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

FORM 10-Q

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

For the quarterly period ended June 30, 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 August 5, 2021, there were 81,382,372 shares of the Registrant's common stock outstanding.

INDEX

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.

PART I - FINANCIAL INFORMATION
Item 1. Financial Statements:

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

	June 30, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 32,614	$ 25,522
Accounts receivable, net	2,042	3,819
Inventory	76	883
Prepaid expenses and other current assets	2,286	992
Total current assets	37,018	31,216
Property and equipment, net	8,684	10,550
Operating lease right-of-use assets	1,756	2,452
Intangible assets, net	447	542
Goodwill	278	278
Other assets	227	472
TOTAL ASSETS	$ 48,410	$ 45,510
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 3,924	$ 4,148
Other current liabilities	2,509	2,106
Current portion of long-term notes payable	–	2,059
Deferred revenue	86	168
Total current liabilities	6,519	8,481
Common stock warrant liability	14,059	5,975
Operating lease liabilities	550	1,476
Other long-term liabilities	514	723
Long-term notes payable	–	1,517
Total liabilities	21,642	18,172
Commitments and Contingencies (Note 14)		
STOCKHOLDERS' EQUITY		
Preferred stock - 25,000,000 shares authorized, 0 shares issued and outstanding at June 30, 2021 and December 31, 2020	–	–
Common stock – $.001 par value; 250,000,000 shares authorized; 80,742,443 and 54,857,099 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	81	55
Additional paid-in capital	525,496	505,494
Accumulated deficit	(498,809)	(478,211)
Total stockholders' equity	26,768	27,338
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 48,410	$ 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 June 30,		For the Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Net revenues				
Products	$ 1,195	$ 944	$ 2,924	$ 1,372
Services	1,342	1,322	4,322	1,827
Total net revenues	2,537	2,266	7,246	3,199
Cost of sales				
Products	207	275	448	615
Services	717	607	2,641	783
Total cost of sales	924	882	3,089	1,398
Gross profit	1,613	1,384	4,157	1,801
Operating costs and expenses				
Research and development	4,190	3,164	6,621	6,537
General and administrative	4,941	5,211	11,312	15,816
Sales and marketing	1,099	2,024	2,625	5,718
Restructuring and other charges	11	2,084	436	2,536
Total operating costs and expenses	10,241	12,483	20,994	30,607
Operating loss	(8,628)	(11,099)	(16,837)	(28,806)
Other income (expenses)				
Gain on extinguishment of debt	3,612	–	3,612	–
Change in fair value of common stock warrant liability	1,807	(1,591)	(2,220)	2,941
Inducement loss on sale of liability classified warrants	–	–	(5,197)	–
Interest expense, net	(39)	(65)	(77)	(77)
Other income, net	60	78	121	225
Net loss	$ (3,188)	$ (12,677)	$ (20,598)	$ (25,717)
Net loss per share attributable to common stockholders				
Basic	$ (0.04)	$ (0.33)	$ (0.26)	$ (0.72)
Diluted	$ (0.04)	$ (0.33)	$ (0.26)	$ (0.72)
Weighted average shares outstanding				
Basic	80,602,931	38,428,289	78,392,881	35,724,141
Diluted	81,162,256	38,428,289	78,392,881	35,724,141

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

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Net loss	$ (3,188)	$ (12,677)	$ (20,598)	$ (25,717)
Other comprehensive income/(loss):				
Unrealized gain on available-for-sale securities	–	7	–	11
Reclassification of realized gains included in net loss	–	(10)	–	(83)
Comprehensive loss	$ (3,188)	$ (12,680)	$ (20,598)	$ (25,789)

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

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

	For the Three and Six Months Ended June 30, 2021					
	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Number	Amount	Capital	Income	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

	For the Three and Six Months Ended June 30, 2020					
	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Number	Amount	Capital	Income	Deficit	Equity
Balance – December 31, 2019	27,374,653	$ 27	$ 474,174	$ 72	$ (435,357)	$ 38,916
Issuance of common stock, net of issuance costs of $1,319	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

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

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

	For the Six Months Ended June 30,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (20,598)	$ (25,717)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,124	3,784
Depreciation and amortization	1,437	1,549
Amortization of intangible assets	95	95
Amortization of debt discount	–	13
Bad debt expense	134	–
Inventory write-off	697	–
Gain on extinguishment of debt – PPP loan	(3,612)	–
Change in fair value of common stock warrant liability	2,220	(2,941)
Inducement loss on sale of liability classified warrants	5,197	–
Loss on restructuring and other charges	269	–
Loss on abandonment of property and equipment	–	1,529
Loss on sale of property and equipment	7	–
Other non-cash adjustments	–	(21)
Changes in operating assets and liabilities:		
Accounts receivable	1,643	(384)
Inventory	110	(29)
Prepaid expenses and other current assets	(1,294)	(1,189)
Operating lease right-of-use assets	666	899
Other assets	245	3
Accounts payable and accrued expenses	(221)	(2,109)
Other current liabilities	(14)	9
Deferred revenue	(82)	(1)
Operating lease liabilities	(728)	(903)
Net cash used in operating activities	(10,705)	(25,413)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(18)	(1,170)
Proceeds from sale of property and equipment	10	–
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 (used in) provided by investing activities	(8)	17,802
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from term note payable and financing arrangements	1,028	4,629
Principal payments on term note payable and financing arrangements	(359)	(830)
Principal payments on financing leases	(272)	(243)
Net proceeds from the sale of common stock and warrants	–	24,276
Net proceeds from the sale of common stock, warrants and pre-funded warrants	9,884	–
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	(188)	(6)
Proceeds from stock options exercised	3	31
Proceeds from ESPP purchase	28	40
Net cash provided by financing activities	17,805	27,897
Net increase in cash and cash equivalents	7,092	20,286
Cash and cash equivalents - beginning of period	25,522	10,218
Cash and cash equivalents - end of period	$ 32,614	$ 30,504
Supplemental cash flow information:		
Cash paid for interest	$ 66	$ 81
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	$ –
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

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 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 investigational new drug application (IND) under Section 351 of that Act, under an enforcement discretion position stated by the United States Food and Drug Administration (FDA) in a regenerative medicine policy framework to help facilitate regenerative medicine therapies. On or about April 21, 2021, the FDA announced that enforcement discretion would not be extended beyond May 31, 2021. As a result of this development and based on the Company's interactions with the FDA, the Company planned to file its IND in the second half of 2021 and decided to terminate commercial sales of SkinTE on May 31, 2021, and wind down its SkinTE commercial operation. As a result, there will be no revenues from commercial SkinTE sales after June 2021, and the Company expects corresponding costs will be lower in the second half of 2021 compared to the first half of 2021.

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 June 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 $0.3 million for the three months ended June 30, 2021, in research and development within the accompanying consolidated statement of operations. The Company recorded inventory charges of $0.7 million for the six months ended June 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 June 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 records 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 consist of a single performance obligation that the Company satisfies at a point in time. In general, the Company recognizes product revenue upon delivery to the customer.

In the contract services segment, the Company records service revenues from the sale of its 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 June 30, 2021, and December 31, 2020, the Company had unbilled receivables of $0.3 million and $0.2 million, respectively, and deferred revenue of $0.1 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 six months ended June 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 six months ended June 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 six months ended June 30, 2021 and 2020.

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, and is currently evaluating the impact that the standard will have 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 June 30, 2021, the Company had an accumulated deficit of $498.8 million. As of June 30, 2021, the Company had cash and cash equivalents of $32.6 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):

	June 30, 2021			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities:				
Common stock warrant liability	$ –	$ –	$ 14,059	$ 14,059
Total	$ –	$ –	$ 14,059	$ 14,059

	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 six months ended June 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 June 30, 2021
Warrant liabilities					
February 14, 2020 issuance	$ 328	$ –	$ 168	$ –	$ 496
December 23, 2020 issuance	5,647	–	3,802	(8,964)	485
January 14, 2021 issuance	–	8,629	(1,700)	–	6,929
January 25, 2021 issuance	–	6,199	(50)	–	6,149
Inducement loss on initial fair value (1)	–	–	5,197	–	–
Total	$ 5,975	$ 14,828	$ 7,417	$ (8,964)	$ 14,059

(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 six months ended June 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 June 30, 2020
Warrant liabilities					
February 14, 2020 issuance	$ –	$ 11,677	$ (2,941)	$ –	$ 8,736

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 six months ended June 30, 2021, are as follows:

	For the Six Months ended June 30, 2021
Stock price	$ 1.02 – 1.21
Exercise price	$ 0.10 – 1.38
Risk-free rate	0.42 – 1.13%
Volatility	99.0 – 102.8%
Remaining term (years)	4.48 – 5.87

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

	For the Six Months ended June 30, 2020
Stock price	$ 1.24 – 1.69
Exercise price	$ 2.80
Risk-free rate	0.45 – 1.51%
Volatility	93.4 – 97.5%
Remaining term (years)	6.62 – 6.99

5. PROPERTY AND EQUIPMENT, NET

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

	June 30, 2021	December 31, 2020
Machinery and equipment	$ 11,139	$ 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	7	87
Furniture and equipment	144	148
Total property and equipment, gross	16,526	17,814
Accumulated depreciation and amortization	(7,842)	(7,264)
Total property and equipment, net	$ 8,684	$ 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. On or about April 21, 2021, the FDA announced that enforcement discretion would not be extended beyond May 31, 2021. As a result of this development and based on the Company's interactions with the FDA, 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 operation. 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 six months ended June 30, 2021. There was no impairment charge recorded during the second quarter of 2021.

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
General and administrative expense	$ 292	$ 408	$ 596	$ 800
Research and development expense	444	389	841	749
Total depreciation and amortization expense	$ 736	$ 797	$ 1,437	$ 1,549

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 obtain 6,307 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 9 to 34 months as of June 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 June 30, 2021, the maturities of operating and finance lease liabilities were as follows (in thousands):

	Operating leases	Finance leases
2021 (excluding the six months ended June 30, 2021)	$ 744	$ 327
2022	1,219	405
2023	3	336
2024	2	43
Total lease payments	1,968	1,111
Less:		
Imputed interest	(122)	(116)
Total	$ 1,846	$ 995

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

Finance leases	June 30, 2021	December 31, 2020
Finance lease right-of-use assets included within property and equipment, net	$ 961	$ 1,301
Current finance lease liabilities included within other current liabilities	$ 483	$ 556
Non-current finance lease liabilities included within other long-term liabilities	512	711
Total finance lease liabilities	$ 995	$ 1,267

Operating leases

	June 30, 2021	December 31, 2020
Current operating lease liabilities included within other current liabilities	$ 1,296	$ 1,485
Operating lease liabilities – non current	550	1,476
Total operating lease liabilities	$ 1,846	$ 2,961

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Operating lease costs included within operating costs and expenses	$ 393	$ 548	$ 787	$ 1,104
Finance lease costs:				
Amortization of right-of-use assets	$ 163	$ 174	$ 328	$ 349
Interest on lease liabilities	26	39	56	82
Total	$ 189	$ 213	$ 384	$ 431

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

	For the Six Months Ended June 30,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash out flows from operating leases	$ 849	$ 1,108
Operating cash out flows from finance leases	$ 56	$ 82
Financing cash out flows from finance leases	$ 272	$ 243
Lease liabilities arising from obtaining right-of-use assets:		
Remeasurement of operating lease liability due to lease modification/termination	$ 386	$ 131

As of June 30, 2021, and December 31, 2020, the weighted average remaining lease term for operating leases was 1.4 and 2.1 years, respectively, and the weighted average discount rate used for operating leases was 9.94% and 9.75%, respectively. As of June 30, 2021, and December 31, 2020, the weighted average remaining lease term for finance leases was 2.3 and 2.6 years, respectively, and the weighted average discount rate used for finance leases was 9.78% for both periods.

7. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

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

	June 30, 2021	December 31, 2020
Accounts payable	$ 265	$ 1,193
Salaries and other compensation	1,463	1,129
Legal and accounting	151	241
Accrued severance	147	330
Benefit plan accrual	560	659
Clinical trials	534	–
Accrued offering costs	400	–
Other	404	596
Total accounts payable and accrued expenses	$ 3,924	$ 4,148

8. OTHER CURRENT LIABILITIES

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

	June 30, 2021	December 31, 2020
Current finance lease liabilities	$ 483	$ 556
Current operating lease liabilities	1,296	1,485
Short-term financing arrangement	709	20
Other	21	45
Total other current liabilities	$ 2,509	$ 2,106

The short-term financing balance is related to a financing arrangement entered into during the six months ended June 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 June 30, 2021, the Company had 1,423,724 shares available for future issuances under the 2020 Plan.

2019 Plan

On October 5, 2018, the Company's Board approved the Company's 2019 Equity Incentive Plan (the "2019 Plan"). The 2019 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights and other types of stock-based awards to the Company's employees, officers, directors and consultants. The Compensation Committee of the Board will administer the 2019 Plan, including determining which eligible participants will receive awards, the number of shares of common stock subject to the awards and the terms and conditions of such awards. Up to 3,000,000 shares of common stock are issuable pursuant to awards under the 2019 Plan. Unless earlier terminated by the Board, the 2019 Plan shall terminate at the close of business on October 5, 2028. As of June 30, 2021, the Company had 11,159 shares available for future issuances under the 2019 Plan.

2017 Plan

On December 1, 2016, the Company's Board approved the Company's 2017 Equity Incentive Plan (the "2017 Plan"). The purpose of the 2017 Plan is to promote the success of the Company and to increase stockholder value by providing an additional means through the grant of awards to attract, motivate, retain and reward selected employees, consultants and other eligible persons. The 2017 Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights and other types of stock-based awards to the Company's employees, officers, directors and consultants. The Compensation Committee of the Board will administer the 2017 Plan, including determining which eligible participants will receive awards, the number of shares of common stock subject to the awards and the terms and conditions of such awards. Up to 7,300,000 shares of common stock are issuable pursuant to awards under the 2017 Plan. Unless earlier terminated by the Board, the 2017 Plan shall terminate at the close of business on December 1, 2026. As of June 30, 2021, the Company had 184,467 shares available for future issuances under the 2017 Plan.

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

	Number of Shares		Weighted-Average Exercise Price
Outstanding – December 31, 2020	4,794,567	$	10.03
Granted	1,410,231	$	1.29
Exercised (1)	(2,500)	$	1.10
Forfeited	(262,082)	$	12.38
Outstanding – June 30, 2021	5,940,216	$	7.85
Options exercisable, June 30, 2021	4,370,581	$	10.18

(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 reserved 500,000 shares of common stock for purchase under the ESPP. The initial offering period began January 1, 2019, and ended on June 30, 2019, with the first purchase date. Subsequent offering periods will automatically commence on each January 1 and July 1 and will have a duration of six months ending with a purchase date June 30 and December 31 of each year. On each purchase date, ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of (1) the fair market value per share of the common stock on the offering date or (2) the fair market value of the common stock on the purchase date.

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	3,363,997
Vested (1)	(1,233,371)
Forfeited	(165,870)
Unvested – June 30, 2021	5,433,725

(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 June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
General and administrative expense	$ 1,104	$ 143	$ 2,333	$ 3,220
Research and development expense	273	404	596	367
Sales and marketing expense	96	16	195	197
Restructuring and other charges	167	–	167	–
Total stock-based compensation expense	$ 1,640	$ 563	$ 3,291	$ 3,784

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

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 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 expire five years form 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 June 30, 2021, using the following inputs:

Accompanying common warrants:

	January 14, 2021	June 30, 2021
Stock price	$ 1.21	$ 1.02
Exercise price	$ 1.20	$ 1.20
Risk-free rate	0.49%	0.78%
Volatility	100.1%	102.0%
Remaining term (years)	5.0	4.5

Placement agent warrants:

	January 14, 2021	June 30, 2021
Stock price	$ 1.21	$ 1.02
Exercise price	$ 1.38	$ 1.38
Risk-free rate	0.49%	0.78%
Volatility	99.3%	102.0%
Remaining term (years)	5.0	4.5

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 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 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 June 30, 2021, using the following inputs:

Accompanying new common stock warrants:

	January 25, 2021	June 30, 2021
Stock price	$ 1.02	$ 1.02
Exercise price	$ 1.20	$ 1.20
Risk-free rate	0.42%	0.78%
Volatility	99.0%	102.0%
Remaining term (years)	5.0	4.6

Placement agent warrants:

	January 22, 2021	June 30, 2021
Stock price	$ 1.05	$ 1.02
Exercise price	$ 1.20	$ 1.20
Risk-free rate	0.44%	0.78%
Volatility	99.6%	102.0%
Remaining term (years)	5.0	4.6

The following table summarizes warrant activity for the six months ended June 30, 2021.

	Outstanding December 31, 2020	Warrants Issued	Warrants Exercised	Outstanding June 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 June 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 Six Months Ended	
Numerator:	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
Net loss	$ (3,188)	$ (12,677)	$ (20,598)	$ (25,717)
Less: Gain from change in fair value of warrant liabilities	(107)	–	–	–
Net loss available to common stockholders	$ (3,295)	$ (12,677)	$ (20,598)	$ (25,717)

Denominator:	For the Three Months Ended June 30, 2021	For the Three Months Ended June 30, 2020	For the Six Months Ended June 30, 2021	For the Six Months Ended June 30, 2020
Basic weighted average number of common shares (1)	80,602,931	38,428,289	78,392,881	35,724,141
Incremental shares from assumed exercise of warrants	559,325	–	–	–
Diluted weighted average number of common shares	81,162,256	38,428,289	78,392,881	35,724,141

(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 June 30, 2021	For the Three Months Ended June 30, 2020	For the Six Months Ended June 30, 2021	For the Six Months Ended June 30, 2020
Stock Options	5,940,216	5,110,582	5,940,216	5,110,582
Restricted stock	5,433,725	4,331,324	5,433,725	4,331,324
Common stock warrants	18,133,360	10,638,298	19,314,143	10,638,298

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 make 24 monthly payments of principal and interest in the amount of $150,563. The promissory note evidencing the Loan contains customary events of default relating to, among other things, payment defaults, making materially false and misleading representations to the SBA or Lender, or breaching the terms of the Loan documents. The occurrence of an event of default may result in the repayment of all amounts outstanding, collection of all amounts owing from the Borrower, or filing suit and obtaining judgment against the Borrower. Under the terms of the CARES Act, PPP loan recipients can apply for and be granted forgiveness for all or a portion of a loan granted under the PPP. 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, 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 both the three and six months ended June 30, 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 operation. 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. The Company recognized $0.1 million of expense related to employee severance and benefit arrangements for the three and six-month periods ended June 30, 2021. Severance costs will be paid by the end of the third quarter of 2021. The Company also recognized incremental expense of $0.2 million for the three and six-month periods ending June 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.

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 provides that Arches will perform specimen testing services for customers referred by Co-Diagnostics to Arches. Co-Diagnostics will arrange all logistics for delivering specimens to Arches for COVID-19 testing for those customers of Co-Diagnostics electing to use the service. Arches bills Co-Diagnostics for the testing services and Co-Diagnostics manages all customer billing. The Rental Agreement for LGC Genomics Oktopure Extraction Machine between Arches and Co-Diagnostics provides that Co-Diagnostics will 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 is 12 months and requires 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 can be canceled by the Company at any time by providing 60 days written notice, and the Rental Agreement can 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 is July 26, 2021, and no longer in effect on July 27, 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 with an initial payment due in July 2021 of $510,857, and then payable periodically as services are provided over the nearly three-year term of the clinical trial. Either party may terminate the agreement without cause on 60 days' notice to the other party.

Legal Proceedings

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. At June 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 June 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 approximately 7,250 square feet of rental space in the building located at 40 West 57th Street in New York City. The lease is for a term of three years. The annual lease rate is $60 per square foot. Initially the Company 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. During Q1 2021, the Company decreased the space leased from 5,500 square feet to 4,747 square feet. The Company is using 1,099 square feet, and Cohen LLC is using approximately 3,648 square feet as of June 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 $63,000 of sublease income related to this agreement for the three months ended June 30, 2021 and 2020, respectively, and $109,000 and $132,000 for the six months ended June 30, 2021 and 2020, respectively. The sublease income is included in other income, net in the condensed consolidated statement of operations. As of June 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 June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Net revenues by segment:				
Reportable segments:				
Regenerative medicine	$ 1,195	$ 944	$ 2,924	$ 1,372
Contract services	1,342	1,322	4,322	1,827
Total net revenues	$ 2,537	$ 2,266	$ 7,246	$ 3,199
Net (loss)/income by segment:				
Reportable segments:				
Regenerative medicine	$ (3,229)	$ (12,567)	$ (20,931)	$ (25,270)
Contract services	41	(110)	333	(447)
Total net loss	$ (3,188)	$ (12,677)	$ (20,598)	$ (25,717)

17. SUBSEQUENT EVENT

The COVID-19 Laboratory Services Agreement between Arches and Co-Diagnostics described in Note 14, above, terminated and was no longer in effect on July 27, 2021. On July 28, 2021, Arches gave written notice to Co-Diagnostics that it was terminating the Rental Agreement for LGC Genomics Oktopure Extraction Machine between Arches and Co-Diagnostics effective that day.

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, 2021, 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. SkinTE was registered and listed with the United States Food and Drug Administration ("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 is prudent to submit an investigational new drug application ("IND") for SkinTE and an eventual biologics license application ("BLA") because we believe it will create a more valuable asset with a greater likelihood of achieving widespread commercial adoption, and to avoid the possibility of a protracted dispute with the FDA. On July 23, 2021, we submitted an IND through our subsidiary, PolarityTE MD, Inc., and our business resources and activities are now focused primarily on advancing our IND, which if accepted by the FDA, will allow us to conduct clinical trials of a type that could potentially support a BLA application. We continued to sell SkinTE until 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 will not generate any revenue from the sale of SkinTE after the second quarter of 2021. We also eliminated our sales team on June 1, 2021, and moved to cut other costs associated with our commercial sales activity to offset the loss of SkinTE revenue.

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. At the end of May 2020, we began to offer COVID-19 testing services to generate additional revenue in the contract services segment and thereby help defray our operating expenses.

In the first quarter of 2021, 57% of our testing and research services net revenues were generated by COVID-19 testing and 93% of our COVID-19 testing revenues were obtained under 30-day renewable testing agreements with multiple nursing home and pharmacy facilities in the state of New York controlled by a single company (the "NY Client"). On March 26, 2021, we were advised by the NY Client it is adopting on-site employee testing at its facilities as allowed under new regulations in the state of New York. In June 2021, the number of tests performed for the NY Client was nil and we have not found customers to replace the revenue lost from the NY Client. In the second quarter of 2021, 10% of our testing and research services net revenues were generated by COVID-19 testing, and we expect this percentage will continue to decline unless and until we are able to locate new customers. We are a relatively unknown testing laboratory, so we have relied on word of mouth and management relationships to connect with prospects and vied for new business on the basis of price and service. We cannot predict how well, if at all, this marketing approach will work in finding new customers, how quickly we may be able to find new customers to replace the net revenues lost from the NY Client, or how much any such revenues may be. Even if we are able to find new customers for the COVID-19 testing business there remain substantial uncertainties around the COVID-19 testing business due to rapid developments in testing and vaccines. We intend to carefully monitor the performance of our COVID-19 testing business and scale our laboratory testing operations accordingly, and in the future may discontinue the testing business if we are unable to grow the business to a level where it is a positive contributor to our capital resources.

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 six months of 2021. The increase in revenues from IBEX services helped to offset the loss of COVID-19 testing revenues in the second quarter of 2021. Nevertheless, revenues from our services business declined 55% in the second quarter of 2021 compared to the first quarter of the year. Revenues from our services business were $4.3 million for the first six months of 2021. Due to the circumstances described above, we expect revenues from our services business will be significantly less in the last six months of 2021 compared to the last six months of 2020.

PPP Loan

As previously reported in the Current Report on Form 8-K filed with the SEC on April 15, 2020, our subsidiary, PolarityTE MD, Inc. (the "Borrower"), 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 the Borrower 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, the Borrower applied to the Lender for forgiveness of the PPP Loan in its entirety (as provided for in the CARES Act) based on the Borrower's use of the PPP Loan for payroll costs, rent, and utilities. On October 26, 2020, the Borrower 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 the Borrower'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, relieving the Borrower of any liability.

Our Plan Going Forward

Our business resources are, and will be for the foreseeable future, focused primarily on the advancement of our IND and subsequent 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 IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA within the 30-day time period raises concerns or questions about the conduct of the clinical trial. In such a case, the IND sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin.

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. It should be noted that the design and parameters of the DFU Trial could change as a result of the FDA's response to our IND. 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.

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 Use IND is limited to our direct costs of manufacture. Accordingly, Expanded Access INDs are not a means of replacing revenue we lost when we ceased commercial sale of SkinTE, but we believe this may enable us to provide SkinTE to providers treating persons with life-threatening or serious diseases and conditions and maintain on-going relationships with physicians we believe to be key opinion leaders 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.

Liquidity and Capital Resources

As of June 30, 2021, we had $32.6 million in cash and cash equivalents and working capital of approximately $30.5 million. We believe the cash and cash equivalents on our balance sheet will fund our business activities through the end of 2021 and into, but not beyond, the third quarter of 2022. In the second quarter of 2021 cash used in operating activities was $4.1 million, or an average of $1.4 million per month, compared to $6.6 million cash used in operating activities, or an average of $2.2 million per month, in the first quarter of 2021 and compared to $11.6 million cash used in operating activities, or an average of $3.9 million per month, in the second quarter of 2020.

In June 2021 our PPP Loan in the amount of $3.6 million was forgiven, so we will not need to use our capital resources to repay the PPP Loan in future periods.

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 with an initial payment due in July 2021 of $0.5 million and then payable periodically as services are provided over the nearly three-year term of the DFU Trial. 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 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 will not contribute to defraying our operating costs in the foreseeable future. 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. The cessation of our commercial SkinTE operation in the second quarter is likely to have an adverse effect on our working capital in future periods that we cannot predict at this time.

In the six-month period ended June 30, 2021, the gross profit from services amounted to approximately $1.7 million, which contributed to covering our operating costs for the period. As discussed above, we expect our service revenue will be substantially diminished on a go forward basis due to the loss of COVID-19 testing business. There was a significant loss of COVID-19 testing revenues in the second quarter of 2021 that was partially offset by increased preclinical research revenues generated by IBEX, so services revenues decreased in the second quarter of 2021, compared to the first quarter of the year. 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. We cannot predict whether or to what extent our COVID-19 testing business will recover, if at all, in future periods. 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. The loss of COVID-19 business in the second quarter of 2021 will likely have an adverse effect on our working capital in future periods that we cannot predict at this time.

As of the date of issuance of these unaudited interim condensed financial statements, we expect that our cash and cash equivalents of $32.6 million as of June 30, 2021, will not be sufficient to fund our current business plan including related operating expenses and capital expenditure requirements beyond July 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 such 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

Comparison of the six months ended June 30, 2021, compared to the six months ended June 30, 2020.

(in thousands)	For the Six Months Ended		Increase (Decrease)	
	June 30, 2021	June 30, 2020	Amount	%
	(Unaudited)			
Net revenues				
Products	$ 2,924	$ 1,372	$ 1,552	113%
Services	4,322	1,827	2,495	137%
Total net revenues	7,246	3,199	4,047	127%
Cost of sales				
Products	448	615	(167)	-27%
Services	2,641	783	1,858	237%
Total cost of sales	3,089	1,398	1,691	121%
Gross profit	4,157	1,801	2,356	131%
Operating costs and expenses				
Research and development	6,621	6,537	84	1%
General and administrative	11,312	15,816	(4,504)	-28%
Sales and marketing	2,625	5,718	(3,093)	-54%
Restructuring and other charges	436	2,536	(2,100)	-83%
Total operating costs and expenses	20,994	30,607	(9,613)	-31%
Operating loss	(16,837)	(28,806)	11,969	-42%
Other income (expense)				
Gain on extinguishment of debt	3,612	–	3,612	*
Change in fair value of common stock warrant liability	(2,220)	2,941	(5,161)	-175%
Inducement loss on sale of liability classified warrants	(5,197)	–	(5,197)	*
Interest income (expense), net	(77)	(77)	–	0%
Other income, net	121	225	(104)	-46%
Net loss	$ (20,598)	$ (25,717)	$ 5,119	-20%

* Not meaningful

Comparison of the three months ended June 30, 2021, compared to the three months ended June 30, 2020.

(in thousands)	For the Three Months Ended		Increase (Decrease)	
	June 30, 2021	June 30, 2020	Amount	%
	(Unaudited)			
Net revenues				
Products	$ 1,195	$ 944	$ 251	27%
Services	1,342	1,322	20	2%
Total net revenues	2,537	2,266	271	12%
Cost of sales				
Products	207	275	(68)	-25%
Services	717	607	110	18%
Total cost of sales	924	882	42	5%
Gross profit	1,613	1,384	229	17%
Operating costs and expenses				
Research and development	4,190	3,164	1,026	32%
General and administrative	4,941	5,211	(270)	-5%
Sales and marketing	1,099	2,024	(925)	-46%
Restructuring and other charges	11	2,084	(2,073)	-99%
Total operating costs and expenses	10,241	12,483	(2,242)	-18%
Operating loss	(8,628)	(11,099)	2,471	-22%
Other income (expense)				
Gain on extinguishment of debt	3,612	–	3,612	*
Change in fair value of common stock warrant liability	1,807	(1,591)	3,398	-214%
Inducement loss on sale of liability classified warrants	–	–	–	*
Interest income (expense), net	(39)	(65)	26	-40%
Other income, net	60	78	(18)	-23%
Net loss	$ (3,188)	$ (12,677)	$ 9,489	-75%

* Not meaningful

Discussion of Results of Operations

There have been significant changes in items affecting our results of operations for the six-month period ended June 30, 2021, compared to the six-month period ended June 30, 2020, due to:

- The decision in April 2020 to file an IND with the FDA for SkinTE and, as a result, transition from a commercial stage company to a clinical stage company;
- The COVID-19 testing business that began in the last week of May 2020 that generated significant services revenues through March 2021, but has since substantially diminished; and
- The COVID-19 pandemic, which had a negative impact on revenues from the sale of SkinTE and IBEX services in the six-month period ended June 30, 2020, but not in the six-month period ended June 30, 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 March and May 2020 and on June 1, 2021, and reducing the services and infrastructure needed to support a larger work force and commercial sales effort.

Net Revenues. Net revenues increased $4.0 million, or 127%, for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, and $0.3 million, or 12%, for the three months ended June 30, 2021, compared to the same period in 2020.

We effectuated a substantial reduction in force for our commercial operations in May 2020, which together with the effect of COVID-19 on selling product to healthcare institutions caused us to adopt a sales strategy in May 2020 to focus on regions and facilities where we had repeat users of SkinTE. As a result of this strategy, products net revenues increased by 113% for the six-month period ended June 30, 2021, compared to the same period in 2020. Products net revenues also showed an increase 27% for the three-months ended June 30, 2021, compared to the same period in 2020, even though we ceased making product sales at the end of May 2021.

Net revenues from services remained essentially unchanged for the three months ended June 30, 2021, compared to the same period in 2020, but the mix of business activity generating those revenues changed from a majority of service revenues generated by COVID-19 testing in the second quarter of 2020 to a majority of service revenues generated by pre-clinical research services in 2021. Our COVID-19 testing services continued to be a significant contributor to overall services revenues in the first quarter of 2021 and, as a result, our services revenues increased 137% for the six months ended June 30, 2021, compared to the same period in 2020.

Cost of Sales. Cost of sales increased $1.7 million, or 121%, for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, and $0.04 million, or 5%, for the three months ended June 30, 2021, compared to the same period in 2020.

Cost of sales for products revenues decreased 27% period over period for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, and decreased 25% period over period for the three months ended June 30, 2021, compared to the three months ended June 30, 2020, even though revenues were higher in 2021 for both the six and three-month periods, which is attributable to the economies of scale we achieved by selling product for larger wound sizes in 2021 compared to 2020.

Cost of sales for services revenues increased 237% period over period for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, and increased 18% period over period for the three months ended June 30, 2021, compared to the three months ended June 30, 2020, which is primarily attributable to the cost of sales pertaining to the COVID-19 testing service that only began in the last week of May 2020, including a write-off of inventory for the COVID-19 testing business in the first quarter of 2021 due to the substantial decrease in that business during the quarter.

Operating Costs and Expenses. Operating costs and expenses decreased $9.6 million, or 31%, for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, and $2.2 million, or 18%, for the three months ended June 30, 2021, compared to the same period in 2020.

Research and development expenses increased 1% period over period for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, and increased 32% period over period for the three months ended June 30, 2021, compared to the three months ended June 30, 2020. The substantial increase in the three-month period ended June 30, 2021, is primarily attributable to the costs in our clinical trials driven by completing our diabetic foot ulcers trial, increase in lab supplies for work on preparing the technical items for our IND, and consulting services for preparing our IND, which was only partially offset by savings from reductions in staff made during the second quarter of 2020 in the research and development department.

As noted above, we effectuated a substantial reduction in force for our commercial operations in May 2020. Consequently, there were significant reductions in cash compensation, stock compensation, consulting fees, and travel expense, as well as significant credits from forfeiture of stock awards by persons no longer employed by us. 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. The cost cutting measures described above are the primary causes of a 28% decrease in general and administrative expense period over period for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, and 5% decrease period over period for the three months ended June 30, 2021, compared to the three months ended June 30, 2020.

When we reduced our commercial sales team and related commercial activities beginning in May 2020, we also took steps to reduce staff and consultants in sales and marketing. Consequently, there were significant reductions in cash compensation, stock compensation, consulting fees, and travel expense, as well as significant credits from forfeiture of stock awards by persons no longer employed by us, which resulted in a 54% decrease in sales and marketing expense for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, and 46% decrease for the three months ended June 30, 2021, compared to the same period in 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 six-month period ended June 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 six month-period ended June 30, 2021, we recognized a loss on impairment of property and equipment in the amount of $0.4 million and severance charges of $0.3 million, which were offset by a $0.3 million gain on the termination of our Augusta node lease. Consequently, there was an 83% decrease in restructuring and other charges for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, and 99% decrease for the three months ended June 30, 2021, compared to the same period in 2020.

Operating Loss and Net Loss. Operating loss decreased $12.0 million, or 42%, for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, and $2.5 million, or 22%, for the three months ended June 30, 2021, compared to the same period in 2020. Net loss decreased $5.1 million, or 20%, for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, and $9.5 million, or 75%, for the three months ended June 30, 2021, compared to the same period in 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 charge for common stock warrants of $2.2 million for the six months ended June 30, 2021, and recorded a gain of $1.8 million for the three months ended June 30, 2021. 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 six months ended June 30, 2021, this gain was offset by a day one loss on warrants issued in January 2021 of $5.2 million plus a loss on the change in fair value of common stock warrant liability of $2.2 million, which are primarily responsible for other expense of $3.8 million for the six months ended June 30, 2021, and the $3.8 million difference between our operating loss and net loss for the six months ended June 30, 2021.

As noted above, we recognized the gain on the PPP Loan forgiveness in the second quarter of 2021. There was no day one loss on warrants issued recorded in the second quarter of 2021, but there was a gain on the change in fair value of common stock warrant liability of $1.8 million. Consequently, we recognized other income for the three months ended June 30, 2021, of $5.4 million, which is the primary cause for the reduction of our net loss compared to our operating loss.

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 June 30,		For the Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
GAAP Net Loss	$ (3,188)	$ (12,677)	$ (20,598)	$ (25,717)
Change in fair value of common stock warrant liability	(1,807)	1,591	2,220	(2,941)
Inducement loss on sale of liability classified warrants	–	–	5,197	–
Non-GAAP adjusted net loss attributable to common stockholders - basic	$ (4,995)	$ (11,086)	$ (13,181)	$ (28,658)
Gain from change in fair value of warrant liabilities	(107)	–	–	–
Non-GAAP adjusted net loss attributable to common stockholders - diluted	$ (5,102)	$ (11,086)	$ (13,181)	$ (28,658)
GAAP net loss per share attributable to common stockholders				
Basic	$ (0.04)	$ (0.33)	$ (0.26)	$ (0.72)
Diluted	$ (0.04)	$ (0.33)	$ (0.26)	$ (0.72)
Non-GAAP adjusted net loss per share attributable to common stockholders				
Basic	$ (0.06)	$ (0.29)	$ (0.17)	$ (0.80)
Diluted	$ (0.06)	$ (0.29)	$ (0.17)	$ (0.80)

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 Item 1A. Risk Factors, beginning on page 20.

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 June 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 June 30, 2021.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

You should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, which could materially affect our business, financial position, or future results of operations. The risks described in that Annual Report are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially, adversely affect our business, financial position, or future results of operations.

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 $20.6 million for the six months ended June 30, 2021, and at June 30, 2021, we had an accumulated deficit of $498.8 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 to, but not beyond, July 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.

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

During the three-month period ended June 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
April 2021	47,238	$ 0.90	N/A	N/A
May 2021	–	$ –	N/A	N/A
June 2021	10,020	$ 1.12	N/A	N/A
Total	57,258	$ 1.01		

Item 5. Other Information

We began a multicenter, randomized controlled trial evaluating SkinTE plus standard of care (SOC) versus SOC alone in treatment of diabetic foot ulcers (the "DFU RCT"). In July 2021, we announced final data from the DFU RCT. The size of the study is 100 patients who were evaluated across 13 sites, with 50 participants receiving SkinTE plus SOC and 50 receiving SOC alone. The trial met the primary endpoint of wound closure at 12 weeks and secondary endpoint of Percent Area Reduction (PAR) assessed at 4, 6, 8, 10, and 12 weeks. Final analysis of the DFU RCT shows the following:

- **Primary Endpoint:** 70% (35/50) of participants receiving SkinTE plus SOC had wound closure at 12 weeks versus 34% (17/50) of participants receiving SOC alone (p=0.00032)
- **Secondary Endpoint:** Percent Area Reduction (PAR) assessed at 4, 6, 8, 10, and 12 weeks was significantly greater for the SkinTE plus SOC treatment group vs SOC alone (p=0.009)
- 90% (45/50) of SkinTE plus SOC treated participants received a single application of SkinTE
- Treatment with SkinTE plus SOC increased the odds of wound closure by 5.37 times versus SOC (p=0.001)

Mean (SD) values for PAR at weeks 4, 6, 8, 10, and 12 by treatment group

Week	SkinTE	SOC
4	74.0 (27.63)	22.0 (149.92)
6	82.9 (26.35)	21.2 (160.60)
8	80.7 (35.16)	26.8 (147.42)
10	79.7 (54.07)	45.6 (114.18)
12	84.3 (39.46)	50.5 (92.24)

- 148 Adverse Events (AEs) were allocated to 49 subjects. The SkinTE plus SOC treatment group had 66 AEs allocated to 21 subjects while the SOC treatment group had 82 AEs allocated to 28 subjects. There were 26 Serious Adverse Events (SAEs), 12 in the SkinTE plus SOC treatment group (7 subjects) and 14 in the SOC treatment group (9 subjects).

- Wound size for the SkinTE plus SOC treatment group was 3.5 cm^2 versus 3.2 cm^2 for the SOC treatment group (p=0.46). A comparison by treatment group for wound-related variables showed that variables were well balanced between groups with the exception of sharp debridement count, which was marginally statistically significantly higher in the SOC group compared to the SkinTE group, due to shorter wound closure times in the SkinTE group.

We incorporated data from the trial as part of the IND we submitted to the FDA on July 23, 2021, but the DFU RCT will not be considered to be a registrational trial as part of a BLA submission.

Item 6. Exhibits

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

31.1	Certification Pursuant to Rule 13a-14(a)
31.2	Certification Pursuant to Rule 13a-14(a)
32.1	Certification Pursuant to Rule 13a-14(b) and Section 1350, Chapter 63 of Title 18, United States Code
101.INS	XBRL Instance Document - the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document
101.SCH	XBRL Schema Document
101.CAL	XBRL Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Label Linkbase Document
101.PRE	XBRL Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

POLARITYTE, INC.

Date: August 12, 2021

/s/ David Seaburg

David Seaburg
Chief Executive Officer
Duly Authorized Officer

Date: August 12, 2021

/s/ Jacob Patterson

Jacob Patterson
Interim Chief Financial Officer
Chief Accounting Officer

EXHIBIT 31.1

CERTIFICATION

I, David Seaburg, certify that:

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

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

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

4. The registrant's other certifying 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: August 12, 2021

/s/ David Seaburg

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: August 12, 2021

/s/ Jacob Patterson

Interim 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 June 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: August 12, 2021

/s/ David Seaburg
David Seaburg
Chief Executive Officer

/s/ Jacob Patterson
Jacob Patterson
Interim Chief Financial Officer