and manufacturing capabilities for SkinTE and focused on advancing commercialization of SkinTE.

Following informal, voluntary discussions between us and the FDA we were advised by the FDA in April 2020 that its preliminary assessment is that SkinTE does not meet the requirements to be regulated as a 361 HCT/P. Rather, FDA's view is that SkinTE is a biological product that should be regulated under Section 351 of the Public Health Service Act. We re-evaluated our regulatory approach and determined it is prudent to submit an investigational new drug application (IND), and thereafter a biologics license application (BLA) for SkinTE, and to adjust the focus of our commercial effort for SkinTE based on the following factors:

- license exclusivity for 12 years that arises under a BLA could enhance the value of SkinTE;
- clinical testing in the BLA process could advance commercial acceptance of SkinTE;
- the possibility the FDA could restrict our commercial sale of SkinTE in the future; and
- the contraction of the commercial opportunity for SkinTE in March and April 2020 because healthcare providers were dedicating resources to the care and treatment of COVID-19 patients and the acute and traumatic care needs of the general population and, as a result, were putting a hold on elective procedures in many regions across the country.

Contract Services Segment

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

In April 2020 we received unsolicited inquiries from third parties regarding our laboratory and its capacity to perform COVID-19 testing, which we attribute to the surge in COVID-19 testing throughout the United States and what we believe to be a lack of laboratory testing capacity to meet the surging demand. Management evaluated Arches' resources and found that it has the capability of performing molecular polymerase chain reaction testing for COVID-19. Management decided that COVID-19 testing offered an opportunity to use existing resources to generate additional revenue in the contract services segment and thereby help defray our operating expenses. Consequently, we applied to the Centers for Medicare and Medicaid Services for a certificate of registration for our laboratory under the Clinical Laboratory Improvement Amendments and obtained that certificate in late April 2020. We started providing COVID-19 testing services on May 27, 2020.

Revenue Recognition

In the regenerative medicine products segment, we record product revenues primarily from the sale of our 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. Contract services include research and laboratory testing services to unrelated third parties on a contract basis. These customer contracts generally consist of a single performance obligation that the Company satisfies at a point in time. The Company recognizes revenue upon delivery of testing results to the customer.

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 June 30, 2020 compared to the three months ended June 30, 2019.

(in thousands)	For the Three Months Ended		Increase (Decrease)	
	June 30, 2020	June 30, 2019	Amount	%
	(Unaudited)			
Net revenues				
Products	$ 944	$ 504	$ 440	87%
Services	1,322	822	500	61%
Total net revenues	2,266	1,326	940	71%
Cost of sales				
Products	275	342	(67)	(20)%
Services	607	254	353	139%
Total cost of sales	882	596	286	48%
Gross profit	1,384	730	654	90%
Operating costs and expenses				
Research and development	3,164	4,764	(1,600)	(34)%
General and administrative	5,211	15,060	(9,849)	(65)%
Sales and marketing	2,024	3,981	(1,957)	(49)%
Restructuring and other charges	2,084	–	2,084	*
Total operating costs and expenses	12,483	23,805	(11,322)	(48)%
Operating loss	(11,099)	(23,075)	11,976	(52)%
Other income (expense)				
Change in fair value of common stock warrant liability	(1,591)	–	(1,591)	*
Interest income, net	(65)	29	(94)	(324)%
Other income, net	78	254	(176)	(69)%
Net loss	$ (12,677)	$ (22,792)	$ 10,115	(44)%

Net Revenues

For the three-month period ended June 30, 2020, we recorded net revenues of $2.266 million, which represents an increase of $0.940 million or 71% from the $1.326 million of net revenues recorded for the three months ended June 30, 2019. The $0.940 million increase in net revenues was due to an increase in revenue in both our regenerative medicine product segment and the contract services segment.

Regenerative Medicine Product Segment

As noted above, we plan to submit to FDA an IND and BLA for SkinTE. We are in the process of arranging meetings with FDA to determine the most appropriate development plan for a BLA submission. 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 May 31, 2021, which marks the end of a period of enforcement discretion that FDA announced in revised final guidance issued in July 2020 that it would generally observe unless there are reported or potential significant safety concerns, and beyond May 2021. It is not customary for the FDA to allow wide-spread commercial sales of a product subject to a pending BLA.

At the same time as the regulatory development described above, we were experiencing the effects of the COVID-19 pandemic. Throughout the country, healthcare assets in terms of facilities and providers were dedicated in March, April, and May to the care and treatment of COVID-19 patients while still trying to meet the acute and traumatic care needs of the general population. The substantial rise in COVID-19 cases in the first part of the summer indicates that the dedication of resources to the treatment of COVID-19 will continue for the immediate future. Consequently, medical care and procedures that are considered “elective” have been put on hold in many regions across the country. We experienced the effect of the COVID-19 pandemic in our commercial operations in March 2020, when there was a drop in paid cases in that month followed by cancellation or postponement of SkinTE procedures scheduled for April 2020. This negative impact was most evident in chronic wounds without amputation risk and we expect this impact to continue in subsequent periods as long as the pandemic continues to surge.

We do not know, and cannot predict, whether FDA will allow us to continue selling SkinTE while our BLA is pending. Accordingly, management determined it was prudent under the circumstances discussed above to focus our commercialization effort on the territories where we have current and repeat users of SkinTE. As a result, in May 2020 we eliminated 40 positions in the regenerative medicine product segment, including 24 positions engaged in performing sales and marketing functions. Net revenues for SkinTE in the second quarter of 2020 are $0.944 million compared to $0.428 million for the first quarter of 2020. The number of paid SkinTE cases in the second quarter of 2020 increased by 9.9% over the first quarter from 81 in the first quarter to 88 in the second quarter while net revenues more than doubled, and this disjunction is attributable to the larger wound sizes in traumatic wounds treated with SkinTE in the second quarter so that the average revenue per paid case was higher in the second quarter of 2020 compared to the first quarter. Of SkinTE revenues for the second quarter, $0.489 million, or 51.8%, of net revenues was generated by three hospital systems, and one of these hospital systems alone was the source of 31.2% of the revenues.

For the three-month period ended June 30, 2020, net revenues from the regenerative medicine product segment are $0.944 million, which represents an increase of $0.440 million or 87% from the $0.504 million of net revenues from the regenerative medicine product segment recorded for the three months ended June 30, 2019. This change is attributable to an increase of 91.3% in the number of paid cases from 46 in the second quarter of 2019 to 88 in the second quarter of 2020, and the higher average revenue per paid case we experienced in the second quarter of 2020.

Contract Services Segment

As noted above we began COVID-19 testing at the beginning of June 2020, so that at June 30, 2020, we had testing agreements with 29 nursing homes located in the state of New York controlled by a single company. On May 10, 2020, the Governor of the State of New York issued an order requiring COVID-19 testing of all employees working in nursing homes within the state weekly, which has been renewed on a monthly basis. Previously the New York Governor issued an order, Executive Order 202.10 (the "Executive Order') that, among other things, suspended the requirement that a laboratory outside New York obtain a clinical laboratory permit from New York State if the laboratory holds a CLIA certificate and is engaged to test for COVID-19 in specimens collected from persons in New York State. The Executive Order had a limited duration until April 22, 2020 but has been extended monthly and now expires August 8, 2020. We have not received any indication from the State of New York that the Executive Order will not be renewed in August 2020. This new testing service contributed $0.712 million to net revenues for the contract services segment in the second quarter of 2020 and the remainder was generated by our historical clinical service offerings. Net revenues for contract services segment in the second quarter of 2020 are $1.322 million compared to $0.505 million for the first quarter of 2020. This change is primarily attributable to the revenues generated by the new COVID-19 testing services offered by Arches.

Gross Profit

Cost of sales for the product segment as a percentage of product revenues was 68% in the second quarter of 2019 compared to 29% for the second quarter of 2020. Built in production capacity results in a lower incremental cost per unit as product sales increase. There was a reduction in staff that reduced fixed overhead costs increasing gross profit. Cost of sales for the services segment as a percentage of service revenues was 31% in the second quarter of 2019 compared to 46% for the second quarter of 2020, which we attribute to variations in service specific materials requirements for performing services in the second 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 increased as a percentage higher than net revenues period over period from $.73 million for the three-month period ended June 30, 2019 to $1.38 million for the three-month period ended June 30, 2020, or an increase in gross profit of 90%.

Research and Development

For the three-month period ended June 30, 2020, we recorded research and development expenses totaling $3.16 million, which represents a decrease of $1.60 million, or 34%, from $4.76 million of research and development expenses for the three months ended June 30, 2019. There was a reduction in staff in research and development that reduced compensation and benefits costs by $0.50 million and stock compensation expense decreased $1.08 million.

General and Administrative Expenses

General and administrative expenses totaled $5.21 million for the three-month period ended June 30, 2020, which represents a decrease of $9.85 million as compared to $15.06 million of general and administrative expenses incurred during the three months ended June 30, 2019. The primary drivers for this decrease is a $6.75 million reduction in stock compensation expense, due to restricted stock and option forfeitures related to the reduction in force taken during the second quarter of 2020, a $0.99 million reduction in legal, accounting, and consulting fees, a $0.76 million reduction in compensation-related expenses, and a $0.28 million reduction in travel expenses in the second quarter of 2020 compared to the second quarter of 2019.

Sales and Marketing

Sales and marketing expenses totaled $2.02 million for the three-month period ended June 30, 2020, which represents a decrease of $1.96 million, as compared to $3.98 million of sales and marketing expenses incurred during the three months ended June 30, 2019. There was a reduction in staff in sales and marketing that reduced compensation and benefits costs by $0.47 million and reduction of marketing and consultant spending of $1.47 million in the second quarter of 2020 compared to the second quarter of 2019. The contract service segment does not have a meaningful sales and marketing component to its business.

Restructuring and Other Charges

Restructuring and other charges totaled $2.08 million for the three-month period ended June 30, 2020. There were no restructuring and other charges for the three-month period ended June 30, 2019. Management approved several actions designed to improve operational efficiency and financial results including a reduction in force taken during the second quarter of 2020 that increased severance expense by $0.55 million. Management also recorded $1.53 million of asset abandonments within the Company's regenerative medicine business segment during the three-month period ended June 30, 2020.

Comparison of the six months ended June 30, 2020 compared to the six months ended June 30, 2019.

(in thousands)	For the Six Months Ended June 30, 2020	June 30, 2019	Increase (Decrease) Amount	%
	(Unaudited)			
Net revenues				
Products	$ 1,372	$ 801	$ 571	71%
Services	1,827	1,990	(163)	(8)%
Total net revenues	3,199	2,791	408	15%
Cost of sales				
Products	615	615	–	0%
Services	783	757	26	3%
Total cost of sales	1,398	1,372	26	2%
Gross profit	1,801	1,419	382	27%
Operating costs and expenses				
Research and development	6,537	10,116	(3,579)	(35)%
General and administrative	15,816	32,255	(16,439)	(51)%
Sales and marketing	5,718	7,934	(2,216)	(28)%
Restructuring and other charges	2,536	–	2,536	*
Total operating costs and expenses	30,607	50,305	(19,698)	(39)%
Operating loss	(28,806)	(48,886)	20,080	(41)%
Other income (expense)				
Change in fair value of common stock warrant liability	2,941	–	2,941	*
Interest income, net	(77)	99	(176)	(178)%
Other income, net	225	422	(197)	(47)%
Net loss	$ (25,717)	$ (48,365)	$ 22,648	(47)%

Net Revenues

For the six-month period ended June 30, 2020, we recorded net revenues of $3.20 million, which represents an increase of $.41 million or 15% from the $2.79 million of net revenues recorded for the six months ended June 30, 2019. The $.41 million increase in net revenues was due primarily to an increase in revenue in our regenerative medicine product segment.

Regenerative Medicine Product Segment

As noted above, we plan to submit to FDA an IND and BLA for SkinTE. We do not know, and cannot predict, whether FDA will allow us to continue selling SkinTE while our BLA is pending. Accordingly, management determined it was prudent under the circumstances discussed above focus our commercialization effort on the territories where we have current and repeat users of SkinTE. As a result, in May 2020 we eliminated 40 positions in the regenerative medicine product segment, including 24 positions engaged in performing sales and marketing functions. Net revenues for SkinTE in the six-month period ended June 30, 2020 increased by 71% over the comparable period in 2019 to $1.37 million for the six months ended June 30, 2020, compared to $0.80 million for the six months ended June 30, 2019. This change is attributable to an increase of 94.25% in the number of paid SkinTE cases from 87 in the first half of 2019 to 169 for the first half of 2020, and the higher average revenue per paid case we experienced in the second quarter of 2020. Of SkinTE revenues for the six months ended June 30, 2020, $0.325 million, or 23.6%, of net revenues was generated by one hospital system.

Contract Services Segment

As noted above we began COVID-19 testing at the beginning of June 2020, so that at June 30, 2020, we had testing agreements with 29 nursing homes located in the state of New York controlled by a single company. This new testing service contributed $0.712 million to net revenues for the contract services segment in the first half of 2020 and the remainder was generated by our historical clinical service offerings. Net revenues for contract services segment in the six months ended June 30, 2020 are $1.827 million compared to $1.990 million for the six months ended June 30, 2019. This change is attributable to a decline in net revenues from pre-clinical testing services that was only partially offset by net revenues generated by the new COVID-19 testing services offered by Arches.

Gross Profit

Cost of sales for the product segment as a percentage of product revenues was 77% in the first six months of 2019 compared to 45% for the first six months of 2020. Built in production capacity results in a lower incremental cost per unit as product sales increase. There was a reduction in staff that reduced fixed overhead costs increasing gross profit. Cost of sales for the services segment as a percentage of service revenues was 38% in the first six months of 2019 compared to 43% for the first six months of 2020, which we attribute to variations in service specific materials requirements for performing services in the first half of 2020 compared to the first half of 2019. As a result of the changes in net revenues and cost of sales in both segments, the combined effect is that gross profit increased as a percentage higher than net revenues period over period from $1.42 million for the six-month period ended June 30, 2019 to $1.80 million for the six-month period ended June 30, 2020, or an increase in gross profit of 27%.

Research and Development

For the six-month period ended June 30, 2020, we recorded research and development expenses totaling $6.54 million, which represents a decrease of $3.58 million, or 35%, from $10.12 million of research and development expenses for the six months ended June 30, 2019. There was a reduction in staff in research and development that reduced compensation and benefits costs by $1.22 million and stock compensation expense decreased $2.20 million.

General and Administrative Expenses

General and administrative expenses totaled $15.82 million for the six-month period ended June 30, 2020, which represents a decrease of $16.44 million as compared to $32.26 million of general and administrative expenses incurred during the six months ended June 30, 2019. The primary driver for this decrease is a $12.71 million reduction in stock compensation expense due to restricted stock and option forfeitures in the first half of 2020 compared to the first half of 2019.

Sales and Marketing

Sales and marketing expenses totaled $5.72 million for the six-month period ended June 30, 2020, compared to $7.93 million of sales and marketing expenses incurred during the six months ended June 30, 2019. There was a reduction in staff in sales and marketing in the second quarter of 2020 that reduced compensation and benefits costs and reduced marketing and consultant spending compared to the second quarter of 2019.The service segment does not have a meaningful sales and marketing component to its business.

Restructuring and Other Charges

Restructuring and other charges totaled $2.54 million for the six-month period ended June 30, 2020. There were no restructuring and other charges for the six-month period ended June 30, 2019. Management approved several actions designed to improve operational efficiency and financial results including a reduction in force taken during the first half of 2020 that increased severance expense by $1.01 million. Management also recorded $1.53 million of asset abandonments within the Company's regenerative medicine business segment during the six-month period ended June 30, 2020.

Liquidity and Capital Resources

As of June 30, 2020, our cash and cash equivalents totaled $30.50 million and our working capital was approximately $26.13 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 June 30, 2020, was approximately $461.07 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.

As of August 6, 2020, the date of issuance of these unaudited interim condensed financial statements, the Company expects that its cash and cash equivalents of $30.50 million as of June 30, 2020, will not be sufficient to fund its current business plan including related operating expenses and capital expenditure requirements into the second quarter of 2021. Accordingly, there is substantial doubt about the Company's ability to continue as a going concern as the Company does not believe that its cash and cash equivalents will be sufficient to fund such business plan for at least twelve months from the date of issuance of these interim financial statements. The Company plans to address this condition by raising additional capital to finance its operations. Although the Company has been successful in raising capital in the past, financing may not be available on terms favorable to us, if at all, so there is no assurance that it will be successful in obtaining additional financing. Therefore, it is not considered probable, as defined in applicable accounting standards, that the Company's plans to raise additional capital will alleviate the substantial doubt regarding its ability to continue as a going concern.

For the foreseeable future we will continue to pursue fundraising opportunities when available. 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 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:

	Six Months Ended	
(in thousands)	June 30, 2020	June 30, 2019
Net cash provided by (used in)		
Operating activities	$ (25,413)	$ (28,789)
Investing activities	17,802	(8,277)
Financing activities	27,897	27,280
Net increase/(decrease) in cash and cash equivalents	$ 20,286	$ (9,786)

Cash used in operating activities

During the six-month period ended June 30, 2020, net cash used in operating activities was $25.41 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 $25.72 million adjusted by $2.94 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 $3.78 million for stock compensation expense.

During the six-month period ended June 30, 2019, net cash used in operating activities was $28.79 million, which was due to a net loss of $48.37 million offset primarily by the non-cash expenses of $18.91 million for stock compensation expense

Cash provided by (used in) investing activities

During the six-month period ended June 30, 2020, net cash provided by investing activities was $17.80 million, which was due primarily to proceeds from the sale and maturities of available for sale securities.

During the six-month period ended June 30, 2019, net cash used in investing activities was $8.28 million, which was due primarily due to purchases of available for sale securities.

Cash provided by financing activities

During the six-month period ended June 30, 2020, net cash provided by financing activities was $27.90 million due to proceeds from financing arrangements and net proceeds received from the sale of common stock and warrants.

During the six-month period ended June 30, 2019, net cash provided by financing activities was $27.28 million primarily due to proceeds received from the sale of common stock.

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.

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.

The Company records service revenues from the sale of its preclinical research services and contract services. Preclinical research services 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. Contract services includes research and laboratory testing services to unrelated third parties on a contract basis. These customer contracts generally consist of a single performance obligation that the Company satisfies at a point in time. The Company recognizes revenue upon delivery of testing results to the customer.

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.

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

We previously identified a material weakness in our internal control over financial reporting as of December 31, 2019, that continued to exist as of March 31, 2020, which was the failure 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. This change in our internal control over financial reporting remediated the material weakness as of June 30, 2020.

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 June 30, 2020, our principal executive and financial officers concluded that, as of such date, our disclosure controls and procedures were effective. There were no changes in our internal control over financial reporting during the three-month period ended June 30, 2020.

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, and our Quarterly Report on Form 10-Q for the period ended March 31, 2020, which could materially affect our business, financial position, or future results of operations. The risks described in that Annual Report and Quarterly 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 and our Quarterly Report on Form 10-Q for the period ended March 31, 2020.

Risks Related to Our Financial Position and Capital Requirements

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

We reported a net loss of $25.7 million for the six months ended June 30, 2020 and at June 30, 2020, we had an accumulated deficit of $461.1 million. We believe we can fund our current business plan including related operating expenses and capital expenditure requirements into the second quarter of 2021. Accordingly, there is substantial doubt about our ability to continue as a going concern beyond the second quarter of 2021 unless we can raise additional capital from external sources.

We expect to incur significant operating costs in the near term as we pursue the regulatory process for filing an IND and BLA with FDA, conduct clinical trials and studies, and pursue product research, all while operating our business segments and incurring continuing fixed costs related to the maintenance of our assets and business. We cannot predict whether we will be restricted by FDA with respect to SkinTE sales while our BLA is pending, and the net revenues generated from COVID-19 testing is a very recent development, so we are unable to predict any future trend for this testing revenue. In any event, we do not expect net revenues from our business segments will be enough to defray our costs of doing business. Consequently, we expect to incur significant losses in the future, and those losses could be more severe as a result of unforeseen expenses, difficulties, complications, delays, and other unknown events, including the unpredictable effects of the COVID-19 pandemic.

We will need additional funding to meet our future business needs and we may be unable to raise additional funds in a timely manner or on terms that are acceptable to us. If are not able to obtain sufficient funds, we may have 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.

Item 6. Exhibits

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

10.1	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 - the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL 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.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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: August 6, 2020

/s/ David Seaburg

David Seaburg
Chief Executive Officer
Duly Authorized Officer

Date: August 6, 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: August 6, 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: August 6, 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 June 30, 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: August 6, 2020

/s/ David Seaburg
David Seaburg
Chief Executive Officer

/s/ Jacob Patterson
Jacob Patterson
Interim Chief Financial Officer