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

FORM 10-Q

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

For the quarterly period ended September 30, 2021

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 NASDAQ

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 November 5, 2021, there were 81,932,523 shares of the Registrant's common stock outstanding.

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As used in this report, the terms "we," "us," "our," "the Company," and "PolarityTE" mean PolarityTE, Inc., a Delaware corporation, and our wholly owned Nevada subsidiaries (direct and indirect), PolarityTE, Inc., PolarityTE MD, Inc., Arches Research, Inc., Utah CRO Services, Inc., IBEX Preclinical Research, Inc., and IBEX Property LLC., unless otherwise indicated or required by the context.

POLARITYTE, the PolarityTE Logo, WELCOME TO THE SHIFT, WHERE SELF REGENERATES SELF, COMPLEX SIMPLICITY, IBEX, ARCHES, and SKINTE are all trademarks or registered trademarks of PolarityTE. Solely for convenience, the trademarks and trade names in this report may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that we will not assert, to the fullest extent under applicable law, our rights thereto.

Item 1. Financial Statements:

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

	September 30, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 27,351	$ 25,522
Accounts receivable, net	1,186	3,819
Inventory	–	883
Prepaid expenses and other current assets	2,384	992
Total current assets	30,921	31,216
Property and equipment, net	8,025	10,550
Operating lease right-of-use assets	1,411	2,452
Intangible assets, net	400	542
Goodwill	278	278
Other assets	225	472
TOTAL ASSETS	$ 41,260	$ 45,510
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 3,685	$ 4,148
Other current liabilities	2,053	2,106
Current portion of long-term notes payable	–	2,059
Deferred revenue	255	168
Total current liabilities	5,993	8,481
Common stock warrant liability	7,705	5,975
Operating lease liabilities	226	1,476
Other long-term liabilities	435	723
Long-term notes payable	–	1,517
Total liabilities	14,359	18,172
Commitments and Contingencies (Note 14)		
STOCKHOLDERS' EQUITY		
Preferred stock - 25,000,000 shares authorized, 0 shares issued and outstanding at September 30, 2021 and December 31, 2020	–	–
Common stock – $.001 par value; 250,000,000 shares authorized; 81,563,295 and 54,857,099 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	82	55
Additional paid-in capital	526,649	505,494
Accumulated deficit	(499,830)	(478,211)
Total stockholders' equity	26,901	27,338
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 41,260	$ 45,510

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 September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Net revenues				
Products	$ –	$ 1,156	$ 2,924	$ 2,528
Services	1,116	2,181	5,438	4,008
Total net revenues	1,116	3,337	8,362	6,536
Cost of sales				
Products	–	210	448	825

Services	634	1,142	3,275	1,925
Total cost of sales	634	1,352	3,723	2,750
Gross profit	482	1,985	4,639	3,786
Operating costs and expenses				
Research and development	3,870	2,698	10,491	9,235
General and administrative	3,687	6,264	14,999	22,080
Sales and marketing	93	1,606	2,718	7,324
Restructuring and other charges	242	–	678	2,536
Total operating costs and expenses	7,892	10,568	28,886	41,175
Operating loss	(7,410)	(8,583)	(24,247)	(37,389)
Other income (expenses)				
Gain on extinguishment of debt	–	–	3,612	–
Change in fair value of common stock warrant liability	6,354	1,503	4,134	4,444
Inducement loss on sale of liability classified warrants	–	–	(5,197)	–
Interest expense, net	(29)	(58)	(106)	(135)
Other income, net	64	57	185	282
Net loss	$ (1,021)	$ (7,081)	$ (21,619)	$ (32,798)
Net loss per share attributable to common stockholders				
Basic	$ (0.01)	$ (0.18)	$ (0.27)	$ (0.89)
Diluted	$ (0.01)	$ (0.18)	$ (0.27)	$ (0.89)
Weighted average shares outstanding				
Basic	81,284,678	38,761,141	79,367,407	36,743,864
Diluted	81,754,705	38,761,141	79,419,667	36,743,864

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 September 30,		For the Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Net loss	$ (1,021)	$ (7,081)	$ (21,619)	$ (32,798)
Other comprehensive income/(loss):				
Unrealized gain on available-for-sale securities	–	–	–	11
Reclassification of realized gains included in net loss	–	–	–	(83)
Comprehensive loss	$ (1,021)	$ (7,081)	$ (21,619)	$ (32,870)

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 Nine Months Ended September 30, 2021				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Number	**Amount**	**Capital**	**Deficit**	**Equity**
Balance – December 31, 2020	54,857,099	$ 55	$ 505,494	$ (478,211)	$ 27,338
Issuance of common stock and pre-funded warrants through underwritten offering, net of issuance costs of $114	6,670,000	7	1,248	–	1,255
Issuance of common stock upon exercise of warrants	10,713,543	10	6,661	–	6,671
Reclassification of warrant liability upon exercise	–	–	8,964	–	8,964
Issuance of common stock upon exercise of pre-funded warrants	7,658,953	8	–	–	8
Stock-based compensation expense	–	–	1,651	–	1,651
Stock option exercises	2,500	–	3	–	3
Vesting of restricted stock units	565,427	–	–	–	–
Shares withheld for tax withholding	(116,593)	–	(139)	–	(139)
Forfeiture of restricted stock awards	(34,620)	–	–	–	–
Net loss	–	–	–	(17,410)	(17,410)
Balance – March 31, 2021	80,316,309	$ 80	$ 523,882	$ (495,621)	$ 28,341
Stock-based compensation expense	–	–	1,640	–	1,640
Purchase of ESPP shares	49,248	–	28	–	28
Vesting of restricted stock units	434,144	1	(1)	–	–
Shares withheld for tax withholding	(57,258)	–	(53)	–	(53)
Net loss	–	–	–	(3,188)	(3,188)
Balance – June 30, 2021	80,742,443	$ 81	$ 525,496	$ (498,809)	$ 26,768
Stock-based compensation expense	–	–	1,317	–	1,317
Vesting of restricted stock units	1,025,865	1	(1)	–	–
Shares withheld for tax withholding	(205,013)	–	(163)		(163)
Net loss	–	–	–	(1,021)	(1,021)
Balance – September 30, 2021	81,563,295	$ 82	$ 526,649	$ (499,830)	$ 26,901

	For the Three and Nine Months Ended September 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 $1,319	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)
Cancellation 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
Stock-based compensation expense	–	–	2,179	–	–	2,179
Stock option exercises	208	–	–	–	–	–
Vesting of restricted stock units	485,614	1	(1)	–	–	–
Shares withheld for tax withholding	(70,727)	–	(105)	–	–	(105)
Net loss	–	–	–	–	(7,081)	(7,081)
Balance – September 30, 2020	38,912,005	$ 39	$ 492,676	$ –	$ (468,155)	$ 24,560

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 Nine Months Ended September 30,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (21,619)	$ (32,798)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	4,389	5,963
Depreciation and amortization	2,083	2,337
Amortization of intangible assets	142	142
Amortization of debt discount	–	17
Bad debt expense	99	–
Inventory write-off	747	–
Gain on extinguishment of debt – PPP loan	(3,612)	–
Change in fair value of common stock warrant liability	(4,134)	(4,444)
Inducement loss on sale of liability classified warrants	5,197	–
Loss on restructuring and other charges	321	–
Loss on abandonment and disposal of property and equipment	–	1,566
Loss on sale of property and equipment	7	–
Other non-cash adjustments	–	(21)
Changes in operating assets and liabilities:		
Accounts receivable	2,534	(1,648)
Inventory	136	(655)
Prepaid expenses and other current assets	(1,392)	(332)
Operating lease right-of-use assets	1,011	1,348
Other assets	247	130
Accounts payable and accrued expenses	(456)	(2,349)
Other current liabilities	(29)	–
Deferred revenue	87	(73)
Operating lease liabilities	(1,082)	(1,353)
Net cash used in operating activities	(15,324)	(32,170)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(18)	(1,225)
Proceeds from sale of property and equipment	23	–
Purchase of available-for-sale securities	–	(14,144)
Proceeds from maturities of available-for-sale securities	–	16,945
Proceeds from sale of available-for-sale securities	–	16,171
Net cash provided by investing activities	5	17,747
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from term note payable and financing arrangements	1,028	4,630
Principal payments on term note payable and financing arrangements	(708)	(1,096)
Principal payments on financing leases	(413)	(376)
Net proceeds from the sale of common stock, warrants and pre-funded warrants	9,884	24,276

Proceeds from the sale of new warrants		1,002		–
Proceeds from warrants exercised		6,671		–
Proceeds from pre-funded warrants exercised		8		–
Cash paid for tax withholdings related to net share settlement		(355)		(114)
Proceeds from stock options exercised		3		31
Proceeds from ESPP purchase		28		40
Net cash provided by financing activities		17,148		27,391
Net increase in cash and cash equivalents		1,829		12,968
Cash and cash equivalents - beginning of period		25,522		10,218
Cash and cash equivalents - end of period	$	27,351	$	23,186
Supplemental cash flow information:				
Cash paid for interest	$	96	$	139
Supplemental schedule of non-cash investing and financing activities:				
Fair value of placement agent warrants issued in connection with offering	$	838	$	–
Reclassification of warrant liability to stockholders' equity upon exercise of warrant	$	8,964	$	–
Unpaid tax liability related to net share settlement	$	–	$	5
Unpaid liability for acquisition of property and equipment	$	–	$	10
Accrued offering costs	$	400	$	–
Allocation of proceeds to warrant liability	$	8,629	$	11,677

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

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

1. PRINCIPAL BUSINESS ACTIVITY AND BASIS OF PRESENTATION

PolarityTE, Inc. (together with its subsidiaries, the "Company") is a clinical stage biotechnology company developing regenerative tissue products and biomaterials. The Company also operates a laboratory testing and clinical research business using equipment, personnel, and facilities it acquired to advance the development of regenerative tissue products.

The Company's first regenerative tissue product is SkinTE. In July 2021, the Company submitted an investigational new drug application ("IND") for SkinTE to the United States Food and Drug Administration (the "FDA") through its subsidiary, PolarityTE MD, Inc. Prior to June 1, 2021, the Company sold SkinTE under Section 361 of the Public Health Service Act in 2020 and into 2021 and, after the Company's decision to file an IND under Section 351 of that Act, under an enforcement discretion position stated by the FDA in a regenerative medicine policy framework to help facilitate regenerative medicine therapies. The FDA's stated period of enforcement discretion ended May 31, 2021. Consequently, the Company terminated commercial sales of SkinTE on May 31, 2021, and ceased its SkinTE commercial operations, and has transitioned to a clinical stage company pursuing an IND for SkinTE. As a result, there are no revenues from commercial SkinTE sales after June 2021, and the Company has eliminated or reduced costs associated with commercial sale of SkinTE.

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 periods presented. 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, 2020, has been derived from the audited consolidated 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, 2020, filed with the Securities and Exchange Commission on Form 10-K on March 30, 2021.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

Use of estimates. The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities or the disclosure of gain or loss contingencies at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Among the more significant estimates included in these financial statements is the extent of progress toward completion of contracts, stock-based compensation, the valuation of common stock warrant liabilities, and the impairment of property and equipment. 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. As of September 30, 2021, the Company did not hold any cash equivalents.

Inventory. Inventory comprises raw materials, which are valued at the lower of cost or net realizable value, on a first-in, first-out basis. The Company evaluates the carrying value of its inventory on a regular basis, taking into account anticipated future sales compared with quantities on hand, and the remaining shelf life of goods on hand to record an inventory reserve. The Company recorded inventory charges of $0.7 million for the nine months ended September 30, 2021, of which $0.3 million and $0.4 million were recorded in research and development and cost of sales, respectively, within the accompanying consolidated statement of operations. No inventory reserve was recorded as of September 30, 2021, or December 31, 2020.

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 current 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. Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration that 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 recorded product revenues primarily from the sale of SkinTE, its regenerative tissue product. When the Company marketed its SkinTE product, it was sold to healthcare providers (customers), primarily through direct sales representatives. Product revenues consisted of a single performance obligation that the Company satisfies at a point in time. In general, the Company recognized product revenue upon delivery to the customer.

In the contract services segment, the Company records service revenues from the sale of its preclinical research services, which includes delivery of preclinical studies and other research services to unrelated third parties. Service revenues generally consist of a single performance obligation that the Company satisfies over time using an input method based on costs incurred to date relative to the total costs expected to be required to satisfy the performance obligation. The Company believes that this method provides an appropriate measure of the transfer of services over the term of the performance obligation based on the remaining services needed to satisfy the obligation. This requires the Company to make reasonable estimates of the extent of progress toward completion of the contract. As a result, unbilled receivables and deferred revenue are recognized based on payment timing and work completed. Generally, a portion of the payment is due upfront and the remainder upon completion of the contract, with most contracts completing in less than a year. 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. As of September 30, 2021, and December 31, 2020, the Company had unbilled receivables of $0.5 million and $0.2 million, respectively, and deferred revenue of $0.3 million and $0.2 million, respectively. The unbilled receivables balance is included in consolidated accounts receivable. Revenue of $0.2 million was recognized during the nine months ended September 30, 2021, that was included in the deferred revenue balance as of December 31, 2020.

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 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 agreements. Under certain change of control provisions, some warrants issued by the Company could require cash settlement which necessitates such 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 commensurate with the expected term of the option. 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 to compensation expense over the vesting period of, generally, six months to three years.

Net Loss Per Share. Basic net 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. Gains on warrant liabilities are only considered dilutive when the average market price of the common stock during the period exceeds the exercise price of the warrants. All common stock warrants issued participate on a one-for-one basis with common stock in the distribution of dividends, if and when declared by the Board of Directors, on the Company's common stock. For purposes of computing earnings per share (EPS), these warrants are considered to participate with common stock in earnings of the Company. Therefore, the Company calculates basic and diluted EPS using the two-class method. Under the two-class method, net income for the period is allocated between common stockholders and participating securities according to dividends declared and participation rights in undistributed earnings. No income was allocated to the warrants for the three and nine months ended September 30, 2021 as results of operations were a loss for each period and the warrant holders are not required to absorb losses. The Company has issued pre-funded warrants from time to time at an exercise price of $0.001 per share. The shares of common stock into which the pre-funded warrants may be exercised are considered outstanding for the purposes of computing earnings per share because the shares may be issued for little or no consideration, are fully vested, and are exercisable after the original issuance date.

Impairment of Long-Lived Assets. The Company reviews long-lived assets, including property and equipment, and intangible assets 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.

Goodwill. Under accounting guidelines, goodwill is not amortized, but must be tested for impairment annually, or more frequently if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit below the carrying amount. The Company reviews goodwill for impairment annually and whenever events or changes indicate that the carrying value of an asset may not be recoverable. These events or circumstances could include a significant change in the business climate, legal factors, operating performance indicators, competition, or sale or disposition of significant assets or products. Application of these impairment tests requires significant judgment. There were no goodwill impairments recorded during the nine months ended September 30, 2021 and 2020.

Offering Costs. The Company capitalizes direct and incremental costs (i.e., consisting of legal, accounting, and other fees and costs) associated with equity financings until such financings are consummated, at which time such costs are recorded in additional paid-in capital against the gross proceeds of the equity financings. If the related equity financing is abandoned, the previously deferred offering costs will be charged to expense in the period in which the offering is abandoned.

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.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* (ASU 2020-06). ASU 2020-06 simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. Those instruments that do not have a separately recognized embedded conversion feature will no longer recognize a debt issuance discount related to such a conversion feature and would recognize less interest expense on a periodic basis. It also removes from ASC 815-40-25-10 certain conditions for equity classification and amends certain guidance in ASC Topic 260 on the computation of EPS for convertible instruments and contracts in an entity's own equity. An entity can use either a full or modified retrospective approach to adopt the ASU's guidance. As a smaller reporting company, the Company is required to adopt this ASU for the fiscal year beginning January 1, 2024, with early adoption permitted for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company is currently assessing the impact and timing of adoption of this ASU.

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt— Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging— Contracts in Entity's Own Equity (Subtopic 815-40)* (ASU 2021-04). ASU 2021-04 updates current accounting guidance for modifications or exchanges of freestanding equity-classified written call options that remain equity-classified after modification or exchange as an exchange of the original instrument for a new instrument. The ASU specifies that the effects of modifications or exchanges of freestanding equity-classified written call options that remain equity after modification or exchange should be recognized depending on the substance of the transaction, whether it be a financing transaction to raise equity (topic 340), to raise or modify debt (topic 470 and 835), or other modifications or exchanges. If the modification or exchange does not fall under topics 340, 470, or 835, an entity may be required to account for the effects of such modifications or exchanges as dividends which should adjust net income (or loss) in the basic EPS calculation. The Company is required to apply the amendments within this ASU prospectively to modifications or exchanges occurring on or after the effective date of the amendment. The Company plans to adopt this ASU on January 1, 2022. The Company does not expect the adoption of the new guidance to have a significant impact on its consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncements

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes by removing certain exceptions to the current guidance, and improving the consistent application of and simplification of other areas of the guidance. The Company adopted this standard prospectively on January 1, 2021. The adoption of this ASU did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

3. LIQUIDITY AND NEED FOR ADDITIONAL CAPITAL

The Company has experienced recurring losses and cash outflows from operating activities. As of September 30, 2021, the Company had an accumulated deficit of $499.8 million. As of September 30, 2021, the Company had cash and cash equivalents of $27.4 million. The Company has been funded historically through sales of equity and debt.

On January 14, 2021, the Company completed a registered direct offering of 6,670,000 shares of its common stock, par value $0.001 per share, pre-funded warrants to purchase up to 2,420,910 shares of common stock and accompanying common warrants to purchase up to 9,090,910 shares of common stock. Each share of common stock and pre-funded warrant were sold together with a common warrant. The combined offering price of each common share and accompanying common warrant was $1.100 and for each pre-funded warrant and accompanying common warrant was $1.099. The pre-funded warrants had an exercise price of $0.001 each and were exercised in full in January 2021. Each common warrant is exercisable for one share of the Company's common stock at an exercise price of $ 1.20 per share. The warrants are immediately exercisable and will expire five years from the date of issuance. The holder of the warrants may not exercise any portion of the warrants to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, which percentage may be changed at the holder's election to a lower percentage at any time or to a higher percentage not to exceed 9.99% upon 61 days' notice to the Company. The Company also issued to designees of the placement agent for the registered direct offering, warrants to purchase up to 6.0% of the aggregate number of common stock shares and pre-funded warrants sold in the offering (or warrants to purchase up to 545,455 shares of common stock). The placement agent warrants have substantially the same terms as the common warrants, except that the placement agent warrants have an exercise price equal to 125% of the purchase price per share (or $1.375 per share). The Company received net proceeds of $9.2 million in connection with the offering, after deducting placement agent fees and related offering expenses.

On January 22, 2021, the Company entered into a letter agreement with the holder of warrants to purchase 10,688,043 shares of common stock at an exercise price of $0.624 per share that were issued to the holder in the registered direct offering that closed on December 23, 2020. Under the letter agreement the holder agreed to exercise the 10,688,043 warrants in full and the Company agreed to issue and sell to the holder new common warrants to purchase up to 8,016,033 shares of the Company's common stock, par value $0.001 per share, at a price of $0.125. Each new warrant is exercisable for one share of common stock at an exercise price of $1.20 per share. The new warrants are immediately exercisable and will expire five years from the date of issuance. The holder of the warrants may not exercise any portion of the warrants to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, which percentage may be changed at the holder's election to a lower percentage at any time or to a higher percentage not to exceed 9.99% upon 61 days' notice to the Company. The Company also issued to designees of the placement agent for the registered direct offering in December 2020, warrants to purchase 6.0% of the aggregate number of new warrants issued under the letter agreement (or warrants to purchase up to 480,962 shares of common stock). The placement agent warrants have substantially the same terms as the new warrants. The Company received net proceeds of $6.7 million from the exercise of the existing warrants and $0.9 million from the sale of the newly issued warrants, after deducting placement agent fees and related offering

expenses. The offering closed on January 25, 2021.

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's significant operating losses raise substantial doubt regarding the Company's ability to continue as a going concern for at least one year from the date of issuance of these condensed consolidated financial statements. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might result from the outcome of this uncertainty. The Company is a clinical stage biotechnology company that has historically incurred losses and negative cash flows. Consequently, the future success of the Company depends on its ability to attract additional capital and, ultimately, on its ability to successfully complete the regulatory approval process for its product, SkinTE, and develop future profitable operations. 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.

4. FAIR VALUE

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

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

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

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

	September 30, 2021			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Common stock warrant liability	$ –	$ –	$ 7,705	$ 7,705
Total	$ –	$ –	$ 7,705	$ 7,705

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Common stock warrant liability	$ –	$ –	$ 5,975	$ 5,975
Total	$ –	$ –	$ 5,975	$ 5,975

The following table presents the change in fair value of the liability classified common stock warrants for the nine months ended September 30, 2021 (in thousands):

	Fair Value at December 31, 2020	Initial Fair Value at Issuance	(Gain) Loss Upon Change in Fair Value	Liability Reduction Due to Exercises	Fair Value on September 30, 2021
Warrant liabilities					
February 14, 2020 issuance	$ 328	$ –	$ (6)	$ –	$ 322
December 23, 2020 issuance	5,647	–	3,585	(8,964)	268
January 14, 2021 issuance	–	8,629	(4,858)	–	3,771
January 25, 2021 issuance	–	6,199	(2,855)	–	3,344
Inducement loss on initial fair value [(1)]	–	–	5,197	–	–
Total	$ 5,975	$ 14,828	$ 1,063	$ (8,964)	$ 7,705

(1) Concurrent with the issuance of the January 25, 2021 warrants, upon the exercise of the December 23, 2020 warrants, an inducement loss of $5.2 million was recorded as the fair value of the initial warrant liability for the new warrants of $6.2 million exceeded the gross proceeds received upon sale of the new warrants of approximately $1.0 million

The following table presents the change in fair value of the liability classified common stock warrants for the nine months ended September 30, 2020 (in thousands):

	Fair Value at December 31, 2019	Initial Fair Value at Issuance	(Gain) Loss Upon Change in Fair Value	Liability Reduction Due to Exercises	Fair Value on September 30, 2020
Warrant liabilities					
February 14, 2020 issuance	$ –	$ 11,677	$ (4,444)	$ –	$ 7,233

The Company uses the Monte Carlo simulation model to determine the fair value of the liability classified warrants. Input assumptions used to measure the fair value of these freestanding instruments during the nine months ended September 30, 2021, are as follows:

	For the Nine Months ended September 30, 2021
Stock price	$ 0.65 – 1.21
Exercise price	$ 0.10 – 1.38
Risk-free rate	0.42 – 1.13%

Volatility	99.0 – 102.8%
Remaining term (years)	4.23 – 5.87

Input assumptions used to measure the fair value of these freestanding instruments during the nine months ended September 30, 2020, are as follows:

	For the Nine Months ended September 30, 2020
Stock price	$ 1.04 – 1.69
Exercise price	$ 2.80
Risk-free rate	0.41 – 1.51%
Volatility	93.4 – 99.6%
Remaining term (years)	6.37 – 6.99

5. PROPERTY AND EQUIPMENT, NET

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

	September 30, 2021	December 31, 2020
Machinery and equipment	$ 11,113	$ 12,232
Land and buildings	2,000	2,000
Computers and software	1,129	1,240
Leasehold improvements	2,107	2,107
Construction in progress	6	87
Furniture and equipment	144	148
Total property and equipment, gross	16,499	17,814
Accumulated depreciation and amortization	(8,474)	(7,264)
Total property and equipment, net	$ 8,025	$ 10,550

The Company sold SkinTE under Section 361 of the Public Health Service Act in 2020 and into 2021 and, after the Company's decision to file an IND under Section 351 of that Act, under an enforcement discretion position stated by the FDA in a regenerative medicine policy framework to help facilitate regenerative medicine therapies. The FDA's stated period of enforcement discretion ended May 31, 2021. Consequently, the Company terminated commercial sales of SkinTE on May 31, 2021, and ceased its SkinTE commercial operations. As a result, there are no revenues from commercial SkinTE sales after June 1, 2021, and the Company has eliminated or reduced costs associated with commercial sale of SkinTE. At March 31, 2021, approximately $3.0 million of total property and equipment was related to commercial SkinTE operations, of which approximately $2.5 million was repurposed by the Company primarily as research and development equipment. The Company evaluated the future use of its commercial property and equipment and recorded an impairment charge of approximately $0.4 million during the first quarter of 2021. The impairment charges occurred within the Company's regenerative medicine business segment and are included in restructuring and other charges within the accompanying consolidated statement of operations for the nine months ended September 30, 2021. There was no impairment charge recorded during the third quarter of 2021. 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 September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
General and administrative expense	$ 71	$ 402	$ 667	$ 1,202
Research and development expense	575	386	1,416	1,135
Total depreciation and amortization expense	$ 646	$ 788	$ 2,083	$ 2,337

6. LEASES

The Company leases facilities and certain equipment under noncancelable leases that expire at various dates through June 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.

Operating Leases

On December 27, 2017, the Company entered into a commercial lease agreement with Adcomp LLC, a Utah limited liability company, pursuant to which the Company leased approximately 178,528 rentable square feet of warehouse, manufacturing, office, and lab space in Salt Lake City, Utah from the landlord. The initial term of the lease is five years, and it expires on November 30, 2022. The Company has a one-time option to renew for an additional five years.The initial base rent under this lease is $98,190 per month ($0.55 per sq. ft.) for the first year of the initial lease term and increases 3.0% per annum thereafter. Because the rate implicit in the lease is not readily determinable, the Company has used an incremental borrowing rate of 10% to determine the present value of the lease payments.

In April 2019, the Company entered into an operating lease to obtain6,307 square feet of manufacturing, laboratory, and office space. The original term of the lease expired in April 2024 and required monthly lease payments subject to annual increases. During the third quarter of 2020, the Company initiated a business analysis to determine the long-term strategy of the remote facility and cost to remain operational. During the fourth quarter of fiscal year 2020, it was determined that the Company would cease operations and vacate the facility. As a result, the Company determined that the approved plan to vacate the lease represented a triggering event requiring the long-lived assets attributable to the disposal group be assessed for impairment. Given the facts and circumstances, the Company determined that the carrying value of the related assets of the disposal group were not recoverable. As a result, the carrying values were reduced to $0 as of December 31, 2020. During the second quarter of 2021, the Company terminated the lease effective June 30, 2021. The Company recorded a net gain on termination of $0.3 million which was included in restructuring and other charges on the condensed consolidated statement of operations.

Financing Leases

In November 2018 and April 2019, the Company entered into financing leases primarily for laboratory equipment used in research and development activities. The financing leases have remaining terms that range from 6 to 31 months as of September 30, 2021, and include options to purchase equipment at the end of the lease. Because the rate implicit in the lease is not readily determinable, the Company has used an incremental borrowing rate of approximately 10% to determine the present value of the lease payments for these leases.

As of September 30, 2021, the maturities of operating and finance lease liabilities were as follows (in thousands):

	Operating leases	Finance leases
2021 (excluding the nine months ended September 30, 2021)	$ 350	$ 164
2022	1,219	405
2023	3	336
2024	2	42
Total lease payments	1,574	947
Less:		
Imputed interest	(82)	(93)
Total	$ 1,492	$ 854

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

Finance leases

	September 30, 2021	December 31, 2020
Finance lease right-of-use assets included within property and equipment, net	$ 798	$ 1,301
Current finance lease liabilities included within other current liabilities	$ 420	$ 556
Non-current finance lease liabilities included within other long-term liabilities	434	711
Total finance lease liabilities	$ 854	$ 1,267

Operating leases

	September 30, 2021	December 31, 2020
Current operating lease liabilities included within other current liabilities	$ 1,266	$ 1,485
Operating lease liabilities – non current	226	1,476
Total operating lease liabilities	$ 1,492	$ 2,961

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating lease costs included within operating costs and expenses	$ 385	$ 531	$ 1,172	$ 1,635
Finance lease costs:				
Amortization of right-of-use assets	$ 163	$ 175	$ 491	$ 524
Interest on lease liabilities	24	36	80	118
Total	$ 187	$ 211	$ 571	$ 642

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

	For the Nine Months Ended September 30,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash out flows from operating leases	$ 1,243	$ 1,640
Operating cash out flows from finance leases	$ 80	$ 118
Financing cash out flows from finance leases	$ 413	$ 376
Lease liabilities arising from obtaining right-of-use assets:		
Remeasurement of operating lease liability due to lease modification/termination	$ 386	$ 131

As of September 30, 2021, and December 31, 2020, the weighted average remaining lease term for operating leases was1.2 and 2.1 years, respectively, and the weighted average discount rate used for operating leases was 10.01% and 9.75%, respectively. As of September 30, 2021, and December 31, 2020, the weighted average remaining lease term for finance leases was 2.1 and 2.6 years, respectively, and the weighted average discount rate used for finance leases was9.78% for both periods.

7. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

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

	September 30, 2021	December 31, 2020
Accounts payable	$ 457	$ 1,193
Salaries and other compensation	1,113	1,129
Legal and accounting	159	241
Accrued severance	64	330
Benefit plan accrual	565	659
Clinical trials	140	–
Accrued offering costs	400	–
Other	787	596
Total accounts payable and accrued expenses	$ 3,685	$ 4,148

8. OTHER CURRENT LIABILITIES

The following table presents the major components of other current liabilities (in thousands):

	September 30, 2021	December 31, 2020
Current finance lease liabilities	$ 420	$ 556
Current operating lease liabilities	1,266	1,485
Short-term financing arrangement	363	20
Other	4	45
Total other current liabilities	$ 2,053	$ 2,106

The short-term financing balance is related to a financing arrangement entered into during the nine months ended September 30, 2021 to fund an insurance contract. Under the financing arrangement, the amounts will be repaid in nine equal monthly installments, with an interest rate of 3.85%.

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 7,191,917 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. The 2020 Plan provides that effective on January 1 of each year the number of shares of common stock reserved and available for issuance under the 2020 Plan shall be cumulatively increased by the lesser of 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31 or such lesser number of shares as determined by the 2020 plan administrator. As of September 30, 2021, the Company had 1,265,210 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 September 30, 2021, the Company had 49,097 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 September 30, 2021, the Company had 211,134 shares available for future issuances under the 2017 Plan.

A summary of the Company's employee and non-employee stock option activity for the nine months ended September 30, 2021, is presented below:

	Number of Shares	Weighted-Average Exercise Price
Outstanding – December 31, 2020	4,794,567	$ 10.03
Granted	1,412,731	$ 1.29
Exercised (1)	(2,500)	$ 1.10
Forfeited	(306,067)	$ 11.19
Outstanding – September 30, 2021	5,898,731	$ 7.88
Options exercisable, September 30, 2021	4,613,866	$ 9.68

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

Employee Stock Purchase Plan (ESPP)

In May 2018, the Company adopted the Employee Stock Purchase Plan ("ESPP"). The Company has initially 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, 2020	3,468,969
Granted	3,903,044
Vested (1)	(2,375,905)
Forfeited	(364,510)
Unvested – September 30, 2021	4,631,598

(1) The number of vested restricted stock units and awards 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 September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
General and administrative expense	$ 911	$ 1,655	$ 3,245	$ 4,875
Research and development expense	354	388	950	755
Sales and marketing expense	–	136	194	333
Restructuring and other charges	52	–	219	–
Total stock-based compensation expense	$ 1,317	$ 2,179	$ 4,608	$ 5,963

10. SALE OF COMMON STOCK, WARRANTS AND PRE-FUNDED WARRANTS

On January 14, 2021, the Company completed a registered direct offering of6,670,000 shares of its common stock, par value $0.001 per share, pre-funded warrants to purchase up to 2,420,910 shares of common stock and accompanying common warrants to purchase up to9,090,910 shares of common stock. Each share of common stock and pre-funded warrant was sold together with a warrant. The combined offering price of each common stock share and accompanying warrant was $1.10 and for each pre-funded warrant and accompanying warrant was $1.099. The pre-funded warrants had an exercise price of $0.001 each and were exercised in full in January 2021. Each warrant is exercisable for one share of the Company's common stock at an exercise price of $1.20 per share. The warrants are immediately exercisable and will expirefive years from the date of issuance. The holder of the warrants may not exercise any portion of the warrants to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, which percentage may be changed at the holder's election to a lower percentage at any time or to a higher percentage not to exceed 9.99% upon 61 days' notice to the Company. The Company also issued to designees of the placement agent warrants to purchase 6.0% of the aggregate number of common stock shares and pre-funded warrants sold in the offering (or warrants to purchase up to 545,455 shares of common stock). The placement agent warrants have substantially the same terms as the warrants, except that the placement agent warrants have an exercise price equal to 125% of the purchase price per share (or $1.375 per share). The net proceeds to the Company from the offering were $9.2 million, after direct offering expenses of $0.8 million payable by the Company.

As the common stock warrants and placement agent common stock warrants could each require cash settlement in certain scenarios, the common stock warrants and placement agent common stock warrants were classified as liabilities upon issuance and were initially recorded at estimated fair values of $8.1 million and $0.5 million, respectively. Since the pre-funded warrants did not contain the same cash settlement provision, these warrants were classified as a component of stockholders' equity within additional paid-in-capital. The pre-funded warrants were equity classified because they met characteristics of the equity classification criteria. The total proceeds from the offering were first allocated to the liability classified warrants, based on their estimated fair values, with the residual $1.4 million allocated to the common stock and pre-funded common stock warrants in equity. Issuance costs allocated to the equity classified pre-funded common stock warrants and common stock of $0.1 million were recorded as a reduction to additional paid-in capital. Issuance costs allocated to the liability classified warrants of $0.7 million were recorded as an expense. The Company measured the fair value of the accompanying common warrants and placement agent warrants using the Monte Carlo simulation model at issuance and again at September 30, 2021, using the following inputs:

Accompanying common warrants:

	January 14, 2021	September 30, 2021
Stock price	$ 1.21	$ 0.65
Exercise price	$ 1.20	$ 1.20
Risk-free rate	0.49%	0.82%
Volatility	100.1%	99.7%
Remaining term (years)	5.0	4.3

Placement agent warrants:

	January 14, 2021	September 30, 2021
Stock price	$ 1.21	$ 0.65
Exercise price	$ 1.38	$ 1.38
Risk-free rate	0.49%	0.82%
Volatility	99.3%	99.7%
Remaining term (years)	5.0	4.3

On January 22, 2021, the Company entered into a letter agreement with the holder of warrants to purchase10,688,043 shares of common stock at an exercise price of $0.624 per share that were issued to the holder in the registered direct offering that closed on December 23, 2020. Under the letter agreement the holder agreed to exercise the 10,688,043 warrants in full and the Company agreed to issue and sell to the holder common warrants to purchase up to8,016,033 shares of the Company's common stock, par value $0.001 per share, at a price of $0.125. Each warrant is exercisable for one share of Common Stock at an exercise price of $1.20 per share. The warrants are immediately exercisable and will expire five years from the date of issuance. A holder may not exercise any portion of the warrants to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, which percentage may be changed at the holder's election to a lower percentage at any time or to a higher percentage not to exceed 9.99% upon 61 days' notice to the Company. The Company also issued to designees of the placement agent, warrants to purchase 6.0% of the

aggregate number of common stock shares and pre-funded warrants sold in the offering (or warrants to purchase up to 480,962 shares of common stock). The placement agent warrants have substantially the same terms as the new warrants. The 10,688,043 warrants issued on December 23, 2020, were exercised on January 22, 2021, and closing of the offering occurred on January 25, 2021. The Company received gross proceeds of approximately $6.7 million from the exercise of the existing warrants and gross proceeds of approximately $1.0 million from the sale of the new warrants.

Immediately prior to the exercise of the existing 10,688,043 liability classified common stock warrants, a remeasurement loss of $3.6 million was recorded. The Company measured the fair value of the common stock warrants using the Monte Carlo simulation model on January 22, 2021, using the following inputs:

	January 22, 2021
Stock price	$ 1.05
Exercise price	$ 0.62
Risk-free rate	0.43%
Volatility	99.4%
Remaining term (years)	4.9

As the new common stock warrants and placement agent common stock warrants could each require cash settlement in certain scenarios, the new common stock warrants and placement agent common stock warrants were classified as liabilities upon issuance and were initially recorded at estimated fair values of $5.8 million and $0.4 million, respectively. Cash issuance costs of $0.1 million were recorded as an expense. The Company measured the fair value of the accompanying common stock warrants and placement agent common stock warrants using the Monte Carlo simulation model at issuance and again at September 30, 2021, using the following inputs:

Accompanying new common stock warrants:

	January 25, 2021	September 30, 2021
Stock price	$ 1.02	$ 0.65
Exercise price	$ 1.20	$ 1.20
Risk-free rate	0.42%	0.83%
Volatility	99.0%	99.7%
Remaining term (years)	5.0	4.3

Placement agent warrants:

	January 22, 2021	September 30, 2021
Stock price	$ 1.05	$ 0.65
Exercise price	$ 1.20	$ 1.20
Risk-free rate	0.44%	0.83%
Volatility	99.6%	99.7%
Remaining term (years)	5.0	4.3

The following table summarizes warrant activity for the nine months ended September 30, 2021.

	Outstanding and exercisable December 31, 2020	Warrants Issued	Warrants Exercised	Outstanding and exercisable September 30, 2021
Transaction				
February 14, 2020 common warrants	565,000	–	(25,500)	539,500
December 23, 2020 common warrants	10,688,043	–	(10,688,043)	–
December 23, 2020 placement agent warrants	641,283	–	–	641,283
December 23, 2020 pre-funded warrants	5,238,043	–	(5,238,043)	–
January 14, 2021 common warrants	–	9,090,910	–	9,090,910
January 14, 2021 placement agent warrants	–	545,455	–	545,455
January 14, 2021 pre-funded warrants	–	2,420,910	(2,420,910)	–
January 25, 2021 common warrants	–	8,016,033	–	8,016,033
January 22, 2021 placement agent warrants	–	480,962	–	480,962
Total	17,132,369	20,554,270	(18,372,496)	19,314,143

On March 30, 2021, the Company entered into a sales agreement with Cantor Fitzgerald & Co. to sell shares of common stock having aggregate sales proceeds of up to $50.0 million, from time to time, through an “at the market” equity offering program under which Cantor Fitzgerald & Co. will act as sales agent. As of September 30, 2021, no common stock had been sold.

Pursuant to an Equity Purchase Agreement dated as of December 5, 2019 (the “Purchase Agreement”) that the Company entered into with Keystone Capital Partners, LLC (“Keystone”), Keystone agreed to purchase up to $25.0 million of shares of our common stock, subject to certain limitations, at our direction from time to time during the 36-month term of the Purchase Agreement. In anticipation of the “at the market” equity offering program described above, the Company provided notice to Keystone of its decision to terminate the Purchase Agreement, which was effective on March 26, 2021.

11. NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

The following tables present reconciliations for the numerators and denominators of basic and diluted net loss per share:

	For the Three Months Ended		For the Nine Months Ended	
Numerator:	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
Net loss	$ (1,021)	$ (7,081)	$ (21,619)	$ (32,798)
Less: Gain from change in fair value of warrant liabilities	(174)	–	(27)	–
Net loss available to common stockholders	$ (1,195)	$ (7,081)	$ (21,646)	$ (32,798)

Denominator:	For the Three Months Ended September 30, 2021	For the Three Months Ended September 30, 2020	For the Nine Months Ended September 30, 2021	For the Nine Months Ended September 30, 2020
Basic weighted average number of common shares (1)	81,284,678	38,761,141	79,367,407	36,743,864
Incremental shares from assumed exercise of warrants	470,027	–	52,260	–
Diluted weighted average number of common shares	81,754,705	38,761,141	79,419,667	36,743,864

(1) In December 2020 and January 2021, the Company sold pre-funded warrants to purchase up to 5,238,043 and 2,420,910 shares of common stock, respectively. The shares of common stock associated with the pre-funded warrants are considered outstanding for the purposes of computing earnings per share prior to exercise because the shares may be issued for little or no consideration, are fully vested, and are exercisable after the original issuance date. The pre-funded warrants sold in December 2020 and January 2021 were exercised during the period and included in the denominator for the period of time the warrants were outstanding.

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:

	For the Three Months Ended September 30, 2021	For the Three Months Ended September 30, 2020	For the Nine Months Ended September 30, 2021	For the Nine Months Ended September 30, 2020
Stock Options	5,898,731	5,038,914	5,898,731	5,038,914
Restricted stock	4,631,598	3,874,945	4,631,598	3,874,945
Common stock warrants	18,774,643	10,638,298	18,672,860	10,638,298
Shares committed under ESPP	27,197	–	27,197	–

12. DEBT

PPP Loan

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. On October 15, 2020, the Borrower applied to the Lender for forgiveness of the PPP loan in its entirety based on the Borrower's use of the PPP loan for payroll costs, rent, and utilities. In June of 2021, the Company received notice of forgiveness of the PPP loan in whole and the Lender was paid by the SBA, including all accrued unpaid interest. The Company recorded the forgiveness of $3.6 million of principal and accrued interest, which were included in gain on extinguishment of debt on the condensed consolidated statement of operations for the nine months ended September 30, 2021.

On September 17, 2021, the Company received notice from the Lender that the SBA is continuing to review the PPP Loan. As part of this review, the SBA requested documents that the Company is required to maintain but may not have been required to submit with its application for the PPP Loan. These documents included an affiliation worksheet showing the relationship between the Company and PTE-MD and affiliated subsidiaries, documents showing the use of the PPP Loan proceeds, documents showing the calculation of the loan amount requested in the Company's loan application, federal tax returns, and documents showing employee compensation information. The Company submitted the documents to the SBA through the Lender on September 28, 2021.

13. RESTRUCTURING AND OTHER CHARGES

As discussed in Note 5, the Company decided to file an IND in the second half of 2021, cease commercial sales of SkinTE by May 31, 2021, and wind down its SkinTE commercial operations. As a result, management approved several actions as part of a restructuring plan. Costs associated with the restructuring plan were included in restructuring and other charges on the condensed consolidated statement of operations.

The Company evaluated the future use of its commercial property and equipment and recorded an impairment charge of approximately $0.4 million for the three months ended March 31, 2021. No property and equipment impairment charges were recorded during the three months ended June 30, 2021 or the three months ended September 30, 2021. The Company recognized $0.2 million and $0.4 million of expense related to employee severance and benefit arrangements for the three and nine month periods ended September 30, 2021. Remaining severance costs will be paid by the end of the fourth quarter of 2021. The Company also recognized incremental expense of $0.2 million for the nine month period ended September 30, 2021 related to the remeasurement of employee stock options that were modified due to restructuring. Lastly, during the second quarter of 2021 and effective June 30, 2021, the Company terminated a lease which included manufacturing, laboratory, and office space. The Company recorded a net gain on termination of $0.3 million which was included in restructuring and other charges on the condensed consolidated statement of operations during the second quarter of 2021.

14. COMMITMENTS AND CONTINGENCIES

Commitments

On September 2, 2020, Arches Research, Inc., a subsidiary of PolarityTE, Inc. ("Arches") entered into two agreements with Co-Diagnostics, Inc. ("Co-Diagnostics"). The COVID-19 Laboratory Services Agreement between the parties provided that Arches would perform specimen testing services for customers referred by Co-Diagnostics to Arches. Co-Diagnostics would arrange all logistics for delivering specimens to Arches for COVID-19 testing for those customers of Co-Diagnostics electing to use the service. Arches would bill Co-Diagnostics for the testing services and Co-Diagnostics would manage all customer billing. The Rental Agreement for LGC Genomics Oktopure Extraction Machine between Arches and Co-Diagnostics provided that Co-Diagnostics would make available to Arches the Oktopure high throughput extraction machine that Arches will use to perform COVID-19 testing. The term of the rental agreement was 12 months and required Arches to use Co-Diagnostics tests exclusively in the machine. In the second quarter of 2021, the rental agreement was amended to remove the minimum monthly purchase obligation of reagents and was replaced by a $3,300 monthly rental fee. The COVID-19 Laboratory Services Agreement could be canceled by the Company at any time by providing 60 days written notice, and the Rental Agreement could be canceled at any time by written notice given within 60 days after termination of the Laboratory Services Agreement. On May 27, 2021, the Company gave written notice to Co-Diagnostics of termination of the COVID-19 Laboratory Services Agreement, so the last day of that agreement was July 26, 2021, and no longer in effect on July 27, 2021. On July 27, 2021, the Company gave written notice to Co-Diagnostics of termination of the Rental Agreement, so the last day of that agreement was July 29, 2021.

On June 25, 2021, the Company entered into a statement of work with a contract research organization to provide services for a proposed clinical trial described as a multi-center, prospective, randomized controlled trial evaluating the effects of SkinTE in the treatment of full-thickness diabetic foot ulcers at a cost of approximately $5.1 million consisting of $3.1 million of service fees and $2.0 million of estimated costs. In July 2021 the Company prepaid 10% of the total cost recited in the work order, or $0.5 million, which will be applied to payment of the final invoice under the work order. Over the approximately three-year term of the clinical trial the service provider shall submit to the Company for payment invoices on a monthly basis for units of work stated in the work order that are completed and billable expenses incurred. During the three-month period ended September 30, 2021, the Company received invoices for work performed and expenses incurred totalling $0.2 million. Either party may terminate the agreement without cause on 60 days' notice to the other party.

Legal Proceedings

On September 24, 2021, a class action complaint alleging violations of the Federal securities laws was filed in the United States District Court, District of Utah, by Marc Richfield against the Company and two present officers and one former officer of the Company, Case No. 2:21-cv-00561-DAO (the "Complaint"). The Complaint alleges 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(b) and 20(a) of the Securities and Exchange Act of 1934, as amended, and Rule 10b-5 adopted thereunder. Specifically, the Complaint alleges that the defendants misrepresented or failed to disclose that: (i) the IND for the Company's product, SkinTE, filed with the FDA was deficient with respect to certain chemistry, manufacturing, and control items; (ii) as a result, it was unlikely that the FDA would approve the IND in its current form; (iii) accordingly, the Company had materially overstated the likelihood that the SkinTE IND would obtain FDA approval; and (iv) as a result, the public statements regarding the IND were materially false and misleading. At this early stage of the proceedings the Company has not yet filed any pleading responding to the complaint and is unable to make any prediction regarding the outcome of the litigation.

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 stated above, at September 30, 2021, the Company was not party to any legal or arbitration proceedings that may have significant 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's is either a party adverse to the Company or its subsidiaries or has a material interest adverse to the Company or its subsidiaries.

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. As of September 30, 2021, the Company has no remaining liability related to future cash payments under the agreement. The fair value of the restricted stock units was $0.8 million and was fully expensed upon Dr. Lough's termination.

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 will occupy and pay for only 3,275 square feet of space, and the Company is not obligated under the lease to pay for the remaining 3,975 square feet covered by the lease unless it elects to occupy that additional space. The Company believes the terms of the lease are very favorable to us, and the Company obtained these favorable terms through the assistance of Peter A. Cohen, a director, which he provided so that the company he owns, Peter A. Cohen, LLC ("Cohen LLC"), could sublease a portion of the office space. The Company is using 1,099 square feet, and Cohen LLC is using approximately 3,648 square feet as of September 30, 2021. The monthly lease payment for 4,747 square feet is $23,737. Of this amount $18,243 is allocated pro rata to Cohen, LLC based on square footage occupied. Additional lease charges for operating expenses and taxes are allocated under the sublease based on the ratio of rent paid by the Company and Cohen LLC to total rent. Once the space is fully occupied, the Company will reduce the overall annual lease rate for the Cohen LLC space to $58.60 per square foot. However, the Company has yet to fully occupy the 7,250 square feet covered by the office lease and the lease expires at the end of October 2021. The Company recognized $55,000 and $52,000 of sublease income for the three months ended September 30, 2021 and 2020, respectively, and $165,000 and $184,000 for the nine months ended September 30, 2021 and 2020, respectively. The sublease income is included in other income, net in the statement of operations. As of September 30, 2021, and December 31, 2020, 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), the Chief Executive Officer of the Company.

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).

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Net revenues by segment:				
Reportable segments:				
Regenerative medicine	$ –	$ 1,156	$ 2,924	$ 2,528
Contract services	1,116	2,181	5,438	4,008
Total net revenues	$ 1,116	$ 3,337	$ 8,362	$ 6,536
Net (loss)/income by segment:				
Reportable segments:				
Regenerative medicine	$ (972)	$ (7,246)	$ (21,903)	$ (32,516)
Contract services	(49)	165	284	(282)
Total net loss	$ (1,021)	$ (7,081)	$ (21,619)	$ (32,798)

17. SUBSEQUENT EVENTS

The Company planned to vacate the rental space in the building located at 40 West 57th Street in New York City when the office lease described in Note 15, above, was scheduled to expire on October 31, 2021. Cohen LLC wished to remain in the space, so the Company assigned the lease for the space to Cohen LLC under an agreement that relieved the Company of any further liability under the lease, made Cohen LLC the tenant under the lease, and provided for Cohen LLC's month-to-month tenancy after October 31, 2021. The landlord consented to the assignment and was a party to the agreement.

On October 25, 2021, a stockholder derivative complaint alleging violations of the Federal securities laws was filed in the United States District Court, District of Utah, by Steven Battams against the Company, each member of the Board of directors, and two officers of the Company, Case No. 2:21-cv-00632-DBB (the "Stockholder Derivative Complaint"). The Stockholder Derivative Complaint alleges 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(b) and 20(a) of the Securities and Exchange Act of 1934, as amended, and Rule 10b-5 adopted thereunder. Specifically, the Stockholder Derivative Complaint alleges that the defendants misrepresented or failed to disclose that: (i) the IND for the Company's product, SkinTE, filed with the FDA was deficient with respect to certain chemistry, manufacturing, and control items; (ii) as a result, it was unlikely that the FDA would approve the IND in its current form; (iii) accordingly, the Company had materially overstated the likelihood that the SkinTE IND would obtain FDA approval; and (iv) as a result, the public statements regarding the IND were materially false and misleading. At this early stage of the proceedings the Company has not yet filed any pleading responding to the complaint and is unable to make any prediction regarding the outcome of the litigation.

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 for the year ended December 31, 2020, Current Report on Form 8-K filed with the Securities and Exchange Commission ("SEC") on July 26, 2021, 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

PolarityTE, Inc., headquartered in Salt Lake City, Utah, is a clinical stage biotechnology company developing regenerative tissue products and biomaterials. We also operate a laboratory testing and clinical research business using equipment, personnel, and facilities we acquired to advance our development of regenerative tissue products.

Regenerative Tissue Product

Our first regenerative tissue product is SkinTE. On July 23, 2021, we submitted an investigational new drug application ("IND") for SkinTE to the United States Food and Drug Administration (the "FDA") through our subsidiary, PolarityTE MD, Inc. ("PTE-MD"). Our business resources are, and will be for the foreseeable future, focused primarily on the advancement of our IND and subsequent biologic license application ("BLA") to attain a license to manufacture and distribute SkinTE in interstate commerce for one or more therapeutic indications. An IND is a request for authorization from the FDA to ship and administer an investigational drug or biological product to humans.

The proposed therapeutic indication listed in the IND for SkinTE is chronic cutaneous ulcers. The IND proposes an initial Phase 2/3 clinical trial described as a multi-center, prospective, randomized controlled trial evaluating the effects of SkinTE in the treatment of full-thickness diabetic foot ulcers (the "DFU Trial"). As proposed, we will seek to qualify approximately 20 sites for the DFU Trial and enroll 100 subjects, and the estimated length of the DFU Trial is approximately 32 months from commencement after acceptance of our IND by the FDA, assuming the IND is accepted. The IND includes a proposal for a second clinical trial for diabetic foot ulcer or another form of chronic cutaneous ulcer, such as venous leg ulcer or pressure ulcer, which we plan to determine through a dialogue with the FDA. A separate submission to our IND must be made for each successive clinical trial to be conducted under the IND.

On August 20, 2021, we were advised by the FDA that certain chemistry, manufacturing, and control ("CMC") items need to be addressed prior to proceeding with a pivotal study and, therefore, the FDA was placing the study on clinical hold and planned to issue a clinical hold letter to the Company by September 21, 2021. A clinical hold means that the pivotal study may not begin unless and until the clinical hold is lifted. On September 17, 2021, we received the clinical hold letter from the FDA, which described the FDA's request for information and modifications to the IND that are necessary for the clinical hold to be lifted, as well as non-clinical hold comments. The clinical hold issues that must be resolved before the clinical hold can be lifted involve, our proposed potency assay; drug product dosage, storage, shipping, and release specifications; antibiotics residuals; bacteriostasis and fungistasis testing; and delivery device. Since our receipt of the clinical hold letter, we have engaged informally with the FDA regarding certain items, most notably the proposed potency assay for SkinTE. We have received helpful feedback from the FDA and are currently preparing a complete response to the clinical hold letter.

Our preliminary experience indicates that SkinTE may benefit patients with immediately life-threatening conditions and other serious diseases or conditions. In 2009, the FDA implemented new regulations related to Expanded Access Investigational New Drug Applications ("Expanded Access INDs"), which are often colloquially referred to as "compassionate use," and pertain to the use of an investigational drug or biologic when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition, rather than to obtain the kind of information about the drug that is generally derived from clinical trials. The FDA has proposed several processes for obtaining Expanded Access INDs, which we will evaluate for potential implementation in connection with a successful opening of our IND for SkinTE. Under FDA regulations the amount that may be charged for SkinTE used under an Expanded Access IND must be authorized by the FDA and, if authorized at all, may be limited to our direct costs of manufacture. We believe, however, that an Expanded Access IND may enable us to provide SkinTE to providers treating persons with life-threatening or serious diseases and conditions, and thereby maintain existing, and develop new, relationships with physicians in the wound care industry.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending upon the timing of our clinical trials and our expenditures for satisfying all the conditions of obtaining FDA premarket approval for SkinTE. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued research and development and other current liabilities.

Testing and Research Services

Beginning in 2017 we developed internally a laboratory and research capability to advance the development of SkinTE and related technologies, which we operate through our subsidiary, Arches Research, Inc. ("Arches"). At the beginning of May 2018, we acquired a preclinical research and veterinary sciences business to be used, in part, for preclinical studies on our regenerative tissue products, which we operate through our subsidiary IBEX Preclinical Research, Inc. ("IBEX"). Through Arches and IBEX we also offer research and laboratory testing services to unrelated third parties on a contract basis.

PPP Loan

As previously reported in the Current Report on Form 8-K filed with the SEC on April 15, 2020, PTE-MD entered into a promissory note with KeyBank, N.A., a national banking association (the "Lender") evidencing an unsecured loan in the amount of $3,576,145 made to PTE-MD under the Paycheck Protection Program (the "PPP Loan"). The Paycheck Protection Program was established under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and is administered by the U.S. Small Business Administration (the "SBA").

On October 15, 2020, PTE-MD applied to the Lender for forgiveness of the PPP Loan in its entirety (as provided for in the CARES Act) based on PTE-MD's use of the PPP Loan for payroll costs, rent, and utilities. On October 26, 2020, PTE-MD was advised that the Lender approved the application, and that the Lender was submitting the

application to the SBA for a final decision. The SBA subsequently approved PTE-MD's application for forgiveness of the PPP Loan, and the principal and interest of $3,612,376 was fully paid by the SBA on June 12, 2021.

On September 17, 2021, we received notice from the Lender that the SBA is reviewing the PPP Loan. As part of this review, the SBA requested that we provide documents that we are required to maintain but may not have been required to submit with our application for the PPP Loan. These documents included an affiliation worksheet showing the relationship between us and PTE-MD and affiliated subsidiaries, documents showing the use of the PPP Loan proceeds, documents showing our calculation of the loan amount we requested in our loan application, our federal tax returns, and documents showing employee compensation information. We submitted the documents to the SBA through the Lender on September 28, 2021.

Liquidity and Capital Resources

As of September 30, 2021, we had $27.4 million in cash and cash equivalents and working capital of approximately $24.9 million. We believe the cash and cash equivalents on our balance sheet will fund our business activities into the fourth calendar quarter of 2022. In the third quarter of 2021 cash used in operating activities was $4.6 million, or an average of $1.5 million per month, compared to $6.8 million cash used in operating activities, or an average of $2.3 million per month, in the third quarter of 2020. In June 2021 our PPP Loan in the amount of $3.6 million was forgiven.

As noted above, we are focused primarily on the advancement of our IND and subsequent BLA to attain a license to manufacture and distribute SkinTE. To that end, in June 2021, we engaged a contract research organization to provide services for the DFU Trial at a cost of approximately $5.1 million consisting of $3.1 million of service fees and $2.0 million of estimated costs. In July 2021 we prepaid 10% of the total cost recited in the work order, or $0.5 million, which will be applied to payment of the final invoice under the work order. Over the approximately three-year term of the DFU Trial the service provider shall submit to us for payment invoices on a monthly basis for units of work stated in the work order that are completed and billable expenses incurred. Our expectation is that the second clinical trial would be similar to the DFU Trial with respect to size, length of time to complete, and cost. In the course of advancing our IND and subsequent BLA we may propose additional clinical trials to advance our applications or broaden the therapeutic indications of use for SkinTE. Clinical trials are the major expense we see in the near and long term, and while we are pursuing clinical trials we will continue to incur the costs of maintaining our business. In addition to clinical trials, the most significant uses of cash to maintain our business going forward are compensation and costs of occupying, operating, and maintaining our facilities.

In the six-month period ended June 30, 2021, the gross profit on sales of SkinTE was $2.5 million, which contributed to covering our operating costs for the period. As discussed above, we ceased SkinTE sales at the end of May 2021, so SkinTE sales did not contribute to defraying our operating costs in the third quarter of 2021. To mitigate the effect of this lost revenue we eliminated some staff and resources that supported the SkinTE commercial effort, but we do not expect to see the benefit of these cost reductions until the fourth quarter of 2021 because of severance and other costs associated with winding down our SkinTE commercial activity.

In the nine-month period ended September 30, 2021, the gross profit from services amounted to approximately $2.2 million, which contributed to covering our operating costs for the period. We made the decision to cease COVID-19 testing in August 2021. Beginning in April 2021 there was a significant loss of COVID-19 testing revenues, which was only partially offset by increased preclinical research revenues generated by IBEX. Consequently, services revenues decreased in the third quarter of 2021, compared to the third quarter of 2020. We took steps in the second quarter of 2021 to mitigate the effect of losing COVID-19 testing revenue, including reduction of temporary labor and other resources used for COVID-19 testing. The volatility in revenues generated by our services business makes it impossible to predict whether or to what extent our services business will contribute to defray our operating costs in future periods.

As of the date of issuance of these unaudited interim condensed financial statements, we expect that our cash and cash equivalents of $27.4 million as of September 30, 2021, will not be sufficient to fund our current business plan including related operating expenses and capital expenditure requirements beyond the fourth calendar quarter of 2022. Accordingly, there is substantial doubt about our ability to continue as a going concern, as we do not believe that our cash and cash equivalents will be sufficient to fund our business plan for at least twelve months from the date of issuance of these interim financial statements. We plan to address this condition by raising additional capital to finance our operations. Although we have 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 we will be successful in obtaining additional financing. Therefore, it is not considered probable, as defined in applicable accounting standards, that our plans to raise additional capital will alleviate the substantial doubt regarding our ability to continue as a going concern.

Our actual capital requirements will depend on many factors, including the cost and timing of our IND and subsequent BLA for SkinTE, the cost and timing of clinical trials, the cost of establishing and maintaining our facilities in compliance with cGMP and cGTP (current good tissue practices) regulations, and the cost and timing of advancing our product development initiatives related to SkinTE. 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.

We will need to raise additional capital in the future to fund our effort to obtain FDA approval of SkinTE and maintain our operations in the future. On March 30, 2021, we entered into a sales agreement (the "Sales Agreement") with Cantor, Fitzgerald & Co. ("Cantor"), to sell shares of our common stock having aggregate sales proceeds of up to $50.0 million, from time to time, through an "at the market" equity offering program under which Cantor will act as sales agent. We have not sold any shares under the Sales Agreement as of the date of this filing. Although we have 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 we will be successful in obtaining additional financing. 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 continue operations, any of which would have a material adverse effect on our business, financial condition, and results of operation.

Results of Operations

Changes in Our Operations

There have been significant changes in our operations affecting our results of operations for the three and nine-month periods ended September 30, 2021, compared to the three and nine-month periods ended September 30, 2020.

SkinTE was registered and listed with the FDA in August 2017 based on our determination that SkinTE should be regulated solely under Section 361 of the Public Health Service Act and Part 1271 of Title 21 of the Code of Federal Regulations (i.e., as a so-called 361 HCT/P) and that, as a result, no premarket review or approval by the FDA was required. We proceeded to develop sales and manufacturing capabilities for SkinTE and focused on advancing commercialization of SkinTE. We began a regional commercial rollout of SkinTE in October 2018, and while it was marketed it was used in complex wounds, such as diabetic foot ulcers penetrating to tendon, capsule, and bone classified, Stage 3 and 4 pressure injuries, and acute wounds. Given our significant real-world experience with the application of SkinTE and several supporting publications, we believe SkinTE could significantly improve clinical outcomes. 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 solely as a 361 HCT/P. Rather, the FDA's preliminary assessment was 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 was prudent to submit an IND for SkinTE and an eventual BLA rather than engage in a protracted dispute with the FDA. On July 23, 2021, we submitted an IND through PTE-MD

and our business resources and activities are now focused primarily on advancing our IND, including addressing a clinical hold on our IND imposed by the FDA on August 20, 2021. We ceased selling SkinTE at the end of May 2021, when the period of enforcement discretion previously announced by the FDA with respect to its IND and premarket approval requirements for 361 HCT/Ps came to an end. As a result, we generated revenues from the sale of SkinTE and related sales, marketing, and administrative expenses related to that sales effort during the three and nine months ended September 30, 2020, which were not present during the period beginning in June 2021 and ending September 30, 2021.

Arches began offering COVID-19 testing services in May 2020 under 30-day renewable testing agreements with multiple nursing home and pharmacy facilities in the state of New York controlled by a single company, which substantially added to our services net revenues in the last seven months of 2020 and first three months of 2021. When the New York nursing homes and pharmacies adopted on-site employee testing at the end of March 2021, our COVID-19 testing revenues declined substantially, and on or about August 17, 2021, we decided to cease COVID-19 testing.

The COVID-19 pandemic had a significant adverse effect on the preclinical research services offered by IBEX in 2020, but there has been a resurgence in that business during the first nine months of 2021. The increase in revenues from IBEX services helped to offset the loss of COVID-19 testing revenues in the second and third quarters of 2021. Nevertheless, revenues from our services business declined 63% in the third quarter of 2021 compared to the first quarter of the year. Due to the circumstances described above, we expect revenues from our services business will be derived primarily from IBEX's preclinical research and veterinary sciences business for the remainder of 2021.

As a result of the foregoing developments, we made a number of changes to our operations that impacted our results of operations. These included reductions in our work force in 2020 and 2021, and reducing the services and infrastructure needed to support a larger work force and commercial sales effort.

Comparison of the three months ended September 30, 2021, and the three months ended September 30, 2020.

(in thousands)	For the Three Months Ended		Increase (Decrease)	
	September 30, 2021	September 30, 2020	Amount	%
	(Unaudited)			
Net revenues				
Products	$ –	$ 1,156	$ (1,156)	(100)%
Services	1,116	2,181	(1,065)	(49)%
Total net revenues	1,116	3,337	(2,221)	(67)%
Cost of sales				
Products	–	210	(210)	(100)%
Services	634	1,142	(508)	(44)%
Total cost of sales	634	1,352	(718)	(53)%
Gross profit	482	1,985	(1,503)	(76)%
Operating costs and expenses				
Research and development	3,870	2,698	1,172	43%
General and administrative	3,687	6,264	(2,577)	(41)%
Sales and marketing	93	1,606	(1,513)	(94)%
Restructuring and other charges	242	–	242	100%
Total operating costs and expenses	7,892	10,568	(2,676)	(25)%
Operating loss	(7,410)	(8,583)	1,173	(14)%
Other income (expense)				
Change in fair value of common stock warrant liability	6,354	1,503	4,851	323%
Interest expense, net	(29)	(58)	29	(50)%
Other income, net	64	57	7	12%
Net loss	$ (1,021)	$ (7,081)	$ 6,060	(86)%

Net Revenues. Net revenues decreased $2.2 million, or 67%, for the three months ended September 30, 2021, compared to the same period in 2020.

Products net revenues were $0 for the three months ended September 30, 2021, compared to $1.2 million for the three-month period ended September 30, 2020. We will not engage in any products sales activity in the fourth quarter of 2021, so the only products net revenues we may recognize in that period or subsequent, foreseeable periods are nominal amounts collected on accounts for product shipped prior to the end of May 2021 that were not previously recognized because of concerns with collectability.

Net revenues from services decreased by 49% for the three-month period ended September 30, 2021, compared to the corresponding period in 2020. The substantial majority of our services net revenues in the third quarter of 2021 were generated by IBEX's preclinical research and veterinary sciences business due to the decline in our COVID-19 testing business and cessation of that testing business in August 2021. At this time, we do not plan to offer COVID-19 testing in the future, so services net revenues in future periods will be generated through research services excluding COVID-19 testing that we have offered, historically.

Cost of Sales. Cost of sales decreased $0.7 million, or 53%, for the three months ended September 30, 2021, compared to the three months ended September 30, 2020. There were no costs of sales attributable to products net revenues in the third quarter of 2021 because we ceased SkinTE sales in the second quarter of 2021. Cost of sales for services revenues decreased 44% period over period for the three months ended September 30, 2021, compared to the three months ended September 30, 2020, which is primarily attributable to the decline in our COVID-19 testing business and cessation of that testing business in August 2021.

Operating Costs and Expenses. Operating costs and expenses decreased $2.7 million, or 25%, for the three months ended September 30, 2021, compared to the three months ended September 30, 2020. The reduction in operating costs and expenses is attributable to reductions in general and administrative expenses and sales and marketing expenses that were partially offset by increases in research and development expenses and restructuring and other charges.

Research and development expenses increased 43% period over period for the three months ended September 30, 2021, compared to the three months ended September 30, 2020. The substantial increase in the three-month period ended September 30, 2021, is primarily attributable to an increase in lab supply costs and consulting services for work on the CMC elements of our IND and re-allocation of costs for manufacturing supplies and compensation following the cessation of SkinTE sales from products cost of goods, general and administrative expenses, and sales and marketing expenses to research and development costs.

We effectuated a substantial reduction in work force for our commercial operations in May 2020 and in May 2021. Consequently, there were significant reductions in

cash compensation, stock compensation, consulting fees, and travel expense. As we pared down our staff and sales activity, we also reduced expenses related to a larger operation by terminating our lease for the Utah corporate office in September 2020 and ceasing operations at our manufacturing node in Georgia in the fourth quarter of 2020. Furthermore, with the cessation of SkinTE sales we re-allocated manufacturing supplies and compensation from general and administrative expenses to research and development costs. The cost cutting measures and re-allocation of costs described above are the primary causes of a 41% decrease in general and administrative expense period over period for the three months ended September 30, 2021, compared to the three months ended September 30, 2020.

When we reduced our commercial sales team and related commercial activities beginning in May 2020 and May 2021, we also took steps to reduce staff and consultants in sales and marketing. With the cessation of SkinTE sales several employees who supported sales and marketing moved into new roles in research and development, so their compensation was allocated to research and development. Consequently, there were significant reductions in cash compensation, stock compensation, consulting fees, and travel expense, which resulted in a 94% decrease in sales and marketing expense for the three months ended September 30, 2021, compared to the three months ended September 30, 2020.

In the three-month period ended September 30, 2021, we paid severance and recognized costs for adjustment of equity awards arising from the reduction in force we implemented at the end of May 2021, which were recorded as restructuring and other charges. We did not have restructuring charges in the three-month period ended September 30, 2020.

Operating Loss and Net Loss. Operating loss decreased $1.2 million, or 14%, for the three months ended September 30, 2021, compared to the three months ended September 30, 2020. Net loss decreased $6.1 million, or 86%, for the three months ended September 30, 2021, compared to the three months ended September 30, 2020.

Warrants issued in connection with financings we completed in January 2021 are classified as liabilities and remeasured each period until settled or until classified as equity. As a result of the periodic remeasurement we recorded a gain for change in fair value of common stock warrant liability of $6.4 million for the three months ended September 30, 2021, compared to a gain of $1.5 million for the three months ended September 30, 2020. For additional information on the change in fair value of common stock warrant liability please see Note 10 to the Condensed Consolidated Financial Statements (unaudited) included in this report.

Comparison of the nine months ended September 30, 2021, and the nine months ended September 30, 2020.

(in thousands)	For the Nine Months Ended		Increase (Decrease)	
	September 30, 2021	September 30, 2020	Amount	%
	(Unaudited)			
Net revenues				
Products	$ 2,924	$ 2,528	$ 396	16%
Services	5,438	4,008	1,430	36%
Total net revenues	8,362	6,536	1,826	28%
Cost of sales				
Products	448	825	(377)	(46)%
Services	3,275	1,925	1,350	70%
Total cost of sales	3,723	2,750	973	35%
Gross profit	4,639	3,786	853	23%
Operating costs and expenses				
Research and development	10,491	9,235	1,256	14%
General and administrative	14,999	22,080	(7,081)	(32)%
Sales and marketing	2,718	7,324	(4,606)	(63)%
Restructuring and other charges	678	2,536	(1,858)	(73)%
Total operating costs and expenses	28,886	41,175	(12,289)	(30)%
Operating loss	(24,247)	(37,389)	13,142	(35)%
Other income (expense)				
Gain on extinguishment of debt	3,612	–	3,612	100%
Change in fair value of common stock warrant liability	4,134	4,444	(310)	(7)%
Inducement loss on sale of liability classified warrants	(5,197)	–	(5,197)	(100)%
Interest expense, net	(106)	(135)	29	(21)%
Other income, net	185	282	(97)	(34)%
Net loss	$ (21,619)	$ (32,798)	$ 11,179	(34)%

Net Revenues. Net revenues increased $1.8 million, or 28%, for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020.

Products net revenues of $2.9 million were the same for the nine months ended September 30, 2021, as they were for the six months ended June 30, 2021, due to the cessation of our commercial sales operation for SkinTE at the end of May 2021. As a result of the cessation of our commercial sales operation, products net revenues increased only 16% for the nine months ended September 30, 2021, compared to the corresponding period in 2020. We expect products net revenues for fiscal year 2021 will remain essentially unchanged from the amount recorded for the six-month period ended June 30, 2021, except for nominal amounts we may collect on accounts for product shipped prior to the end of May 2021 that were not previously recognized because of concerns with collectability.

The mix of business activity generating services net revenues changed from a majority of service revenues generated by COVID-19 testing in the nine months ended September 30, 2020, to a majority of service revenues generated by pre-clinical research services in the nine months ended September 30, 2021. Service revenues generated by our pre-clinical research services business in the nine months ended September 30, 2021, were substantially higher than the comparable period in 2020, as this business activity experienced a strong recovery from the poor results in 2020 attributable to the COVID-19 pandemic. Our COVID-19 testing services were a significant contributor to overall services revenues only in the first three months of 2021. As a result of these developments net revenues from services increased by 36% for the nine months ended September 30, 2021, compared to the corresponding period in 2020.

Cost of Sales. Cost of sales increased $1.0 million, or 35%, for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020. This increase is a result of a 70% increase in the cost of sales for services revenues during the first nine months of 2021 that is primarily a result of the increase in business generated by our pre-clinical research services, which was only partially offset by lower cost of sales arising from the fall-off in our COVID-19 testing business after March 2021 and the elimination of cost of sales for our products business during the four-month period ended September 30, 2021, resulting from the cessation of SkinTE sales at the end of May 2021.

Cost of sales attributable to products net revenues was the same for the nine months ended September 30, 2021, as it was for the six months ended June 30, 2021, due to the cessation of our commercial sales operation for SkinTE at the end of May 2021. For the nine-month period ended September 30, 2021, cost of sales for products revenues decreased 46% period over period compared to the nine months ended September 30, 2020, even though revenues were higher in 2021 for the nine-month period, which is attributable to the economies of scale we achieved in the first five months of 2021 by selling product for larger wound sizes in 2021 compared to 2020 and the elimination of products cost of sales during the four-month period ended September 30, 2021.

Operating Costs and Expenses. Operating costs and expenses decreased $12.3 million, or 30%, for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020. The reduction in operating costs and expenses is attributable to reductions in general and administrative expenses, sales and marketing expenses, and restructuring and other charges that were partially offset by increases in research and development expenses.

Research and development expenses increased 14% period over period for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020. The substantial increase in the nine-month period ended September 30, 2021, is primarily attributable to an increase in lab supply costs and consulting services for work on the CMC elements of our IND; re-allocation of costs for manufacturing supplies and compensation following the cessation of SkinTE sales from products cost of goods, general and administrative expenses, and sales and marketing expenses to research and development costs; and, the costs in our pre-IND clinical trials that we concluded during the period.

As noted above, we effectuated a substantial reduction in force for our commercial operations in May 2020 and in May 2021. Consequently, there were significant reductions in cash compensation, stock compensation, consulting fees, and travel expense. As we pared down our staff and sales activity, we also reduced expenses related to a larger operation by terminating our lease for the Utah corporate office in September 2020 and ceasing operations at our manufacturing node in Georgia in the fourth quarter of 2020. Furthermore, with the cessation of SkinTE sales we re-allocated manufacturing supplies and compensation from general and administrative expenses to research and development costs. The cost cutting measures and re-allocation of costs described above are the primary causes of a 32% decrease in general and administrative expense period over period for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020.

When we reduced our commercial sales team and related commercial activities beginning in May 2020 and May 2021, we also took steps to reduce staff and consultants in sales and marketing. With the cessation of SkinTE sales several employees who supported sales and marketing moved into new roles in research and development, so their compensation was allocated to research and development. Consequently, there were significant reductions in cash compensation, stock compensation, consulting fees, and travel expense, which resulted in a 63% decrease in sales and marketing expense for the three months ended September 30, 2021, compared to the three months ended September 30, 2020.

We realized restructuring and other charges as a result of the transition to a clinical stage company, much of which was recognized in the nine-month period ended September 30, 2020. The reduction in force in March 2020 resulted in a severance charge of $0.5 million, and the subsequent reduction in May 2020 resulted in a charge of $0.6 million. In the second quarter of 2020 we also decided to abandon equipment in addition to the development of a vivarium research facility at our Salt Lake City location resulting in a charge of $1.5 million. By contrast, during the nine month-period ended September 30, 2021, we recognized a loss on impairment of property and equipment in the amount of $0.4 million and severance charges of $0.6 million, which were offset by a $0.3 million gain on the termination of our Augusta node lease. Consequently, there was a 73% decrease in restructuring and other charges for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020.

Operating Loss and Net Loss. Operating loss decreased $13.1 million, or 35%, for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020. Net loss decreased $11.2 million, or 34%, for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020.

Warrants issued in connection with financings we completed in January 2021 are classified as liabilities and remeasured each period until settled or until classified as equity. As a result of the periodic remeasurement we recorded a gain for change in fair value of common stock warrant liability of $4.1 million for the nine months ended September 30, 2021, compared to a gain of $4.4 million for the nine months ended September 30, 2020. For additional information on the change in fair value of common stock warrant liability please see Note 10 to the Condensed Consolidated Financial Statements (unaudited) included in this report.

When the PPP Loan was forgiven in June 2021, we recognized a gain on extinguishment of debt in the amount of $3.6 million. For the nine months ended September 30, 2021, this gain was offset by a day one loss on warrants issued in January 2021 of $5.2 million, which together with the change in fair value of common stock warrant liability, primarily accounts for the difference of $2.6 million between our operating loss and net loss for the nine months ended September 30, 2021.

Non-GAAP Financial Measure

The table below shows adjusted net loss, which is a non-GAAP measure that shows net loss before fair value adjustments relating to our common stock warrant liability and warrant inducement loss. We believe this measure is useful to investors because it eliminates the effect of non-operating items that can significantly fluctuate from period to period due to fair value remeasurements. For purposes of calculating non-GAAP per share metrics, the same denominator is used as that which was used in calculating net loss per share under GAAP.

Adjusted Net Loss Attributable to Common Stockholders
(in thousands - unaudited non-GAAP measure)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
GAAP Net Loss	$ (1,021)	$ (7,081)	$ (21,619)	$ (32,798)
Change in fair value of common stock warrant liability	(6,354)	(1,503)	(4,134)	(4,444)
Inducement loss on sale of liability classified warrants	–	–	5,197	–
Non-GAAP adjusted net loss attributable to common stockholders - basic	$ (7,375)	$ (8,584)	$ (20,556)	$ (37,242)
Gain from change in fair value of warrant liabilities	(174)	–	(27)	–
Non-GAAP adjusted net loss attributable to common stockholders - diluted	$ (7,549)	$ (8,584)	$ (20,583)	$ (37,242)
GAAP net loss per share attributable to common stockholders				
Basic	$ (0.01)	$ (0.18)	$ (0.27)	$ (0.89)
Diluted	$ (0.01)	$ (0.18)	$ (0.27)	$ (0.89)
Non-GAAP adjusted net loss per share attributable to common stockholders				
Basic	$ (0.09)	$ (0.22)	$ (0.26)	$ (1.01)
Diluted	$ (0.09)	$ (0.22)	$ (0.26)	$ (1.01)

Critical Accounting Policies and Estimates

Revenue Recognition. With respect to revenue recognition in contract services provided by IBEX, revenues generally consist of a single performance obligation that IBEX 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. We believe 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 that our services personnel at IBEX make reasonable estimates of the extent of progress toward completion of the contract and, as a result, unbilled receivables and deferred revenue are recognized based on payment timing and work completed.

Stock-Based Compensation. We measure all stock-based compensation to employees and non-employees using a fair value method. For stock options with graded vesting, we recognize compensation expense over the service period for each separately vesting tranche of the award as though the award were in substance, multiple awards based on the fair value on the date of grant. The fair value for options issued is estimated at the date of grant using a Black-Scholes option-pricing model. The risk-free rate is derived from the U.S. Treasury yield curve in effect at the time of the grant commensurate with the expected term of the option. The volatility factor is determined based on our 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 our common stock on the date of grant and amortized to compensation expense over the vesting period of, generally, six months to three years.

Common Stock Warrant Liability. The fair value of the common stock warrant liability is estimated using the Monte Carlo simulation model, which involves simulated future stock price amounts over the remaining life of the commitment. The fair value estimate is affected by our stock price as well as estimated change of control considerations.

Disclosure Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements. Risks and uncertainties are inherent in forward-looking statements. Furthermore, such statements may be based on assumptions that fail to materialize or prove incorrect. Consequently, our business development, operations, and results could differ materially from those expressed in forward-looking statements made in this Quarterly Report. We make such forward-looking statements pursuant to the safe harbor provisions in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "would," or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the timing or success of obtaining regulatory licenses or approvals for initiating clinical trials or marketing our products;
- the initiation, timing, progress, and results of our pre-clinical studies or clinical trials;
- sufficiency of our working capital to fund our operations over 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;
- the impact of new accounting pronouncements;
- size and growth of our target markets; and
- the initiation, timing, progress, and results of our research and development programs.

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 delivery of our services;

- the ability to meet demand for our services;
- the ability to deliver our services if employees are quarantined due to the impact of COVID-19;
- 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;
- new discoveries or the development of new therapies or technologies that render our products or services obsolete or unviable;
- 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;
- the ability to gain adoption by healthcare providers of our products for patient care;
- 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
- the other risks and uncertainties described in this report under Part II, Item 1A. Risk Factors.

Forward-looking statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Any forward-looking statement in this Quarterly Report on Form 10-Q and the documents incorporated by reference herein reflects our current view with respect to future events and is subject to these and other risks, uncertainties, and assumptions relating to our operations, results of operations, industry, and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections, and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

Not applicable.

Item 4. Controls and Procedures

Our management, with the participation of our principal executive and financial officers, evaluated the effectiveness of our disclosure controls and procedures as of the

end of the period covered by this report. Based on the evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2021, 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 September 30, 2021, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

See Notes 14 and 17 to the Condensed Consolidated Financial Statements (unaudited) included in this report for information regarding the status of legal proceedings involving the Company.

Item 1A. Risk Factors

You should carefully consider the factors discussed below and in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, and our Current Report on Form 8-K filed with the SEC on July 26, 2021, which could materially affect our business, financial position, or future results of operations. The risks described below and in those reports 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.

Risks Related to Our Financial Condition

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 $21.6 million for the nine months ended September 30, 2021, and at September 30, 2021, we had an accumulated deficit of $499.8 million. We believe our cash and cash equivalents on our balance will fund our current business plan including related operating expenses and capital expenditure requirements into, but not beyond, the fourth calendar quarter of 2022. Accordingly, there is substantial doubt about our ability to continue as a going concern beyond that time 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 SkinTE with the 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 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.

If adequate funds are not available to us in the future, we may be required to delay, reduce the scope of, or eliminate our plans for obtaining regulatory approval for SkinTE or be unable to continue operations over a longer term, any of which would have a material adverse effect on our business, financial condition, and results of operation.

Our wholly owned subsidiary accepted a loan under the CARES Act pursuant to the Paycheck Protection Program ("PPP"), and the loan may subject us to challenges, audits, or investigations regarding qualification for the loan, any of which could reduce our liquidity and have a material adverse effect on our business, financial condition, and results of operations.

On April 15, 2020, PTE-MD entered into a promissory note with the Lender evidencing an unsecured loan in the amount of $3,576,145 made to PTE-MD under the PPP (the "PPP Loan"). On October 15, 2020, PTE-MD applied to the Lender for forgiveness of the PPP Loan in its entirety (as provided for in the CARES Act) based on PTE-MD's use of the PPP Loan for payroll costs, rent, and utilities. On October 26, 2020, PTE-MD was advised that the Lender approved the application, and that the Lender was submitting the application to the SBA for a final decision. The SBA subsequently approved PTE-MD's application for forgiveness of the PPP Loan, and the principal and interest of $3,612,376 was fully paid by the SBA on June 12, 2021.

Pursuant to the requirements under the CARES Act, in connection with the PPP Loan PTE-MD certified that current economic uncertainty made the Loan request necessary to support the ongoing operations of PTE-MD. We believe that certification was made in a manner consistent with SBA guidance that borrowers must make the certification in good faith, taking into account their current business activity and their ability to access other sources of liquidity sufficient to support their ongoing operations in a manner that is not significantly detrimental to the business. In connection with our application for forgiveness of the PPP Loan we provided information on the use of the PPP Loan proceeds for payroll costs, rent, and utilities, which are permitted uses to qualify for forgiveness of the loan.

Under the CARES Act the SBA may review any PPP loan of any size at any time at its discretion. On September 17, 2021, we received notice from the Lender that the SBA is continuing to review the PPP Loan. As part of this review, the SBA requested that we provide documents that we are required to maintain but may not have been required to submit with our application for the PPP Loan. These documents included an affiliation worksheet showing the relationship between us and PTE-MD and affiliated subsidiaries, documents showing the use of the PPP Loan proceeds, documents showing our calculation of the loan amount we requested in our loan application, our federal tax returns, and documents showing employee compensation information. We submitted the documents to the SBA through the Lender on September 28, 2021.

There is no assurance the SBA will conclude PTE-MD properly applied for, and used the proceeds of, the PPP Loan. If there is any adverse finding in the SBA review or if the PTE-MD were alleged, or determined, not to qualify for the Loan or alleged, or found, to have made false certifications in connection with the PPP Loan and its forgiveness, PTE-MD could be required to return the full amount of the Loan, which would reduce its liquidity, and could subject it to fines and penalties, and exclusion from government contracts. In particular, PTE-MD may become subject to actions under the FCA, including its qui tam provisions, which, among other things, prohibits persons from knowingly filing, or knowingly causing to be filed, a false statement, or knowingly using a false statement, to obtain payment from the federal government. Violations of the FCA are subject to treble damages and penalties. In the case of an SBA loan, the government could allege that single damages are the amount of the loan and interest thereon (or more), which under the FCA could then be trebled. Substantial penalties must also be imposed for each submitted false statement when a defendant loses an FCA trial. FCA cases may be initiated by the U.S. Department of Justice or by private persons or entities, often called "whistleblowers," who bring the action on behalf of the United States. PTE-MD may also face enforcement arising under other federal statutes, including criminal laws, and administrative actions and investigations initiated by SBA or other governmental entities. Furthermore, if PTE-MD is identified as an entity that the media, government officials, or others seek to portray as a business that should not have availed itself of PPP funding, PTE-MD may face negative publicity, which could have a materially adverse impact on its business and operations and on our business and operations as its parent. Generally, the cost of defending claims under the FCA, regardless of merit, could be substantial, even as much as the PPP loan proceeds.

Risks Related to our Research & Development, Clinical, and Commercialization Activities

Our product is subject to extensive regulation by the FDA or comparable foreign regulatory authorities, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing, and distribution of SkinTE is subject to extensive regulation by the FDA and other U.S. regulatory agencies, or comparable authorities in foreign markets. In the U.S. we are not permitted, directly or through others, to market our product until the FDA approves a BLA for SkinTE. Similar approval is required in foreign jurisdictions. The process of obtaining these approvals is expensive, often takes many years, and can vary substantially based upon the type, complexity, and novelty of the product candidate involved. Approval policies or regulations may change and may be influenced by the results of other similar or competitive products, making it more difficult for us to achieve such approval in a timely manner or at all. Any guidance that may result from FDA advisory committee discussions may make it more expensive to develop and commercialize our product. In addition, as a company, we have not previously filed a BLA with the FDA or filed a similar application with other foreign regulatory agencies. This lack of experience may impede our ability to obtain FDA or other foreign regulatory agency approval in a timely manner, if at all, for our product.

Despite the time and expense invested, regulatory approval is never guaranteed. The FDA or comparable foreign authorities can delay, limit, or deny approval of a product candidate for many reasons, including:

- a product candidate may not be deemed safe or effective;
- agency officials of the FDA or comparable foreign regulatory authorities may not find the data from non-clinical or preclinical studies and clinical trials generated during development to be sufficient;
- the FDA or comparable foreign regulatory authorities may not approve manufacturing processes or facilities; or
- the FDA or a comparable foreign regulatory authority may change its approval policies or adopt new regulations.

Our inability to obtain these approvals would prevent us from commercializing our product.

The FDA regulatory approval process is lengthy and time-consuming, and we could experience significant delays or other challenges in the clinical development and regulatory approval of our product.

We may experience delays or other challenges in commencing and completing clinical trials for SkinTE. We do not know whether planned clinical trials will begin on time, need to be redesigned, enroll trial subjects on time, or be completed on schedule, if at all. Any of our future clinical trials may be delayed or precluded for a variety of reasons, including issues related to:

- the availability of financial resources for us to commence and complete our planned clinical trials;
- reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining approval of each reviewing institutional review board ("IRB");
- obtaining regulatory approval for clinical trials in each country;
- recruiting sufficient numbers of suitable trial subjects to participate in clinical trials;
- competing priorities at clinical trial sites or departures of study investigators or personnel;
- having trial subjects complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites;
- developing one or more new formulations or routes of administration; or
- manufacturing sufficient quantities of our product candidate for use in clinical trials.

Trial subject enrollment, a significant factor in the timing and success of clinical trials, is affected by many factors including the size and nature of the trial subject population, the proximity of trial subjects to clinical sites, the eligibility criteria for the clinical trial, the potential impact of COVID-19 or other pandemic, the design of the clinical trial, competing clinical trials and clinicians, and trial subjects' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any therapies that may be approved for the indications we are investigating. In addition, significant numbers of trial subjects who enroll in our clinical trials may drop out during the clinical trials for various reasons. We endeavor to account for dropout rates in our trials when determining expected clinical trial timelines, but we cannot assure you that our assumptions are correct, or that trials will not experience higher numbers of dropouts than anticipated, which would result in the delay of completion of such trials beyond our expected timelines, if at all.

We could encounter delays if physicians encounter unresolved ethical issues associated with enrolling trial subjects in clinical trials of our product candidate in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be delayed, suspended, or terminated by us, any reviewing IRB, the institutions in which such trial is conducted, the data monitoring committee for such trial, or by the FDA or other regulatory authorities due to a number of factors, including inadequate protocols or other information supporting an IND, failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations, or administrative actions or lack of adequate funding to continue the clinical trial. If we experience suspension or termination of, or delays in the completion of, any clinical trial for our product, the commercial prospects for the product will be harmed, and our ability to generate product revenues will be delayed or diminished. In addition, any delays in initiating or completing our clinical trials will increase our costs, slow down our product development and approval process, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, prospects, financial condition, and results of operations significantly. Furthermore, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product.

In connection with clinical trials, we face risks that:

- regulatory approval of a proposed clinical trial may be delayed or not granted;

- IRBs may delay approval of, or fail to approve, a clinical trial at a prospective site;
- there may be a limited number of, and significant competition for, suitable trial subjects for enrollment in the clinical trials;
- there may be slower than expected rates of trial subject recruitment and enrollment;
- trial subjects may fail to complete the clinical trials;
- there may be an inability or unwillingness of trial subjects or medical investigators to follow our clinical trial protocols;
- there may be an inability to monitor trial subjects adequately during or after treatment;
- there may be termination of the clinical trials by one or more clinical trial sites;
- unforeseen ethical or safety issues may arise;
- conditions of trial subjects may deteriorate rapidly or unexpectedly, which may cause the trial subjects to become ineligible for a clinical trial or may prevent our product from demonstrating efficacy or safety;
- trial subjects may die or suffer other adverse effects for reasons that may or may not be related to our product being tested;
- we may not be able to sufficiently standardize certain of the tests and procedures that are part of our clinical trials because such tests and procedures are highly specialized and involve a high degree of expertise;
- a product candidate may not prove to be efficacious in all or some trial subject populations;
- the results of the clinical trials may not confirm the results of earlier trials;

- the results of the clinical trials may not meet the level of statistical significance required by the FDA or other regulatory agencies;
- there may be data discrepancies or documentation issues in the clinical trials that raise questions about data integrity or reliability; and
- a product candidate may not have a favorable risk/benefit assessment in the disease areas studied.

We cannot assure you that any future clinical trial for our product will be started or completed on schedule, or at all. Any failure or significant delay in completing clinical trials for our product would harm the commercial prospects for the product and adversely affect our financial results. Difficulties and failures can occur at any stage of clinical development, and we cannot assure you that we will be able to successfully complete the development and commercialization of our product in any indication.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including (i) government budget and funding levels, (ii) the ability to hire and retain key personnel and accept the payment of user fees, and (iii) statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect its business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Even if we obtain and maintain regulatory approval for our product in one jurisdiction, we may never obtain regulatory approval for the product in any other jurisdiction, which would limit our market opportunities and adversely affect our business.

Obtaining and maintaining regulatory approval for our product in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in other jurisdictions. For example, even if the FDA grants marketing approval for SkinTE, comparable regulatory authorities in foreign countries must also approve the manufacturing, marketing, and promotion of the product in those countries. Approval procedures vary amongst jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our product is also subject to approval.

Regulatory authorities in countries outside of the United States also have requirements for approval of product candidates that we must comply with prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our product in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval for any product may be withdrawn. If we fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product will be harmed, which would adversely affect our business, prospects, financial condition, and results of operations.

Even if any of our product candidates receive regulatory approval, our product candidates may still face future development and regulatory difficulties.

If our product receives regulatory approval, the FDA or comparable foreign regulatory authorities may still impose significant restrictions on the indicated uses or marketing of the product or impose ongoing requirements for potentially costly post-approval studies and trials or other risk mitigation measures. In addition, regulatory agencies subject a product, its manufacturer, and the manufacturer's facilities to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory

agency may impose restrictions on that product, any future licensee, or us, including requiring withdrawal of the product from the market. Our product candidates will also be subject to ongoing FDA or comparable foreign regulatory authorities' requirements for the labeling, packaging, storage, advertising, promotion, record-keeping, and submission of safety and other post-market information on the drug. If our product fails to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or other notices of possible violations;
- impose civil or criminal penalties or fines or seek disgorgement of revenue or profits;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us or our licensees;
- withdraw any regulatory approvals;
- impose restrictions on operations, including costly new manufacturing requirements, or shut down our manufacturing operations; or
- seize or detain product or require a product recall.

The FDA and comparable foreign authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA and comparable foreign authorities strictly regulate the promotional claims that may be made about drug and biological products, such as SkinTE, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or comparable foreign authorities as reflected in the product's approved labeling. If we receive marketing approval for our product for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment that our products could be used in such manner.

However, if we are found to have promoted our products for any off-label uses, the federal government could levy civil, criminal, or administrative penalties, and seek to impose fines on us. Such enforcement has become more common in the industry. The FDA or comparable foreign authorities could also request that we enter into a consent decree or a corporate integrity agreement or seek a permanent injunction against us under which specified promotional conduct is monitored, changed, or curtailed. If we cannot successfully manage the promotion of our product, if approved, we could become subject to significant liability, which would materially adversely affect our business, financial condition, and results of operations.

We, and any contract manufacturer we may engage in the future, are subject to significant regulation with respect to manufacturing our product. The manufacturing facilities on which we rely may not continue to meet regulatory requirements.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including us and any contract manufacturer we may engage in the future, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with current Good Manufacturing Practices ("cGMP"). These regulations govern manufacturing facilities, processes, and procedures and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes or facilities can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA or change in manufacturing site after a BLA is issued on a timely basis and must adhere to cGMP regulations enforced by the FDA or comparable foreign authorities through their facilities inspection program. The facilities and quality systems of our facility where we will manufacture SkinTE must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product. In addition, the regulatory authorities may, at any time, with or without cause, audit or inspect a manufacturing facility involved with the preparation of our product or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If our facility does not pass a pre-approval plant inspection, regulatory approval of our product may not be granted or may be substantially delayed until any deficiencies are corrected to the satisfaction of the regulatory authority, if ever. If we engage contract manufacturers in the future we intend to oversee the contract manufacturers, but we cannot control the manufacturing process and will be completely dependent on our contract manufacturing partners for compliance with the regulatory requirements.

The regulatory authorities also may, at any time following approval of a product for sale, audit our facility or the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business, financial condition, and results of operations.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or comparable foreign authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a product candidate, withdrawal of an approval, or suspension of production. As a result, our business, financial condition, and results of operations may be materially and adversely affected.

Additionally, if supply from our facility or the facility of a future contract manufacturer is interrupted, an alternative manufacturer would need to be qualified through a BLA supplement, or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies or trials if a new manufacturer is relied upon for commercial production. Switching manufacturing facilities may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals, or commercialization of our product. Furthermore, if our facility or future contract manufacturers fail to meet production requirements and we are unable to secure one or more replacement manufacturing facilities capable of production at a substantially equivalent cost, our clinical trials may be delayed, or we could lose potential revenue.

If we fail to obtain and sustain an adequate level of reimbursement for our product by third-party payors, potential future sales would be materially adversely affected.

There will be no viable commercial market for our product, if approved, without reimbursement from third-party payors. Reimbursement policies may be affected by future healthcare reform measures. We cannot be certain that reimbursement will be available for our product. Additionally, even if there is a viable commercial market, if the level of reimbursement is below our expectations, our anticipated revenue and gross margins will be adversely affected.

Third-party payors, such as government or private healthcare insurers, carefully review and increasingly question and challenge the coverage of and the prices charged for drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan, and other factors. Reimbursement rates may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. There is a current trend in the U.S. healthcare industry toward cost containment.

Large public and private payors, managed care organizations, group purchasing organizations, and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge the prices charged for, medical products and services, and many third-party payors limit coverage of or reimbursement for newly approved healthcare products. In particular, third-party payors may limit the covered indications. Cost-control initiatives could decrease the price we might establish for products, which could result in product revenues being lower than anticipated. If we are unable to show a significant benefit relative to existing therapies, Medicare, Medicaid, and private payors may not be willing to provide reimbursement for our product, which would significantly reduce the likelihood of our product gaining market acceptance.

We expect that private insurers will consider the efficacy, cost-effectiveness, safety, and tolerability of our product in determining whether to approve reimbursement and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business, financial condition, and results of operations would be materially adversely affected if we do not receive approval for reimbursement of our product from private insurers on a timely or satisfactory basis. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Medicare Part D, which provides a pharmacy benefit to Medicare patients as discussed below, does not require participating prescription drug plans to cover all drugs within a class of products. Our business, financial condition, and results of operations could be materially adversely affected if Part D prescription drug plans were to limit access to, or deny or limit reimbursement of, our product.

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. In many countries, the product cannot be commercially launched until reimbursement is approved. In some foreign markets, prescription drug pricing remains subject to continuing governmental control even after initial approval is granted. The negotiation process in some countries can be very long. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products to other available therapies.

If the prices for our product are reduced or if governmental and other third-party payors do not provide adequate coverage and reimbursement of our product, our future revenue, cash flows, and prospects for profitability will suffer.

Current and future legislation may increase the difficulty and cost of commercializing our product and may affect the prices we may obtain if our product is approved for commercialization.

In the U.S. and some foreign jurisdictions, there have been a number of adopted and proposed legislative and regulatory changes regarding the healthcare system that could prevent or delay regulatory approval of our product, restrict or regulate post-marketing activities, and affect our ability to profitably sell our product.

In the U.S., the Medicare Modernization Act of 2003 ("MMA") changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could limit the coverage and reimbursement rate that we receive for our product. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

The Patient Protection and Affordable Care Act ("PPACA") was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms. The PPACA increased manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate amount for both branded and generic drugs and revised the definition of Average Manufacturer Price, which may also increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also expanded Medicaid drug rebates and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the rebates due on those drugs. The Centers for Medicare & Medicaid Services, which administer the Medicaid Drug Rebate Program, also proposed to expand Medicaid rebates to the utilization that occurs in the territories of the U.S., such as Puerto Rico and the Virgin Islands. Further, beginning in 2011, the PPACA imposed a significant annual fee on companies that manufacture or import branded prescription drug products and required manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole." Legislative and regulatory proposals have been introduced at both the state and federal level to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

There have been prior public announcements by members of the federal government regarding their plans to repeal and replace the PPACA and Medicare. For example, the Tax Cuts and Jobs Act of 2017 eliminated the individual mandate requiring most Americans (other than those who qualify for a hardship exemption) to carry a minimum level of health coverage, effective January 1, 2019. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing approval testing and other requirements.

We are subject to "fraud and abuse" and similar laws and regulations, and a failure to comply with such regulations or prevail in any adverse claim or proceeding related to noncompliance could harm our business, financial condition, and results of operations.

In the U.S., we are subject to various federal and state healthcare "fraud and abuse" laws, including anti-kickback laws, false claims laws, and other laws intended, among other things, to reduce fraud and abuse in federal and state healthcare programs. The federal Anti-Kickback Statute makes it illegal for any person, including a drug manufacturer, or a party acting on its behalf, to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, or other good or service, for which payment in whole or in part may be made under a federal healthcare program, such as Medicare or Medicaid. Although we seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the federal Anti-Kickback Statute.

The federal False Claims Act prohibits anyone from, among other things, knowingly presenting or causing to be presented for payment to the government, including the federal healthcare programs, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Under the Health Insurance Portability and Accountability Act of 1996, we are prohibited from knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services to obtain money or property of any healthcare benefit program. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including penalties, fines, or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid, and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several states.

Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

Neither the government nor the courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If we are found in violation of one of these laws, we could be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from governmental funded federal or state healthcare programs, and the curtailment or restructuring of our operations. If this occurs, our business, financial condition, and results of operations may be materially adversely affected.

If we face allegations of noncompliance with the law and encounter sanctions, our reputation, revenues, and liquidity may suffer, and our product, if approved for commercialization, could be subject to restrictions or withdrawal from the market.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to generate revenues from our product, if approved for commercialization. If regulatory sanctions are applied or if regulatory approval is not granted or is withdrawn, our business, financial condition, and results of operations will be adversely affected. Additionally, if we are unable to generate revenues from product sales, our potential for achieving profitability will be diminished and our need to raise capital to fund our operations will increase.

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

During the three-month period ended September 30, 2021, we withheld or acquired from employees shares of common stock to satisfy statutory withholding tax liability upon the vesting of share-based awards. The following table sets forth information on our acquisition of these shares for each month during the period in which an acquisition occurred.

Issuer Purchases of Equity Securities

Period	(a) Total number of shares (or units) purchased	(b) Average price paid per share (or unit)	(c) Total number of shares (or units) purchased as part of publicly announced plans or programs	(d) Maximum number (or approximate dollar value) of shares (or units) that may yet be purchased under the plans or programs
July 2021	159,243	$ .80	N/A	N/A
August 2021	24,769	$ .83	N/A	N/A
September 2021	21,001	$ .71	N/A	N/A
Total	205,013	$ .78		

Item 6. Exhibits

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

3.1	PolarityTE, Inc., Restated Certificate of Incorporation (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on October 1, 2021).
3.2	PolarityTE, Inc., Amended and Restated Bylaws – September 28, 2021 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on October 1, 2021).
#10.1	Employment Agreement with Richard Hague dated August 18, 2021 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on August 24, 2021).
#10.2	Employment Agreement with Cameron Hoyler dated August 18, 2021 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the SEC on August 24, 2021).
#10.3	Employment Agreement with Jacob Patterson dated August 18, 2021 (incorporated by reference to Exhibit 10.3 to our Form 8-K filed with the SEC on August 24, 2021).
#10.4	Consulting Agreement with David Seaburg dated September 1, 2021
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)

These items are a management contract, compensatory plan, or arrangement.

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: November 10, 2021

/s/ Richard Hague
Richard Hague
Chief Executive Officer
Duly Authorized Officer

Date: November 10, 2021

/s/ Jacob Patterson

Jacob Patterson
Chief Financial Officer
Chief Accounting Officer

CONSULTING AGREEMENT

This CONSULTING AGREEMENT (the "**Agreement**") is made and effective as of the 1st day of September 2021, by and between David Seaburg, an individual ("**Consultant**"), and PolarityTE, Inc., a Delaware corporation ("**PTE**"), and PolarityTE MD, Inc., a Nevada corporation ("**MD**") (PTE and MD are collectively referred to herein as the "**Company**").

WHEREAS, the Company desires to have Consultant provide certain consulting services pursuant to the terms and conditions of this Agreement; and

WHEREAS, Consultant is experienced and qualified to provide the Services, as more fully described below, and shall provide the Services on an ongoing basis to the Company pursuant to the terms and conditions of this Agreement in exchange for the Consulting Fee (defined in Section 3) and expense reimbursement provided for in Section 3.

NOW, THEREFORE. in consideration of the foregoing promises and the mutual covenants herein contained, the parties hereto, intending to be legally bound, agree as follows:

1. CONSULTING SERVICES. During the term of this Agreement, Consultant, in the capacity as an independent contractor, shall provide professional consulting services described on Schedule A, which is incorporated herein (the "**Services**"). The Company acknowledges and hereby agrees that Consultant is not engaged on a full-time basis and Consultant may pursue any other activities and engagements it desires during the term of this Agreement. Consultant shall perform the Services in accordance with all local, state, and federal rules and regulations.

(a) Consultant represents and warrants to the Company that Consultant has the requisite skills, experience, and expertise to provide the Services and will, during the Term of this Agreement, provide the Services for the Company diligently and conscientiously and in a professional manner. Consultant further represents and warrants that:

i. Consultant has received any necessary approvals and consents in connection with entering into this Agreement and performing the Services from any employer, institution, or other entity with whom Consultant also has current business;

ii. Compliance with the terms of the Agreement and performance of the Services will not conflict with, constitute a breach of, or otherwise violate the terms of any agreement or court order to which Consultant is a party;

iii. Compliance with the terms of this Agreement and the performance of the Services do not and will not breach any agreement to keep in confidence proprietary information acquired by the Consultant in confidence; and,

iv. During the performance of the Services, Consultant will not disclose to the Company any proprietary information belonging to a third party.

(b) Upon execution of this Agreement and during the Term of this Agreement, Consultant shall not take part in any activity that causes an actual or potential conflict of interest to arise in connection with activities undertaken on behalf of the Company.

(c) If Consultant is affiliated with any public, private, or governmental institution, Consultant represents and warrants to the Company that Consultant is not required to disclose or assign to any such institution proprietary rights to any inventions or writings made or created by Consultant during the course of the performance of the Services.

(d) The parties agree and acknowledge that for purposes of all equity compensation awards made to the Consultant during his employment with the Company the services provided under this Agreement are a continuation of service so that all such awards will continue to vest and remain exercisable in accordance with their terms.

2. PUBLIC-FACING REQUIREMENTS. Consultant understands and agrees that making a promotional presentation for or on behalf of the Company requires Consultant to adhere to all legal and regulatory requirements related to (a) medical device and pharmaceutical product promotion in general, (b) Federal statutes and regulations administered by the Securities and Exchange Commission, including, but not limited to, Regulation FD, (c) rules of any stock exchange on which the securities of PTE may be listed, and (d) the Company's Policies.

3. COMPENSATION TO CONSULTANT . In consideration for the Consultant's performance of Services described on Schedule A, the Company shall pay Consultant compensation at the rate and on the terms set forth in Schedule A (the "**Consulting Fee**").

4. TERM. The term of this Agreement shall be twelve (12) months and may be renewed for one or more additional terms of twelve (12) months at the end of the initial and each additional term; provided, however, that in the event Consultant ceases to serve as a director of PTE, this Agreement (and the term) may be terminated by the Company at any time on or after the date of cessation of service as a director by written notice to Consultant. Consultant may terminate this Agreement and the term at any time by written notice to the Company.

5. INDEPENDENT CONTRACTOR. Consultant shall act at all times hereunder as an independent contractor as that term is defined in the Internal Revenue Code of 1986, as amended, with respect to the Company, and not as an employee, partner, agent, or co-venturer of or with the Company. Except as set forth herein, the Company shall neither have nor exercise control or direction whatsoever over the operations of Consultant, and Consultant shall neither have nor exercise any control or direction whatsoever over the employees, agents, or subcontractors hired by the Company.

6. NOTICE REGARDING INSIDER TRADING. Consultant hereby acknowledges that Federal securities laws in the United States and other applicable international securities laws prohibit any person who has material, non-public information about a company from purchasing or selling securities of such company or from communicating such information to any other person under circumstances in which it is reasonably foreseeable that such person is likely to purchase or sell such securities.

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7. NO AGENCY CREATED. No agency, employment, partnership, or joint venture shall be created by this Agreement, as Consultant is an independent contractor. Consultant shall have no authority as an agent of the Company or to otherwise bind the Company to any agreement, commitment, obligation, contract, instrument, undertaking, arrangement, certificate, or other matter. Each party hereto shall refrain from making any representation intended to create an apparent agency, employment, partnership, or

joint venture relationship between the parties.

8. INDEMNIFICATION. Consultant shall indemnify and hold harmless the Company, and each person or entity associated or affiliated with the Company, from any damages, claims, liabilities, losses, and expenses, including reasonable attorney's fees, arising out of any act or omission of Consultant in performing the Services or the breach of any provision of this Agreement by Consultant. This Section 9 shall survive termination of this Agreement for a period of three (3) years from the date of termination of this Agreement.

9. ASSIGNMENT. Consultant may not assign any of its rights under this Agreement, except with the prior written consent of the Company. The Company may assign any and all of its rights under this Agreement. If a purported assignment by Consultant is made in violation of this section, it is void. The provisions of this Agreement shall also survive the assignment of this Agreement by the Company to any successor-in-interest or other assignee.

10. CONFIDENTIAL INFORMATION. Consultant acknowledges that during the term of this Agreement, Consultant will have access to and may become acquainted with various information, records, specifications, trade secrets, inventions, innovations, processes, owned or licensed by PTE, or direct or indirect subsidiaries of PTE (the "**Group Companies**" or individually a "**Group Company**"), and/or used by one or more of the Group Companies in connection with the operation of its or their business including, without limitation, a Group Company's business and products, customers, accounts, and procedures. All files, records, documents, specifications, information, and similar items relating to the business of any of the Group Companies (collectively referred to herein as the "**Confidential Information**"), shall remain the exclusive property of the respective Group Companies.

(a) Consultant agrees to maintain as confidential, and not disclose or use any Confidential Information except as specifically authorized by under this Agreement. Consultant shall use best efforts to maintain the confidentiality of all Confidential Information. Consultant shall only disclose the Confidential Information to its employees and permitted agents and consultants on a need-to-know basis to provide the Services under this Agreement, and prior to such disclosure, Consultant shall ensure that any such employee, agent, and consultant agrees to hold the Confidential Information in confidence and not make use of the Confidential Information for any purpose other than those permitted by this Agreement.

(b) Upon termination or expiration of this Agreement, Consultant shall not retain any copies of the Confidential Information without the Company's prior written permission. Upon request by the Company, Consultant shall immediately deliver to the Company all such files, records, documents, specifications, information, and similar items in Consultant's possession or under the Consultant's control. Notwithstanding anything herein to the contrary, Confidential Information shall not include any information which (i) is or becomes generally available to the public other than as a result of a disclosure by Consultant in breach of this Agreement, (ii) is or becomes available to Consultant from a third party which is not bound by a nondisclosure agreement in favor of any of the Group Companies, or (iii) is developed by Consultant without reference to the Confidential Information.

(c) Consultant acknowledges and agrees that these restrictions are reasonable and required for the reasonable protection of the Group Companies and that any breach of this Section will result in irreparable and continuing damage to the Company for which there will be no adequate remedy at law, and the Company shall, accordingly, be entitled to seek injunctive relief (without the necessity of a bond) and other equitable relief for any such breach or threatened breach of this Section and that resort by the Company to any such equitable relief shall not be deemed to waive or to limit in any respect any right or remedy that the Company may have with respect to such breach or threatened breach of this Section.

(d) At no time during any period that Consultant is engaged with the Company may Consultant disclose, use, store on any of the Company's systems, or bring onto the Company's premises any trade secrets or confidential information belonging to any of Consultant's prior employers and/or third parties who have engaged Consultant in a consulting capacity. Consultant further represents and warrants that it is not a party to any existing contract relating to the granting or assignment to others of any interest in the Company's current or future Confidential Information or trade secrets.

(e) The Proprietary Information, Invention Assignment, and Restrictive Covenant Agreement dated March 8, 2019, between PTE and Consultant remains in full force and effect until the expiration of the term stated therein, is not affected by this Agreement, and will survive the execution and delivery of this Agreement.

11. ASSIGNMENT OF INTELLECTUAL PROPERTY. Consultant agrees that as a result of Consultant's work under this Agreement, Consultant will engage in one or more activities that include but are not limited to preparing, writing, creating, evaluating, and/or developing deliverables including artwork, product descriptions, presentations on the business of the Company or its activities, informational text and graphics, data, and materials for promotion, sale, and use in connection with the Company's present product line, future developments, and public relations (hereinafter referred to collectively as the "**Works**"). Consultant agrees to and hereby does transfer entire ownership of any intellectual property rights including all patent, trademark, and copyright rights in the Works to the Company, and further agrees as follows:

(a) In exchange for consideration paid by the Company to Consultant and other good and valuable consideration, the receipt thereof being hereby acknowledged by Consultant, Consultant hereby grants, transfers, assigns, and conveys to the Company, its successors and assigns, the entire worldwide title, right, interest, ownership and all subsidiary rights including moral rights and other rights and any rights existing under the Berne Convention and/or under 17 U.S.C. §106(a) in and to the Works (deemed to be "**Works for Hire**") and any rights under Title 35 U.S.C. and/or foreign equivalents, the right to secure formal rights such as patent, industrial design, and/or copyright registration by registration, application, or otherwise under its own name as the claimant, said transfer including all rights of enforcement and for infringement.

(b) Consultant agrees to execute all documents provided to it by the Company required to perfect its rights under Section 11 and to provide all assistance reasonably requested by and reasonably required by the Company. Consultant agrees to take no actions adverse to the rights granted the Company under Section 11 and agrees to take all actions and cooperate as is necessary and reasonably requested by the Company to perfect such rights including execution of any required documents.

(c) To the extent that Consultant uses any pre-existing materials in the foregoing deliverable items, Consultant hereby grants to the Company an irrevocable, non-exclusive, worldwide, royalty-free license to make, use, sell, reproduce, display, perform, copy, distribute, and prepare derivatives based upon such pre-existing materials as well as the right to sub-license the same to third parties.

(d) Consultant warrants that no portion of the work product delivered to the Company violates or is protected by any right of any third party.

(e) Consultant acknowledges that the Company is not obligated to make any effort to commercialize any deliverable or Work subject to this Agreement and that it is entirely within the sole discretion of the Company to preserve, maintain, register, and/or enforce the same in the United States of America or any foreign country.

12. PROTECTED RIGHTS; LIMITED TRADE SECRET IMMUNITY. Consultant is hereby notified that under the Defend Trade Secrets Act: (i) no individual will be held criminally or civilly liable under federal or state trade secret law for disclosure of a trade secret (as defined in the Economic Espionage Act) that is: (A) made in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and made solely for the purpose of reporting or investigating a suspected violation of law; or, (B) made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal so that it is not made public; and (ii) an individual who pursues a lawsuit for retaliation by an employer for reporting a suspected violation of the law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual files any document containing the trade secret under seal, and does not disclose the trade secret, except as permitted by court order.

13. NO WAIVER. No terms or conditions of this Agreement shall be deemed to have been waived, nor shall any party hereto be stopped from enforcing any provisions of the Agreement, except by written instrument of the party charged with such waiver or estoppel. Any written waiver shall not be deemed a continuing waiver unless specifically stated, shall operate only as to the specific term or condition waived, and shall not constitute a waiver of such term or condition for the future or as to any act other than specifically waived.

14. GOVERNING LAW. This Agreement shall be governed by, construed in accordance with, and enforced under the internal laws of the State of Utah (without giving effect to its conflicts of law principles). Any legal proceeding based on a dispute arising hereunder will be maintained exclusively in federal or state courts with jurisdiction over Salt Lake County in the State of Utah.

15. ENTIRE AGREEMENT. This Agreement contains the entire agreement of the parties hereto in regard to the subject matter hereof and may only be changed by written documentation signed by the party against whom enforcement of the waiver, change, modification, extension, or discharge is sought. Except as provided herein, this Agreement supersedes all prior written or oral agreements by and among the Company or any of its subsidiaries or affiliates and Consultant or any of its affiliates.

16. SECTION HEADINGS. Headings contained herein are for convenient reference only. They are not a part of this Agreement and are not to affect in any way the substance or interpretation of this Agreement.

17. SEVERABILITY. If a court of competent jurisdiction adjudicates any covenant or obligation under this Agreement void or unenforceable, then the Parties intend that the court modify such provision only to the extent necessary to render the covenant or obligation enforceable as modified or, if the covenant or obligation cannot be so modified, the Parties intend that the court sever such covenant or obligation, and that the remainder of this Agreement, and all remaining covenants, obligations and provisions as so modified, shall remain valid, enforceable, and in full force and effect.

18. BINDING EFFECT. This Agreement is binding upon and inures to the benefit of the parties hereto and their respective successors and assigns, subject to the restriction on assignment contained in Section 10 of this Agreement.

19. ATTORNEY'S FEES. The prevailing party in any legal proceeding arising out of or resulting from this Agreement shall be entitled to recover its costs and fees, including, but not limited to, reasonable attorneys' fees and post judgment costs, from the other party.

20. AUTHORIZATION. The persons executing this Agreement on behalf of the Company and Consultant hereby represent and warrant to each other that they are the duly authorized representatives of their respective entities and that each has taken all necessary corporate or partnership action to ratify and approve the execution of this Agreement in accordance with its terms.

21. ADDITIONAL DOCUMENTS. Each of the parties to this Agreement agrees to provide such additional duly executed (in recordable form, where appropriate) agreements, documents, and instruments as may be reasonably requested by the other party in order to carry out the purposes and intent of this Agreement.

22. NOTICES. Any notice required or permitted to be given pursuant to this Agreement shall be in writing (unless otherwise specified herein) and shall be deemed effectively given upon personal delivery or upon receipt by the addressee by courier or by email addressed to each of the other Parties thereunto entitled at the respective address listed below, with a copy by email, or at such other addresses as a party may designate by ten (10) days prior written notice:

If to the Company:
PolarityTE MD, Inc.
Attn: Legal Department
1960 S 4250 W
Salt Lake City, UT 84104
E: Contracts@polarityte.com

If to Consultant:
David Seaburg
XXXXXXXXXXXX
XXXXXXXXXXXX
E: XXXXXXXXXX

23. COUNTERPARTS & SIGNATURES. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original and all of which shall constitute one Agreement. This Agreement, agreements ancillary to this Agreement, and related documents entered into in connection with this Agreement are signed when a party's signature is delivered by facsimile, email, scan, PDF, or another electronic medium. A facsimile, scanned, or other signature delivered via electronic medium shall be deemed in all respects as having the same force and effect as an original signature.

[Signature Page Follows]

IN WITNESS WHEREOF, this Agreement has been executed and delivered as of the date first written above.

For POLARITYTE, INC., and POLARITYTE MD, INC.

By: */s/ Jacob Patterson*
Name: Jacob Patterson
Title: CFO

CONSULTANT

/s/ David Seaburg
David Seaburg

SCHEDULE A

Introduction. Consultant will provide the necessary labor, supervision, equipment, materials, tools, safety, and incidentals for the Scope of Services (as defined below). The following sections provide general information concerning the scope of work, protocols, deliverables, conditions, and mutual agreement associated with the service requirements.

Scope of Services. Consultant shall perform Services at the Company's request, but in no event shall the Company request nor the Consultant provide more than 20 hours of service per week on average each month. Upon the Company's request, Consultant may be responsible for the following non-exhaustive list of activities, subject to further specification in the future:

- Assist with strategic planning;
- Provide capital markets advice;
- Assist the Company with the planning and implementation of public relations programs; and,
- Assist with maintaining physician relationships

Compensation. In consideration for Consultant's performance of the Services set forth in this Schedule A, the Company shall pay to Consultant the following compensation:

(1) $37,500 for each three-month period of service during the term of this Agreement paid in the form of common stock of PTE in that number of shares equal to $37,500 divided by the closing price (as reported on Nasdaq) for the common stock of PTE on the last day of the three-month period of service with respect to which the compensation is paid; provided, however, that for any period of service less than three-months the compensation paid will be prorated on the basis of the actual number of days of service during the period and the number of shares issued will be determined on the basis of the closing price on the last day of service.

(2) On the first scheduled payroll payment date of each calendar month MD shall pay to Consultant cash in an amount equal to $1,600.

(3) MD will make no deductions from any of the payments due to Consultant hereunder for state or federal tax purposes. Consultant agrees that it shall be solely responsible for any and all taxes and other payments due on payments received from the Company.

Reimbursement of Expenses. MD shall reimburse Consultant for all reasonable and necessary business and travel expenses actually incurred by Consultant in performing the Services, subject to receipt of a written request for reimbursement, accompanied by appropriate supporting documentation. MD shall reimburse Consultant for expenses not less frequently than monthly. Consultant will not incur any travel or other expense in excess of $500 for which it will seek reimbursement from MD without the prior written approval of MD.

EXHIBIT 31.1

CERTIFICATION

I, Richard Hague, certify that:

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

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

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

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

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

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

Date: November 10, 2021

/s/ Richard Hague

Chief Executive Officer
(Principal 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 officers 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 we 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 quarterly 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 officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 10, 2021

/s/ Jacob Patterson

Chief Financial Officer
(Principal 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 September 30, 2021 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2021

/s/ Richard Hague
Richard Hague
Chief Executive Officer

/s/ Jacob Patterson
Jacob Patterson
Chief Financial Officer