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

FORM 10-Q

☒ Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended March 31, 2022

or

□ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Transition Period from _____to_____

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 May 11, 2022, there were 100,005,969 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)

	March 31, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	$ 18,723	$ 19,375
Accounts receivable, net	10	978
Assets held for sale	3,550	441
Prepaid expenses and other current assets	1,988	1,595
Total current assets	24,271	22,389
Property and equipment, net	4,197	6,923
Operating lease right-of-use assets	854	1,146
Other assets	720	720
TOTAL ASSETS	$ 30,042	$ 31,178
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 4,609	$ 3,115
Other current liabilities	2,221	1,520
Deferred revenue	–	74
Liabilities held for sale	215	–
Total current liabilities	7,045	4,709
Common stock warrant liability	4,868	6,844
Operating lease liabilities	74	43
Other long-term liabilities	262	338
Total liabilities	12,249	11,934
Commitments and Contingencies (Note 16)		
STOCKHOLDERS' EQUITY		
Preferred stock – 25,000,000 shares authorized, 0 shares issued and outstanding at March 31, 2022 and December 31, 2021	–	–
Common stock - $.001 par value; 250,000,000 shares authorized; 99,334,758 and 82,484,462 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	99	82
Additional paid-in capital	529,863	527,560
Accumulated deficit	(512,169)	(508,398)
Total stockholders' equity	17,793	19,244
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 30,042	$ 31,178

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

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

	For the Three Months Ended March 31,	
	2022	**2021**
Net revenues		
Products	$ –	$ 1,729
Services	741	2,980
Total net revenues	741	4,709
Cost of revenues		
Products	–	241
Services	491	1,924
Total costs of revenues	491	2,165
Gross profit	250	2,544
Operating costs and expenses		
Research and development	2,860	2,431
General and administrative	6,209	6,371
Sales and marketing	–	1,526
Restructuring and other charges	–	425
Impairment of assets held for sale	54	–
Total operating costs and expenses	9,123	10,753
Operating loss	(8,873)	(8,209)
Other income (expense), net		
Change in fair value of common stock warrant liability	5,105	(4,027)
Inducement loss on sale of liability classified warrants	–	(5,197)
Interest expense, net	(15)	(38)
Other income, net	12	61
Net loss and comprehensive loss	$ (3,771)	$ (17,410)
Net loss per share attributable to common stockholders		
Basic	$ (0.04)	$ (0.23)
Diluted	$ (0.09)	$ (0.24)
Weighted average shares outstanding		
Basic	84,113,385	76,158,275
Diluted	89,399,261	76,396,078

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

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

	For the Three Months Ended March 31, 2022						
	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Number	Amount	Number	Amount	Capital	Deficit	Equity
Balance – December 31, 2021	–	$ –	82,484,462	$ 82	$ 527,560	$ (508,398)	$ 19,244
Issuance of preferred stock and warrants through underwritten offering, net of issuance costs of $184	5,000	–	–	–	1,685	–	1,685
Issuance of common stock upon conversion of preferred stock	(5,000)	–	16,393,445	16	(16)	–	–
Stock-based compensation expense	–	–	–	–	762	–	762
Vesting of restricted stock units	–	–	641,894	1	(1)	–	–
Shares withheld for tax withholding	–	–	(185,043)	–	(127)	–	(127)
Net loss	–	–	–	–	–	(3,771)	(3,771)
Balance – March 31, 2022	–	$ –	99,334,758	$ 99	$ 529,863	$ (512,169)	$ 17,793

	For the Three Months Ended March 31, 2021				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Number	Amount	Capital	Deficit	Equity
Balance – December 31, 2020	54,857,099	$ 55	$ 505,494	$ (478,211)	$ 27,338
Issuance of common stock and pre-funded warrants through underwritten offering, net of issuance costs of $114	6,670,000	7	1,248	–	1,255
Issuance of common stock upon exercise of warrants	10,713,543	10	6,661	–	6,671
Reclassification of warrant liability upon exercise	–	–	8,964	–	8,964
Issuance of common stock upon exercise of pre-funded warrants	7,658,953	8	–	–	8
Stock-based compensation expense	–	–	1,651	–	1,651
Stock option exercises	2,500	–	3	–	3
Vesting of restricted stock units	565,427	–	–	–	–
Shares withheld for tax withholding	(116,593)	–	(139)	–	(139)
Forfeiture of restricted stock awards	(34,620)	–	–	–	–
Net loss	–	–	–	(17,410)	(17,410)
Balance – March 31, 2021	80,316,309	$ 80	$ 523,882	$ (495,621)	$ 28,341

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

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

	For the Three Months Ended March 31,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (3,771)	$ (17,410)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	762	1,651
Depreciation and amortization	455	701
Impairment of assets held for sale	54	–
Amortization of intangible assets	–	47
Bad debt expense	–	97
Inventory write-off	–	391
Change in fair value of common stock warrant liability	(5,105)	4,027
Inducement loss on sale of liability classified warrants	–	5,197
Loss on restructuring and other charges	–	425
(Gain) Loss on sale of property and equipment	(2)	7
Changes in operating assets and liabilities:		
Accounts receivable	256	(598)
Inventory	–	119
Prepaid expenses and other current assets	(393)	(1,639)
Operating lease right-of-use assets	292	328
Other assets/liabilities, net	–	245
Accounts payable and accrued expenses	1,702	138
Other current liabilities	(1)	(15)
Deferred revenue	(52)	39
Operating lease liabilities	(238)	(360)
Net cash used in operating activities	(6,041)	(6,610)
CASH FLOWS FROM (USED IN) INVESTING ACTIVITIES		
Purchase of property and equipment	(31)	(12)
Proceeds from sale of property and equipment	7	10
Net cash used in investing activities	(24)	(2)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from insurance financing arrangements	1,027	1,028
Principal payments on term note payable and financing arrangements	(10)	(9)
Principal payments on financing leases	(116)	(135)
Net proceeds from the sale of common stock, warrants and pre-funded warrants	–	9,884
Proceeds from the sale of warrants	–	1,002
Proceeds from warrants exercised	–	6,671
Proceeds from pre-funded warrants exercised	–	8
Proceeds from the sale of warrants and preferred stock net of issuance costs	4,814	–
Cash paid for tax withholdings related to net share settlement	(127)	(125)
Proceeds from stock options exercised	–	3
Net cash provided by financing activities	5,588	18,327
Net increase (decrease) in cash and cash equivalents, including cash classified within assets held for sale	(477)	11,715
Less: net increase in cash and cash equivalents classified within assets held for sale	175	–
Net increase (decrease) in cash and cash equivalents	(652)	11,715
Cash and cash equivalents - beginning of period	19,375	25,522
Cash and cash equivalents - end of period	$ 18,723	$ 37,237
Supplemental cash flow information:		
Cash paid for interest	$ 16	$ 31
Supplemental schedule of non-cash investing and financing activities:		
Fair value of placement agent warrants issued in connection with offering	$ 144	$ 838
Reclassification of warrant liability to stockholders' equity upon exercise of warrant	$ –	$ 8,964
Conversion of Series A and Series B preferred stock into common stock	$ 16	$ –
Allocation of financing to warrant liability	$ 3,129	$ 8,629
Deferred and accrued offering costs	$ 104	$ 500
Reclassification of assets held for sale	$ 3,163	$ –
Reclassification of liabilities held for sale	$ 215	$ –

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.

The Company's first regenerative tissue product is SkinTE. In July 2021, the Company submitted an investigational new drug application ("IND") for SkinTE to the United States Food and Drug Administration (the "FDA") through its subsidiary, PolarityTE MD, Inc. Prior to June 1, 2021, the Company sold SkinTE under Section 361 of the Public Health Service Act in 2020 and into 2021 and, after the Company's decision to file an IND under Section 351 of that Act, under an enforcement discretion position stated by the FDA in a regenerative medicine policy framework to help facilitate regenerative medicine therapies. The FDA's stated period of enforcement discretion ended May 31, 2021. Consequently, the Company terminated commercial sales of SkinTE on May 31, 2021, ceased its SkinTE commercial operations, and transitioned to a clinical stage company pursuing an IND for SkinTE. As a result, there were no product sales from commercial SkinTE after June 2021. The only revenues recognized subsequent to June 2021 for SkinTE were nominal amounts collected on accounts for product shipped prior to the end of May 2021 that were not previously recognized because of concerns with collectability. No revenue for SkinTE was recognized during the three months ended March 31, 2022.

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 accounting principles generally accepted in the United States of America (U.S. GAAP) 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, 2021, has been derived from the audited consolidated financial statements at that date but does not include all of the information and footnotes required by 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, 2021, filed with the Securities and Exchange Commission on Form 10-K on March 30, 2022.

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 allowance for deferred tax assets, 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 March 31, 2022, the Company did not hold any cash equivalents.

Assets and Liabilities Held for Sale. Assets and liabilities to be disposed ("disposal group") of by sale are reclassified into assets held for sale and liabilities held for sale on the Company's condensed consolidated balance sheet. The reclassification occurs when an agreement to sell exists, or management has committed to a plan to sell the assets within one year. Disposal groups are measured at the lower of carrying value or fair value less costs to sell and are not depreciated or amortized. The fair value of a disposal group, less any costs to sell, is assessed each reporting period it remains classified as held for sale and any remeasurement to the lower of carrying value or fair value less costs to sell is reported as an adjustment to the carrying value of the disposal group.

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.

Impairment of Long-Lived Assets. The Company reviews long-lived assets, including property and equipment for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows.

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

The Company recorded product revenues primarily from the sale of SkinTE, its regenerative tissue product. When the Company marketed its SkinTE product, it was sold to healthcare providers (customers), primarily through direct sales representatives. Product revenues consisted of a single performance obligation that the Company satisfied at a point in time. In general, the Company recognized product revenue upon delivery to the customer.

In the contract services segment, the Company records service revenues from the sale of its preclinical research services, which includes delivery of preclinical studies and other research services to unrelated third parties. Service revenues generally consist of a single performance obligation that the Company satisfies over time using an input method based on costs incurred to date relative to the total costs expected to be required to satisfy the performance obligation. The Company believes that this method provides an appropriate measure of the transfer of services over the term of the performance obligation based on the remaining services needed to satisfy the obligation. This requires the Company to make reasonable estimates of the extent of progress toward completion of the contract. As a result, unbilled receivables and deferred revenue are recognized based on payment timing and work completed. Generally, a portion of the payment is due upfront and the remainder upon completion of the contract, with most contracts completing in less than a year. Contract services also includes research and laboratory testing services to unrelated third parties on a contract basis. Due to the short-term nature of the services, these customer contracts generally consist of a single performance obligation that the Company satisfies at a point in time. The Company satisfies the single performance obligation and recognizes revenue upon delivery of testing results to the customer. As of March 31, 2022 and December 31, 2021, the Company had unbilled receivables of $0.3 million and $0.5 million, respectively, and deferred revenue of less than $0.1 million and $0.1 million, respectively. As of March 31, 2022, the unbilled receivable and deferred revenue balances are included in assets held for sale and liabilities held for sale, respectively. Revenue of $0.1 million was recognized during the three months ended March 31, 2022 that was included in the deferred revenue balance as of December 31, 2021.

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 agreement. 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 at fair value each period until settled or until classified as equity.

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

The fair value for options issued is estimated at the date of grant using a Black-Scholes option-pricing model. The risk-free rate is derived from the U.S. Treasury yield curve in effect at the time of the grant 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 recognized as 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), outstanding warrants and preferred stock 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 loss for the period is allocated between common stockholders and participating securities according to dividends declared and participation rights in undistributed losses. No loss was allocated to the warrants or preferred stock for the three months ended March 31, 2022 and 2021 as we incurred a loss for each period and the warrant and preferred stockholders 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 basic 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.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (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 was effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years with early adoption permitted. In November 2019, the FASB issued ASU No. 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates*, which defers the effective date of Topic 326. As a smaller reporting company, Topic 326 will now be effective for the Company beginning January 1, 2023. As such, the Company plans to adopt this ASU beginning January 1, 2023. The Company is currently evaluating the impact that the standard will have on its consolidated financial statements and related disclosures.

Recently Adopted Accounting Pronouncements

In August 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. The Company early adopted this ASU for the fiscal year beginning January 1, 2022. The adoption of this ASU did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

In May 2021, the FASB issued ASU 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)*, which 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 adopted this ASU prospectively for the fiscal year beginning January 1, 2022. 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 GOING CONCERN

The Company is a clinical stage biotechnology company that has incurred recurring losses and negative cash flows from operations since commencing its biotechnology business in 2017. As of March 31, 2022, the Company had an accumulated deficit of $512.2 million. As of March 31, 2022, the Company had cash and cash equivalents of $18.7 million. The Company has been funded historically through sales of equity and debt.

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. 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):

	March 31, 2022			
	Level 1	Level 2	Level 3	Total
Liabilities				
Common stock warrant liability	$ –	$ –	$ 4,868	$ 4,868
Total	$ –	$ –	$ 4,868	$ 4,868

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Liabilities				
Common stock warrant liability	$ –	$ –	$ 6,844	$ 6,844
Total	$ –	$ –	$ 6,844	$ 6,844

The Company assesses its assets held for sale, long-lived assets, including property, plant, and equipment and ROU assets at fair value on a non-recurring basis. The Company reviews the carrying amounts of such assets when events indicate that their carrying amounts may not be recoverable. Any resulting impairment would require that the asset be recorded at its fair value. During the three months ended March 31, 2022, the Company recognized an impairment charge of $0.1 million related to equipment classified in assets held for sale. During the three months ended March 31, 2021, the Company recognized an impairment charge of $0.4 million related to property and equipment. As of each measurement date, the fair value of assets held for sale and property and equipment was determined utilizing Level 3 inputs and were based on a market approach. See Notes 7 and Note 15 for additional details.

The following table presents the change in fair value of the liability classified common stock warrants for the three months ended March 31, 2022 (in thousands):

	Fair Value at December 31, 2021	Initial Fair Value at Issuance	(Gain) Loss Upon Change in Fair Value	Fair Value at March 31, 2022
Warrant liabilities				
February 14, 2020 issuance	$ 291	$ –	$ (179)	$ 112
December 23, 2020 issuance	239	–	(166)	73
January 14, 2021 issuance	3,345	–	(1,856)	1,489
January 25, 2021 issuance	2,969	–	(1,649)	1,320
March 16, 2022 issuance	–	3,129	(1,255)	1,874
Total	$ 6,844	$ 3,129	$ (5,105)	$ 4,868

The following table presents the change in fair value of the liability classified common stock warrants for the three months ended March 31, 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 at March 31, 2021
Warrant liabilities					
February 14, 2020 issuance	$ 328	$ –	$ 217	$ –	$ 545
December 23, 2020 issuance	5,647	–	3,861	(8,964)	544
January 14, 2021 issuance	–	8,629	(797)	–	7,832
January 25, 2021 issuance[(1)]	–	6,199	746	–	6,945
Total	$ 5,975	$ 14,828	$ 4,027	$ (8,964)	$ 15,866

(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 during the three-month period ended March 31, 2021, 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 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 are as follows:

	For the Three Months ended March 31, 2022
Stock price	$ 0.25 – 0.34
Exercise price	$ 0.10 – 1.38
Risk-free rate	1.95 – 2.44%
Volatility	98.4 – 103.6%
Remaining term (years)	1.96 – 4.87

	For the Three Months ended March 31, 2021
Stock price	$ 1.02 – 1.21
Exercise price	$ 0.10 – 1.38
Risk-free rate	0.42 – 1.13%
Volatility	99.0 – 102.7%
Remaining term (years)	4.73 – 5.87

5. ASSETS AND LIABILITIES HELD FOR SALE

In November 2021, the Company committed to a plan to sell a variety of lab equipment within the regenerative medicine products reporting segment. The lab equipment has been designated as held for sale and is presented as such within the condensed consolidated balance sheet as of December 31, 2021 and March 31, 2022.

In March 2022, the Company reached a nonbinding understanding with an unrelated third party that contemplates the sale of IBEX Preclinical Research, Inc. ("IBEX"), the Company's subsidiary which operates within the contract services reporting segment, along with the real property used in the operation of IBEX. The assets and liabilities related to IBEX have been designated as held for sale and are presented as such within the condensed consolidated balance sheet as of March 31, 2022. As of March 31, 2022, the Company measured the assets and liabilities held for sale at the lower of their carrying value or fair value less costs to sell. The operating results of IBEX do not qualify for reporting as discontinued operations.

The following table presents information related to the assets and liabilities that were classified as held for sale (amounts in thousands):

	March 31, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 175	$ –
Accounts receivable, net	712	–
Property and equipment, net	2,663	441
Total assets held for sale	3,550	441
Liabilities		
Accounts payable and accrued expenses	187	–
Other current liabilities	3	–
Deferred revenue	22	–
Other long-term liabilities	3	–
Total liabilities held for sale	215	–
Total net assets held for sale	$ 3,335	$ 441

During the three months ended March 31, 2022, the Company recorded impairment of $0.1 million related to lab equipment designated as held for sale within the regenerative medicine products reporting segment.

6. PREPAID EXPENSES AND OTHER CURRENT ASSETS

The following table presents the major components of prepaid expenses and other current assets (in thousands):

	March 31, 2022	December 31, 2021
Other current receivable	$ 285	$ 67
Short term deposit	150	150
Prepaid insurance	1,062	239
Prepaid expenses	387	445
Deferred offering costs	104	694
Total prepaid expenses and other current assets	$ 1,988	$ 1,595

7. PROPERTY AND EQUIPMENT, NET

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

	March 31, 2022	December 31, 2021
Machinery and equipment	$ 7,782	$ 8,502
Land and buildings	–	2,000
Computers and software	1,107	1,129
Leasehold improvements	2,038	2,107
Construction in progress	–	133
Furniture and equipment	119	123
Total property and equipment, gross	11,046	13,994
Accumulated depreciation	(6,849)	(7,071)
Total property and equipment, net	$ 4,197	$ 6,923

The Company sold SkinTE under Section 361 of the Public Health Service Act in 2020 and into 2021 and, after the Company's decision to file an IND under Section 351 of that Act, under an enforcement discretion position stated by the FDA in a regenerative medicine policy framework to help facilitate regenerative medicine therapies. The FDA's stated period of enforcement discretion ended May 31, 2021. Consequently, the Company terminated commercial sales of SkinTE on May 31, 2021, and ceased its SkinTE commercial operations. As a result, there are no product sales from commercial SkinTE after June 2021 and the Company has eliminated or reduced costs associated with commercial sale of SkinTE.

The Company evaluated the future use of its commercial property and equipment and recorded an impairment charge of approximately $0.4 million during the three months ended March 31, 2021. The impairment charge occurred within the Company's regenerative medicine products business segment and is included in restructuring and other charges within the accompanying condensed consolidated statement of operations for the three months ended March 31, 2021. There were no restructuring charges recorded for the three months ended March 31, 2022. See Note 15.

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

	For the Three Months Ended March 31,	
	2022	2021
General and administrative expense	$ 49	$ 304
Research and development expense	406	397
Total depreciation and amortization expense	$ 455	$ 701

8. LEASES

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

Operating Leases

On December 27, 2017, the Company entered into a commercial lease agreement (the "Lease") with Adcomp LLC (the "Landlord") pursuant to which the Company leases approximately 178,528 rentable square feet of warehouse, manufacturing, office, and lab space in Salt Lake City, Utah (the "Property") 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 and an option to purchase the Property at a purchase price of $17.5 million. The initial base rent under the 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.

On December 16, 2021, the Company gave written notice to the Landlord of its election to exercise the option to purchase the Property, and on March 14, 2022, the Company and Landlord entered into a definitive purchase and sale agreement that provides for a closing of the transaction on November 15, 2022 (the "Purchase Agreement"). In connection with exercising the option to purchase the Property, the Company made an earnest money deposit of $150,000 that may be refunded if closing conditions or contingencies running in the Company's favor are not satisfied or the Landlord defaults in its obligations under the lease or the purchase agreement for the Property. On October 25, 2021, the Company signed a Purchase and Sale Agreement, the terms of which were finalized on December 10, 2021, and subsequently amended by Amendment No. 1 thereto dated March 15, 2022 (the "BCG Agreement"), with BCG Acquisitions LLC ("BCG"). Under the BCG Agreement the Company agreed to sell the Property to BCG or its assigns for $17.5 million after the Company's purchase of the Property from the Landlord. The BCG Agreement provides that the Company and BCG will enter into at closing of the sale of the Property to BCG a 126-month lease, which is included as an exhibit to the BCG Agreement, for approximately 62,500 square feet of space in the building on the Property. Under the BCG Agreement, BCG made an initial earnest money deposit totaling $200,000, which the parties subsequently agreed to reduce to $150,000, that will be refunded if the Company is unable to complete the purchase of the Property from the Landlord under the Purchase Agreement on a timely basis, closing conditions or contingencies running in favor of BCG are not satisfied, or the Company defaults in its obligations under the BCG Agreement. Closing of the foregoing transactions are subject to a number of risks and uncertainties including, but not limited to, satisfaction of all closing conditions, including obtaining financing for the purchase, and closing on the purchase of the Property from the landlord under the Purchase Agreement, and satisfaction of all closing conditions, including obtaining financing for the purchase, and closing on the sale of the Property to BCG under the BCG Agreement.

In April 2019, the Company entered into an operating lease to obtain 6,307 square feet of manufacturing, laboratory, and office space. The lease provided for monthly lease payments subject to annual increases and had an expiration date in April 2024. During 2020, the Company initiated a business analysis to determine the long-term strategy of the remote facility and cost to remain operational. It was determined that the Company would cease operations and vacate the facility. The Company terminated the lease on June 30, 2021.

In November 2021, the Company entered into an operating lease to obtain office equipment with Pacific Office Automation, Inc. The initial term of the lease is three years and it expires on November 2024. The initial base rent under this lease is $3,983 per month for the entire lease term and includes a cash incentive of $0.1 million. Because the rate implicit in the lease is not readily determinable, the Company has used an incremental borrowing rate of 7.42% to determine the present value of the lease payments.

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 less than 1 month to 25 months as of March 31, 2022 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 10% to determine the present value of the lease payments for these leases.

As of March 31, 2022, the maturities of operating and finance lease liabilities were as follows (in thousands):

	Operating leases	Finance leases
2022 (excluding the three months ended March 31, 2022)	$ 920	$ 243
2023	48	312
2024	42	42
Total lease payments	1,010	597
Less:		
Imputed interest	(36)	(52)
Total	$ 974	$ 545

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

Finance leases

	March 31, 2022	December 31, 2021
Finance lease right-of-use assets included within property and equipment, net	$ 405	$ 461
Current finance lease liabilities included within other current liabilities	$ 283	$ 329
Non-current finance lease liabilities included within other long-term liabilities	262	338
Total	$ 545	$ 667

Operating leases

	March 31, 2022	December 31, 2021
Current operating lease liabilities included within other current liabilities	$ 900	$ 1,169
Operating lease liabilities – non-current	74	43
Total	$ 974	$ 1,212

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

	For the Three Months Ended March 31,	
	2022	2021
Operating lease costs included within operating costs and expenses	$ 318	$ 394
Finance lease costs:		
Amortization of right of use assets	$ 51	$ 165
Interest on lease liabilities	16	30
Total	$ 67	$ 195

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

	For the Three Months Ended March 31,	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash out flows from operating leases	$ 264	$ 426
Operating cash out flows from finance leases	$ 16	$ 30
Financing cash out flows from finance leases	$ 116	$ 135
Lease liabilities arising from obtaining right-of-use assets:		
Remeasurement of operating lease liability due to lease modification/termination	$ –	$ 37

As of March 31, 2022 and December 31, 2021, the weighted average remaining lease term for operating leases was 0.9 and 1.0 years, respectively, and the weighted average discount rate used for operating leases was 9.75% and 9.96%, respectively. As of March 31, 2022 and December 31, 2021, the weighted average remaining lease term for finance leases was 1.9 and 2.0 years, respectively, and the weighted average discount rate used for finance leases was 9.62% and 9.63%, respectively.

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

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

	March 31, 2022	December 31, 2021
Accounts payable	$ 713	$ 173
Salaries and other compensation	711	722
Legal and accounting	2,277	1,082
Accrued severance	45	111
Benefit plan accrual	101	102
Clinical trials	200	161
Accrued offering costs	104	400
Other	458	364
Total accounts payable and accrued expenses	$ 4,609	$ 3,115

10. OTHER CURRENT LIABILITIES

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

	March 31, 2022	December 31, 2021
Current finance lease liabilities	$ 283	$ 329
Current operating lease liabilities	900	1,169
Short-term financing arrangement	1,034	–
Other	4	22
Total other current liabilities	$ 2,221	$ 1,520

The short-term financing balance is related to a financing arrangement entered into during the three months ended March 31, 2022 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%.

11. 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 Board designated the Compensation Committee of the Board the administrator of 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 10,488,717 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. Pursuant to the 2020 Plan, the number of shares of common stock available for issuance increased by 3,296,800 shares during January 2022. As of March 31, 2022, the Company had 3,695,164 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 Board designated the Compensation Committee of the Board the administrator of the 2019 Plan, including determining which eligible participants will receive awards, the number of shares of common stock subject to the awards and the terms and conditions of such awards. Up to 3,000,000 shares of common stock are issuable pursuant to awards under the 2019 Plan. Unless earlier terminated by the Board, the 2019 Plan shall terminate at the close of business on October 5, 2028. As of March 31, 2022, the Company had 30,904 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 Board designated the Compensation Committee of the Board the administrator of the 2017 Plan, including determining which eligible participants will receive awards, the number of shares of common stock subject to the awards and the terms and conditions of such awards. Up to 7,300,000 shares of common stock are issuable pursuant to awards under the 2017 Plan. Unless earlier terminated by the Board, the 2017 Plan shall terminate at the close of business on December 1, 2026. As of March 31, 2022, the Company had 469,083 shares available for future issuances under the 2017 Plan.

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

	Number of Shares	Weighted-Average Exercise Price
Outstanding – December 31, 2021	5,772,802	$ 7.91
Granted	8,000	$ 0.62
Forfeited	(470,106)	$ 13.46
Outstanding – March 31, 2022	5,310,696	$ 7.40
Options exercisable, March 31, 2022	4,634,297	$ 8.28

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, 2021	5,163,685
Granted	–
Vested[(1)]	(755,230)
Forfeited	(57,100)
Unvested – March 31, 2022	4,351,355

(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 March 31,	
	2022	2021
General and administrative expense	$ 546	$ 1,229
Research and development expense	216	323
Sales and marketing expense	–	99
Total stock-based compensation expense	$ 762	$ 1,651

12. STOCKHOLDERS' DEFICIT

December 2020 Offering

On December 23, 2020, the Company completed a registered direct offering of 5,450,000 shares of its common stock, par value $0.001 per share, pre-funded warrants to purchase up to 5,238,043 shares of common stock and accompanying common warrants to purchase up to 10,688,043 shares of common stock (the "December 2020 Warrants"). 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 $0.7485 and for each pre-funded warrant and accompanying warrant was $0.7475. The pre-funded warrants had an exercise price of $0.001 each and were exercised in full in January 2021. Each warrant was exercisable for one share of the Company's common stock at an exercise price of $0.624 per share. The warrants were immediately exercisable and expire five years from the date of issuance. The holder of the warrants could 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 could 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 641,283 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 $0.9356 per share). The net proceeds to the Company from the offering were $7.2 million, after offering expenses 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 $5.2 million and $0.3 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 are equity classified because they meet characteristics of the equity classification criteria. The total proceeds from the offering were first allocated to the liability classified warrants, based on their fair values, with the residual $2.5 million allocated on a relative fair value basis to the common stock and pre-funded common stock warrants. Issuance costs allocated to the equity classified pre-funded common stock warrants and common stock of $0.3 million were recorded as a reduction to paid-in capital. Issuance costs allocated to the liability classified warrants of $0.5 million were recorded as an expense.

January 2021 Offerings

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 (the "January 14 Warrants"). 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 January 14 Warrant is exercisable for one share of the Company's common stock at an exercise price of $1.20 per share. The January 14 Warrants are immediately exercisable and will expire five years from the date of issuance. The holder of the January 14 Warrants may not exercise any portion of such 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 January 14 Warrants and placement agent common stock warrants could each require cash settlement in certain scenarios, the January 14 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 are 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 fair values, with the residual $1.4 million allocated on a relative fair value basis to the common stock and pre-funded common stock warrants. 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 paid-in capital. Issuance costs allocated to the liability classified warrants of $0.7 million were recorded as an expense.

On January 22, 2021, the Company entered into a letter agreement with the holder of warrants to exercise the warrants and 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 (the "January 25 Warrants") (and together with the January 14 Warrants, the "Existing 2021 Warrants"). Each January 25 Warrant is exercisable for one share of Common Stock at an exercise price of $1.20 per share. The January 25 Warrants are immediately exercisable and will expire five years from the date of issuance. A holder may not exercise any portion of the January 25 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 December 2020 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 December 2020 Warrants in January 2021, a remeasurement loss of $3.6 million was recorded.

As the new January 25 Warrants and placement agent common stock warrants could each require cash settlement in certain scenarios, the new January 25 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.

March 2022 Offering

On March 16, 2022, the Company completed a registered direct offering of 3,000.000435 shares of Series A convertible preferred stock, 2,000.00029 shares of Series B convertible preferred stock and 16,393,445 warrants to purchase 16,393,445 shares of common stock (the "March 2022 Warrants"). Gross proceeds generated by the offering were $5.0 million. The exercise price of each warrant is $0.35 per share, the warrants become exercisable six months after the date of the offering and will expire two years from the offering date.

Concurrent with the closing of the offering on March 16, 2022, the Company modified the exercise price of the Existing 2021 Warrants. 9,090,910 warrants issued on January 14, 2021, and 8,016,033 warrants issued on January 25, 2021 were modified to reduce the exercise price from $1.20 to $0.35 per share. The exercise price of the placement agent warrants was not modified. The Existing 2021 Warrants remain outstanding and unexercised as of March 31, 2022.

The holders of Series A and Series B convertible preferred stock are entitled to receive dividend payments in the same form as dividends paid on shares of the common stock when, as and if such dividends are paid on shares of the common stock, on an if converted basis. In the event of a liquidation event, the holders of each series of convertible preferred stock are entitled to receive out of the assets, whether capital or surplus, of the Company the same amount that a holder of common stock would receive if the preferred stock were fully converted. Each share of preferred stock is convertible into a number of shares of the Company's common stock, at any time after the offering, at the option of the holder equal to $1,000 per share, divided by the conversion price of $0.305. On March 17, 2022 all shares of Series B preferred stock were converted into 6,557,378 shares of common stock. On March 29, 2022, all shares of Series A preferred stock were converted into 9,836,067 shares of common stock.

The holder of the March 2022 Warrants may not exercise any portion of such 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 5.0% of the aggregate number of March 2022 Warrants sold in the offering, or 819,672 warrants to purchase common stock. The placement agent warrants have substantially the same terms as the March 2022 Warrants, except that the placement agent warrants have an exercise price $0.381 per share, which is 125% of the price at which each share of preferred stock sold in the offering is convertible to common stock.

As the March 2022 Warrants and placement agent warrants could each require cash settlement in certain scenarios, the common stock warrants and placement agent warrants were classified as liabilities upon issuance and were initially recorded at estimated fair values of $3.0 million and $0.1 million, respectively. The Series A and Series B preferred stock 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 fair values, with the residual $1.9 million allocated to the preferred stock. The net proceeds to the Company from the offering were $4.5 million, after direct offering expenses of $0.2 attributable to equity classified preferred stock, which were recorded as a reduction to paid-in capital, and $0.3 million attributable to the liability classified March 2022 Warrants and private placement common stock warrants, which are included in general and administrative within the accompanying condensed consolidated statement of operations for the three months ended March 31, 2022. The Company measured the fair value of the common warrants and placement agent warrants using the Monte Carlo simulation model at issuance and again on March 31, 2022 using the following inputs:

Common warrants:

	March 16, 2022	March 31, 2022
Stock price	$ 0.34	$ 0.25
Exercise price	$ 0.35	$ 0.35
Risk-free rate	1.95%	2.26%
Volatility	101.5%	100.9%
Remaining term (years)	2.0	1.96

Placement agent warrants:

	March 16, 2022	March 31, 2022
Stock price	$ 0.34	$ 0.25
Exercise price	$ 0.38	$ 0.38
Risk-free rate	1.95%	2.26%
Volatility	101.5%	100.9%
Remaining term (years)	2.0	1.96

The following table summarizes warrant activity for the three months ended March 31, 2022:

Transaction	Outstanding December 31, 2021	Warrants Issued	Outstanding March 31, 2022
February 14, 2020 common warrants	539,500	–	539,500
December 23, 2020 placement agent warrants	641,283	–	641,283
January 14, 2021 common warrants	9,090,910	–	9,090,910
January 14, 2021 placement agent warrants	545,455	–	545,455
January 25, 2021 common warrants	8,016,033	–	8,016,033
January 22, 2021 placement agent warrants	480,962	–	480,962
March 16, 2022 common warrants	–	16,393,445	16,393,445
March 16, 2022 placement agent warrants	–	819,672	819,672
Total	19,314,143	17,213,117	36,527,260

On March 30, 2021, the Company entered into a sales agreement ("Sales Agreement") with an investment banking firm 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 the investment banking firm would act as sales agent. On February 28, 2022, the Company exercised its right to terminate the Sales Agreement and was obligated to make a one-time payment to the investment banking firm of $0.4 million. As a result of the termination of the Sales Agreement, the Company expensed previously capitalized deferred offering costs of $0.7 million which are included in general and administrative expense within the accompanying condensed consolidated statement of operations for the three months ended March 31, 2022. No common stock was sold under the Sales Agreement.

13. 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:

Numerator:	For the Three Months Ended March 31, 2022	For the Three Months Ended March 31, 2021
Net loss, primary	$ (3,771)	$ (17,410)
Less: gain from change in fair value of warrant liabilities	(4,694)	(755)
Net loss, diluted	$ (8,465)	$ (18,165)

Denominator:	For the Three Months Ended March 31, 2022	For the Three Months Ended March 31, 2021
Basic weighted average number of common shares[(1)]	84,113,385	76,158,275
Potentially dilutive effect of warrants	5,285,876	237,803
Diluted weighted average number of common shares	89,399,261	76,396,078

(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 in January 2021 and included in the denominator for the period of time the warrants were outstanding.

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

	For the Three Months Ended March 31,	
	2022	2021
Stock options	5,310,696	6,081,710
Restricted stock	4,351,355	3,061,070
Common stock warrants	1,667,700	10,223,233
Shares committed under ESPP	48,085	58,806

14. 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 and the Lender was paid by the SBA, including all accrued unpaid interest. The Company recorded the forgiveness of $3.6 million of principal and accrued interest, which were included in gain on extinguishment of debt on the consolidated statement of operations for the year ended December 31, 2021.

On September 17, 2021, the Company received notice from the Lender that the SBA is continuing to review the PPP Loan. As part of this review, the SBA requested documents that the Company is required to maintain but may not have been required to submit with its application for the PPP Loan. These documents included an affiliation worksheet showing the relationship between the Company and Borrower and affiliated subsidiaries, documents showing the use of the PPP Loan proceeds, documents showing the calculation of the loan amount requested in the Company's loan application, federal tax returns, and documents showing employee compensation information. The Company submitted the documents to the SBA through the Lender on September 28, 2021. There has been no additional communication from the SBA through the date of filing.

15. RESTRUCTURING

As discussed in Note 7, the Company decided to file an IND in the second half of 2021, cease commercial sales of SkinTE by May 31, 2021, and wind down its SkinTE commercial operations. As a result, management approved several actions as part of a restructuring plan. During the three months ended March 31, 2021, the Company recorded $0.4 million of restructuring charges related to property and equipment impairment. There were no restructuring charges recorded during the three months ended March 31, 2022.

16. COMMITMENTS AND CONTINGENCIES

Contingencies

Securities Class Action and Derivative Lawsuits

On September 24, 2021, a class action complaint alleging violations of the Federal securities laws was filed in the United States District Court, District of Utah, by Marc Richfield against the Company and certain officers of the Company, Case No. 2:21-cv-00561-BSJ. The Court subsequently appointed a Lead Plaintiff and ordered the Lead Plaintiff to file an amended Complaint by February 7, 2022, which was extended to February 21, 2022. The Lead Plaintiff filed an amended complaint on February 21, 2022, against the Company, two current officers of the Company, and three former officers of the Company (the "Complaint"). The Complaint alleges that during the period from January 30, 2018, through November 9, 2021, the defendants made or were responsible for, disseminating information to the public through reports filed with the Securities and Exchange Commission and other channels that contained material misstatements or omissions in violation of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, as amended, and Rule 10b-5 adopted thereunder. Specifically, the Complaint alleges that the defendants misrepresented or failed to disclose that: (i) the Company's product, SkinTE, was improperly registered as a 361 HCT/P under Section 361 of the Public Health Service Act and that, as a result, the Company's ability to commercialize SkinTE as a 361 HCT/P was not sustainable because it was inevitable SkinTE would need to be registered under Section 351 of the Public Health Service Act; (ii) the Company characterized itself as a commercial stage company when it knew sales of SkinTE as a 361 HCT/P were unsustainable and that, as a result, it would need to file an IND and become a development stage company; (iii) issues arising from an FDA inspection of the Company's facility in July 2018, were not resolved even though the Company stated they were resolved; and (iv) the IND for SkinTE was deficient with respect to certain chemistry, manufacturing, and control items, including items identified by the FDA in July 2018, and as a result it was unlikely that the FDA would approve the IND in the form it was originally filed. The Company filed a motion to dismiss the complaint for failure to state a claim, on April 22, 2022. The Company believes the allegations in the Complaint are without merit, and intends to defend the litigation, vigorously. At this early stage of the proceedings, we are unable to make any prediction regarding the outcome of the litigation.

On October 25, 2021, a stockholder derivative complaint alleging violations of the Federal securities laws was filed in the United States District Court, District of Utah, by Steven Battams against the Company, each member of the Board of directors, and two officers of the Company, Case No. 2:21-cv-00632-DBB (the "Stockholder Derivative Complaint"). The Stockholder Derivative Complaint alleges that the defendants made, or were responsible for, disseminating information to the public through reports filed with the Securities and Exchange Commission and other channels that contained material misstatements or omissions in violation of Sections 10(b) and 20(a) of the Securities and Exchange Act of 1934, as amended, and Rule 10b-5 adopted thereunder. Specifically, the Stockholder Derivative Complaint alleges that the defendants misrepresented or failed to disclose that: (i) the IND for the Company's product, SkinTE, filed with the FDA was deficient with respect to certain chemistry, manufacturing, and control items; (ii) as a result, it was unlikely that the FDA would approve the IND in its current form; (iii) accordingly, the Company had materially overstated the likelihood that the SkinTE IND would obtain FDA approval; and (iv) as a result, the public statements regarding the IND were materially false and misleading. The parties have stipulated to stay the Stockholder Derivative Complaint until (1) the dismissal of the Complaint described above, (2) denial of a motion to dismiss the Complaint, or (3) notice is given that any party is withdrawing its consent to the stipulated stay of the Stockholder Derivative Complaint proceeding. At this early stage of the proceedings the Company is unable to make any prediction regarding the outcome of the litigation.

Other Matters

In the ordinary course of business, the Company may become involved in lawsuits, claims, investigations, proceedings, and threats of litigation relating to intellectual property, commercial arrangements, employment, regulatory compliance, and other matters. Except as noted above, at March 31, 2022, 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.

Commitments

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

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

On June 25, 2021, the Company entered into a statement of work with a contract research organization to provide services for a proposed clinical trial described as a multi-center, prospective, randomized controlled trial evaluating the effects of SkinTE in the treatment of full-thickness diabetic foot ulcers at a cost of approximately $6.5 million consisting of $3.1 million of service fees and $3.4 million of estimated costs. In July 2021 the Company prepaid 10% of the total cost recited in the original work order, or $0.5 million, which will be applied to payment of the final invoice under the work order. Over the approximately three-year term of the clinical trial the service provider shall submit to the Company for payment invoices on a monthly basis for units of work stated in the work order that are completed and billable expenses incurred. During the three months ended March 31, 2022, the Company received invoices for work performed and expenses incurred totaling $0.2 million. Either party may terminate the agreement without cause on 60 days' notice to the other party.

17. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

On August 21, 2019, the Company and Dr. Denver Lough, a principal shareholder and former officer and director, signed a settlement terms agreement that provides, in part, that the Company pay to Dr. Lough $1,500,000 in cash on October 1, 2019 and an additional $1,500,000 in cash in equal monthly installments beginning November 1, 2019 and ending April 1, 2021. In addition, the Company agreed to award to Dr. Lough 200,000 restricted stock units that vest in 18 equal monthly installments beginning October 1, 2019. As of March 31, 2022, 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 would occupy and pay for only 3,275 square feet of space, and the Company was not obligated under the lease to pay for the remaining 3,975 square feet covered by the lease unless it elected to occupy that additional space. The Company believes the terms of the lease were very favorable to it, and the Company obtained the favorable terms through the assistance of Peter A. Cohen, a director, which he provided so that the company he owns, Peter A. Cohen, LLC ("Cohen LLC"), could sublease a portion of the office space. The lease expired on October 31, 2021. The Company recognized zero and $55,000 of sublease income for the three months ended March 31, 2022 and 2021, respectively. The sublease income is included in other income, net in the condensed consolidated statement of operations.

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

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

	For the Three Months Ended March 31,	
	2022	2021
Net revenues:		
Reportable segments:		
Regenerative medicine products	$ –	$ 1,729
Contract services	741	2,980
Total net revenues	$ 741	$ 4,709
Net income/(loss):		
Reportable segments:		
Regenerative medicine products	$ (3,545)	$ (17,702)
Contract services	(226)	292
Total net loss	$ (3,771)	$ (17,410)

19. SUBSEQUENT EVENTS

At the beginning of May 2018, the Company acquired a preclinical research and veterinary sciences business, which has been used for preclinical studies on the Company's regenerative tissue products and to offer preclinical research services to unrelated third parties on a contract basis. The Company operated this business through our indirect subsidiary, IBEX Preclinical Research, Inc. ("IBEX"). Utah CRO Services, Inc., a Nevada corporation ("Utah CRO"), is a direct subsidiary and held all the outstanding capital stock of IBEX (the "IBEX Shares"). Utah CRO also holds all the member interest of IBEX Property LLC, a Nevada limited liability company ("IBEX Property"), that owned two unencumbered parcels of real property in Logan, Utah, consisting of approximately 1.75 combined gross acres of land, together with the buildings, structures, fixtures, and personal property (the "Property"), which was leased by IBEX Property to IBEX for IBEX to conduct its preclinical research and veterinary sciences business.

On April 14, 2022, Utah CRO entered into a Stock Purchase Agreement (the "Stock Agreement") with an unrelated third party ("Buyer"), pursuant to which Utah CRO agreed to sell all the outstanding IBEX Shares to Buyer in exchange for an unsecured promissory note in the principal amount of $400,000 bearing simple interest at the rate of 10% per annum payable interest only on a quarterly basis and all principal and remaining accrued interest due on the five-year anniversary of the closing of the sale of the IBEX Shares to Buyer. Furthermore, on April 14, 2022, IBEX Property entered into that certain Real Estate Purchase and Sale Agreement (the "Real Estate Agreement") with another unrelated third party ("Purchaser") pursuant to which IBEX Property agreed to sell to Purchaser the Property at a gross purchase price of $2.8 million payable in cash at closing of the transaction. The Buyer and Purchaser are affiliates as a result of common ownership. On April 28, 2022, the parties to the Stock Agreement and Real Estate Agreement signed the documents required to close the transactions contemplated thereby and funds required to close the transaction under the Real Estate Agreement were deposited with the title company handling the closing. Title documents were recorded, and funds disbursed on April 29, 2022, and the Company received the promissory note described above in the principal amount of $400,000, which was consideration for sale of the IBEX common shares, and net cash proceeds of $2.6 million, after deducting closing costs and advisory fees, from sale of the Property under the Real Estate Agreement. The Company does not expect to realize a significant gain or loss as a result of the sale.

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, 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 is a clinical stage biotechnology company developing regenerative tissue products and biomaterials. PolarityTE's first regenerative tissue product is SkinTE, which is intended for the repair, reconstruction, replacement, and supplementation of skin in patients who have a need for treatment of acute or chronic wounds, burns, surgical reconstruction events, scar revision, or removal of dysfunctional skin grafts.

Since the beginning of 2017, PolarityTE has incurred substantial operating losses and its operations have been financed primarily by public equity financings. The clinical trials for SkinTE and the regulatory process will likely result in an increase in PolarityTE's expenses. PolarityTE will continue to incur substantial operating losses as we pursue an investigational new drug application ("IND") and biologics license application ("BLA"), and PolarityTE expects to seek financing from external sources over the foreseeable future to fund its operations.

Regenerative Tissue Product

Our first regenerative tissue product is SkinTE. On July 23, 2021, we submitted an investigational new drug application ("IND") for SkinTE to the U.S. Food and Drug Administration (the "FDA") through our subsidiary, PolarityTE MD, Inc. ("PTE-MD"), as the first step in the regulatory process for obtaining licensure for SkinTE under Section 351 of the Public Health Service Act. The FDA subsequently issued clinical hold correspondence to us identifying certain issues that needed to be addressed before the IND could be approved. We provided responses to the FDA, and on January 14, 2022, the FDA notified us that the clinical hold had been removed. The IND approval enables us to commence the first of two expected pivotal studies needed to support a BLA seeking a chronic cutaneous ulcer indication for SkinTE. Our first planned pivotal study under our IND is a multi-center, randomized controlled trial evaluating SkinTE in the treatment of diabetic foot ulcers (DFUs) classified as Grade 2 in the Wagner classification system ("Wagner 2 DFUs") entitled "Closure Obtained with Vascularized Epithelial Regeneration for DFUs with SkinTE," or "COVER DFUs Trial." We plan to enroll up to 100 patients at up to 20 sites in the U.S. in the COVER DFUs Trial, which will compare treatment with SkinTE plus the standard-of-care to the standard-of-care alone. The first subject was enrolled in the trial on April 27, 2022, and additional subjects have been screened and enrolled since then. The primary endpoint is the incidence of DFUs closed at 24 weeks. Secondary endpoints include percent area reduction ("PAR") at 4, 8, 12, 16, and 24 weeks, improved quality of life, and new onset of infection of the DFU being evaluated. As we pursue the first study, we plan to engage in discussions with the FDA regarding the design and implementation of the second pivotal study.

In March 2022, we submitted to the FDA a request for a Regenerative Medicine Advanced Therapy (RMAT) designation to SkinTE under our IND. Established under the 21st Century Cures Act, RMAT designation is a dedicated program designed to expedite the drug development and review processes for promising regenerative medicine products, including human cellular and tissue-based therapies. A regenerative medicine therapy is eligible for RMAT designation if it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or therapy has the potential to address unmet medical needs for such disease or condition. RMAT designation provides the benefits of intensive FDA guidance on efficient drug development, including the ability for early interactions with the FDA to discuss potential ways to support accelerated approval and satisfy post-approval requirements, potential priority review of the biologics license application (BLA), and other opportunities to expedite development and review. By letter dated May 11, 2022, we were advised by the FDA that it concluded SkinTE meets the criteria for RMAT designation for the treatment of DFUs and venous leg ulcers. The next step for us under the RMAT designation is to prepare for submission a request for a Type B meeting to address a multidisciplinary, comprehensive discussion between PolarityTE and the FDA regarding the SkinTE development program, including planned clinical trials and plans for expediting the manufacturing development strategy.

We expect to incur significant operating costs in the next three to four years 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 and incurring continuing fixed costs related to the maintenance of our assets and business. 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. 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 licensure for SkinTE.

Recent Developments

Sale of IBEX

At the beginning of May 2018, we acquired a preclinical research and veterinary sciences business, which we have used for preclinical studies on our regenerative tissue products and to offer preclinical research services to unrelated third parties on a contract basis. We operated this business through our indirect subsidiary, IBEX Preclinical Research, Inc. ("IBEX"). Utah CRO Services, Inc., a Nevada corporation ("Utah CRO"), is our direct subsidiary and held all the outstanding capital stock of IBEX (the "IBEX Shares"). Utah CRO also holds all the member interest of IBEX Property LLC, a Nevada limited liability company ("IBEX Property"), that owns two unencumbered parcels of real property in Logan, Utah, consisting of approximately 1.75 combined gross acres of land, together with the buildings, structures, fixtures, and personal property (the "Property"), which was leased by IBEX Property to IBEX for IBEX to conduct its preclinical research and veterinary sciences business.

On April 14, 2022, Utah CRO entered into a Stock Purchase Agreement (the "Stock Agreement") with an unrelated third party ("Buyer"), pursuant to which Utah CRO agreed to sell all the outstanding IBEX Shares to Buyer in exchange for an unsecured promissory note in the principal amount of $400,000 bearing simple interest at the rate of 10% per annum payable interest only on a quarterly basis and all principal and remaining accrued interest due on the five-year anniversary of the closing of the sale of the IBEX Shares to Buyer. Furthermore, on April 14, 2022, IBEX Property entered into that certain Real Estate Purchase and Sale Agreement (the "Real Estate Agreement") with another unrelated third party ("Purchaser") pursuant to which IBEX Property agreed to sell to Purchaser the Property at a gross purchase price of $2.8 million payable in cash at closing of the transaction. The Buyer and Purchaser are affiliates as a result of common ownership. On April 28, 2022, the parties to the Stock Agreement and Real Estate Agreement signed the documents required to close the transactions contemplated thereby and funds required to close the transaction under the Real Estate Agreement were deposited with the title company handling the closing. Title documents were recorded, and funds disbursed on April 29, 2022, and we received the promissory note described above in the principal amount of $400,000, which was consideration for sale of the IBEX common shares, and net cash proceeds of $2.6 million, after deducting closing costs and advisory fees, from sale of the Property under the Real Estate Agreement. We do not expect to realize a significant gain or loss as a result of the sale.

Our Business Facility

On December 27, 2017, we entered into a commercial lease agreement ("Lease") with Adcomp LLC, or the landlord, pursuant to which we lease approximately 178,528 rentable square feet of warehouse, manufacturing, office, and lab space in Salt Lake City, Utah (the "Property") from the landlord. The initial term of the Lease is five years and expires on November 30, 2022. Under the Lease we have a one-time option to renew for an additional five years and an option to purchase the Property at a purchase price of $17.5 million. The initial base rent under the 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.

On December 16, 2021, we gave written notice to the landlord of our election to exercise the option to purchase the Property, and on March 14, 2022, we entered into a definitive purchase and sale agreement with the landlord that provides for a closing of the transaction on November 15, 2022 (the "Purchase Agreement"). In connection with exercising the option to purchase the Property, we made an earnest money deposit of $150,000 that may be refunded if closing conditions or contingencies running in our favor are not satisfied or the landlord defaults in its obligations under the Lease or the Purchase Agreement for the Property.

On October 25, 2021, we signed a Purchase and Sale Agreement, the terms of which were finalized on December 10, 2021, and subsequently amended by Amendment No. 1 thereto dated March 15, 2022 (the "BCG Agreement"), with BCG Acquisitions LLC ("BCG"), pursuant to which we agreed to sell the Property to BCG or its assigns for $17.5 million after our purchase of the Property described above. The BCG Agreement provides that we and BCG will enter into at closing of the sale of the Property to BCG a 126-month lease, which is included as an exhibit to the BCG Agreement, for approximately 62,500 square feet of space in the building on the Property. Under the BCG Agreement, BCG made an initial earnest money deposit totaling $200,000, which the parties subsequently agreed to reduce to $150,000, that will be refunded if we are unable to complete the purchase of the Property from the Landlord on a timely basis, closing conditions or contingencies running in favor of BCG are not satisfied, or we default in our obligations under the BCG Agreement.

The closing of the transactions described above are subject to a number of risks and uncertainties including, but not limited to, satisfaction of all closing conditions, including obtaining financing for the purchase, and closing on the purchase of the Property from the landlord under the Purchase Agreement, and satisfaction of all closing conditions, including obtaining financing for the purchase, and closing on the sale of the Property to BCG under the BCG Agreement.

Reverse Stock Split

At a special meeting of stockholders held on May 12, 2022, the stockholders approved an amendment to our certificate of incorporation to effectuate a reverse stock split of our outstanding shares of common stock by a ratio of any whole number between 1-for-10 and 1-for-25, the implementation and timing of which is subject to the discretion of our Board of Directors. The primary goal of the reverse stock split is to increase the per share market price of our common stock to meet the minimum per share bid price requirements for continued listing on The Nasdaq Capital Market.

Intellectual Property

We received notice from the United States Patent and Trademark Office that U.S. patent application no. 17/326,734 will issue on May 24, 2022, as U.S. Patent No. 11,338,060. The claims to be issued are for compositions that relate to our minimally polarized functional unit (MPFU) technology in combination with a cryoprotectant. The Costa Rican Patent Office issued a notification of issuance for patent application no. 2017-0296, Israeli patent application No. 252613 was granted on March 2, 2022, as Israeli Patent No. 252613, and New Zealand patent application no. 755260 was granted on March 25, 2022, as New Zealand Patent No. 755260. The application in Costa Rica and the patents in Israel and New Zealand also relate to our MPFU technology. Additionally, we received a notice of allowance for Vietnamese patent application no. 1-2017-02498, also relating to the our MPFU technology. The total number of our allowed and granted utility patents worldwide is now 18, four in the United States and 14 internationally.

Liquidity and Capital Resources

As of March 31, 2022, we had $18.7 million in cash and cash equivalents and working capital of approximately $17.2 million. We believe cash and cash equivalents on our balance sheet, together with the net proceeds of the IBEX Property sale, will fund our business activities into the fourth calendar quarter of 2022. For the three-month period ended March 31, 2022, cash used in operating activities was $6.0 million, or an average of $2.0 million per month, compared to $6.6 million of cash used in operating activities, or an average of $2.2 million per month, for the three-month period ended March 31, 2021.

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 (“CRO”) to provide services for the COVER DFUs Trial at a cost of approximately $6.5 million consisting of $3.1 million of service fees and $3.4 million of estimated costs. In 2021 we prepaid $0.5 million, which will be applied to payment of the final invoice under the work order. Over the approximately three-year term of the COVER DFUs Trial the service provider will submit to us for payment monthly invoices for units of work stated in the work order that are completed and billable expenses incurred. Our first patient in the COVER DFUs Trial was enrolled on April 27, 2022. We believe that it will take at least 15 months, and perhaps as many as 24 months, to complete enrollment of 100 patients in the COVER DFUs Trial. As enrollment increases, we expect our monthly CRO and related costs of conducting the trial will ramp up.

Our expectation is that the second clinical trial under the IND for SkinTE will be similar to the COVER DFUs 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 application 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, our most significant uses of cash to maintain our business going forward are expected to be compensation, costs of occupying, operating, and maintaining our facilities, and the costs associated with maintaining our status as a publicly traded company listed on Nasdaq. During the 12-month period following the filing of this report our plan is to preserve the facilities, equipment, and staff we need to advance the COVER DFUs Trial and other work necessary for advancing the process for obtaining regulatory approval of SkinTE.

With the acceptance of our IND for SkinTE and the beginning of the COVER DFUs Trial, we do not expect to have the same need for research and development staff associated with product development and, as a result, we reduced research and development staff in April 2022.

As a result of the sale of IBEX described above, after April 2022 we are not engaged in any business activity that will generate cash flows from operations, which in the past contributed to defraying our operating costs.

During the latter part of 2021 and into February 2022, we engaged in discussions with certain third parties regarding potential M&A transactions and strategic initiatives. In the first quarter of 2022 we recognized $1.2 million of one-time costs for professional services associated with such M&A and strategic initiatives, which is in addition to $1.2 million of such costs recognized in the fourth quarter of 2021.

As of the date of this quarterly report we do not expect that our cash and cash equivalents of $18.7 million as of March 31, 2022, together with the net proceeds of the IBEX Property sale, will be sufficient to fund our current business plan including related operating expenses and capital expenditure requirements beyond the fourth calendar quarter of 2022. Accordingly, there is substantial doubt about our ability to continue as a going concern, as we do not believe that our cash and cash equivalents will be sufficient to fund our business plan for at least twelve months from the date of issuance of our quarterly financial statements in this report. 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 we may not be successful in obtaining additional financing. Therefore, it is not considered probable, as defined in applicable accounting standards, that our plan to raise additional capital will alleviate the substantial doubt regarding our ability to continue as a going concern.

To facilitate future financings, on February 11, 2022, we filed a registration statement on Form S-3 to register sales of our securities, which was declared effective on April 7, 2022. Pursuant to General Instruction I.B.6 of Form S-3, the aggregate market value of securities sold by us during the period of 12 calendar months immediately prior to, and including, the sale is limited to one-third of the aggregate market value of the voting and non-voting common equity held by our non-affiliates so long as the aggregate market value of our common stock held by non-affiliates is less than $75.0 million. If after the effective date of the new Form S-3 registration statement the aggregate market value of our outstanding common stock held by non-affiliates equals or exceeds $75.0 million, then the one-third limitation on sales does not apply to additional sales.

Our actual capital requirements will depend on many factors, including the cost and timing of advancing 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 projection of the period of time for 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. Any additional equity financing including financings involving convertible securities, if able to be obtained, may be highly dilutive, on unfavorable terms, or otherwise disadvantageous, to existing stockholders, and debt financing, if available, may involve restrictive covenants or require us to grant a security interest in our assets. If we elect to pursue collaborative arrangements, the terms of such arrangements may require us to relinquish rights to certain of our technologies, products, or marketing territories. Our failure to raise additional capital when needed, and on acceptable terms, would require us to reduce our operating expenses and would limit our ability to continue operations, any of which would have a material adverse effect on our business, financial condition, and results of operation.

Results of Operations

Changes in Polarity's Operations

There have been significant changes in our operations affecting our results of operations for the three-month period ended March 31, 2022, compared to three-month period ended March 31, 2021.

On July 23, 2021, we submitted an IND for SkinTE to the FDA through our subsidiary, PTE-MD, as the first step in the regulatory process for obtaining licensure for SkinTE under Section 351 of the Public Health Service Act. The FDA subsequently issued clinical hold correspondence to us identifying certain issues that needed to be addressed before the IND could be approved. We provided responses to the FDA, and on January 14, 2022, the FDA sent correspondence informing us that the clinical hold had been removed. Acceptance of the IND by the FDA enables us to commence the first of two expected pivotal studies needed to support a BLA seeking a chronic cutaneous ulcer indication for SkinTE. We ceased selling SkinTE at the end of May 2021, when the period of enforcement discretion previously announced by the FDA with respect to its IND and premarket approval requirements for 361 HCT/Ps came to an end, and we do not expect to be able to commercialize SkinTE until our BLA is approved, which we believe will take at least three to four years. Consequently, we recognized products net revenues in the first quarter of 2021, and did not have any such revenues in the first quarter of 2022.

Our subsidiary, Arches Research, Inc. ("Arches") began offering COVID-19 testing services in May 2020 under 30-day renewable testing agreements with multiple nursing home and pharmacy facilities in the state of New York controlled by a single company, which substantially added to our services net revenues in the first three months of 2021. When the New York nursing homes and pharmacies adopted on-site employee testing at the end of March 2021, our COVID-19 testing revenues declined substantially, and in August 2021, we decided to cease COVID-19 testing. Arches focused its research and development resources on supporting our IND and clinical trial efforts for the remainder of 2021 and continued in that role in the first quarter of 2022. However, going forward we do not expect we will have the same need for research and development staff associated with product development and, as a result, we reduced research and development staff in April 2022.

While we were exploring the opportunities for selling IBEX and the IBEX Property, IBEX assumed a more passive approach to marketing its services, which resulted in a decline in IBEX services revenues in the first quarter of 2022 compared to the first quarter of 2021. With the sale of IBEX and the IBEX Property completed at the end of April 2022, we expect our services net revenues will be nominal in the second quarter of 2022 and absent in the last six months of 2022.

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 and reducing the services and infrastructure needed to support a larger work force and commercial sales effort.

Comparison of the three months ended March 31, 2022 compared to the three months ended March 31, 2021.

(in thousands)	For the Three Months Ended		Increase (Decrease)	
	March 31, 2022	March 31, 2021	Amount	%
	(Unaudited)			
Net revenues				
Products	$ –	$ 1,729	$ (1,729)	(100)%
Services	741	2,980	(2,239)	(75)%
Total net revenues	741	4,709	(3,968)	(84)%
Cost of sales				
Products	–	241	(241)	(100)%
Services	491	1,924	(1,433)	(74)%
Total costs of revenues	491	2,165	(1,674)	(77)%
Gross profit	250	2,544	(2,294)	(90)%
Operating costs and expenses				
Research and development	2,860	2,431	429	18%
General and administrative	6,209	6,371	(162)	(3)%
Sales and marketing	–	1,526	(1,526)	(100)%
Restructuring and other charges	–	425	(425)	(100)%
Impairment of assets held for sale	54	–	54	100%
Total operating costs and expenses	9,123	10,753	(1,630)	(15)%
Operating loss	(8,873)	(8,209)	(664)	8%
Other income (expense), net				
Change in fair value of common stock warrant liability	5,105	(4,027)	9,132	(227)%
Inducement loss on sale of liability classified warrants	–	(5,197)	5,197	(100)%
Interest income (expense), net	(15)	(38)	23	(61)%
Other income, net	12	61	(49)	(80)%
Net loss	$ (3,771)	$ (17,410)	$ 13,639	(78)%

Net Revenues and Gross Profit. Net revenues decreased $4.0 million, or 84%, for the three-month period ended March 31, 2022, compared to the three-month period ended March 31, 2021, due to the cessation of SkinTE commercial efforts and COVID-19 testing in 2021 and a decrease in IBEX services net revenues for the three-month period ended March 31, 2022, compared to the three-month period ended March 31, 2021. With the decrease in revenues, cost of sales also decreased by $1.7 million, or 77%. As a result of these changes gross profit decreased by $2.3 million, or 90%, for the three-month period ended March 31, 2022, compared to the three-month period ended March 31, 2021.

Operating Costs and Expenses. Operating costs and expenses decreased $1.6 million, or 15%, for the three-month period ended March 31, 2022, compared to the three-month period ended March 31, 2021.

Research and development expenses increased 18% for the three-month period ended March 31, 2022, compared to the three-month period ended March 31, 2021. The increase is primarily attributable to the SkinTE manufacturing and overhead personnel redirecting their efforts following the cessation of SkinTE sales to research and development activities and increased costs related to quality control supplies and infrastructure implemented for the COVER FDUs Trial. The costs of our pre-IND clinical trials incurred during the three-month period ended March 31, 2021, were slightly more than replaced by costs of the COVER DFUs Trial incurred during the three-month period ended March 31, 2022.

The amount of general and administrative expenses for the three-month period ended March 31, 2022, remained essentially unchanged compared to the three-month period ended March 31, 2021. We effectuated a reduction in force for our commercial operations in the second quarter of 2021. Consequently, there were reductions in cash compensation, stock compensation, consulting fees, and travel expense. Furthermore, with the cessation of SkinTE sales we re-allocated manufacturing supplies and compensation from general and administrative expenses to research and development costs. These reductions were offset by professional fees incurred in connection with our pursuit of a strategic transaction that did not materialize and investment banking fees paid in connection with an at-the-market offering we terminated in the first quarter of 2022.

In the first quarter of 2021, we incurred sales and marketing costs related to our commercial sales effort that did not recur in the first quarter of 2022. In connection with terminating commercial sales of SkinTE, we recorded as a restructuring charge a loss on impairment of property and equipment in the amount of $0.4 million during the first quarter of 2021 and no similar charge was recognized in the first quarter of 2022. The absence of $1.5 million in sales and marketing costs in the first quarter of 2022 compared to the first quarter of 2021 and the $0.4 million of restructuring charges in the first quarter of 2021 that did not recur in the first quarter of 2022 offset the increase in research and development costs from the first quarter of 2021 to the first quarter of 2022, and accounts for the $1.6 million decrease in operating costs and expenses for the three-month period ended March 31, 2022, compared to the three-month period ended March 31, 2021.

Operating Loss and Net Loss. Operating loss increased $0.7 million, or 8%, for the three-month period ended March 31, 2022, compared to the three-month period ended March 31, 2021. The increase in operating loss is due to the substantial reduction in total net revenues for the three-month period ended March 31, 2022, compared to the three-month period ended March 31, 2021, which was only partially offset by decreases in cost of revenues and operating costs and expenses.

Net loss decreased $13.6 million, or 78%, for the three-month period ended March 31, 2022, compared to the three-month period ended March 31, 2021. Warrants issued in connection with financings we completed in 2022, 2021 and 2020 are classified as liabilities and remeasured each period until settled, classified as equity, or expiration. As a result of the periodic remeasurement, we recorded a gain for change in fair value of common stock warrant liability of $5.1 million for the three-month period ended March 31, 2022, compared to a loss of $4.0 million for the three-month period ended March 31, 2021. For additional information on the change in fair value of common stock warrant liability please see Note 4 to the condensed consolidated financial statements included in this report. We issued common stock purchase warrants in January 2021, as an inducement to holders of warrants issued in December 2020 to exercise those December warrants. As a result, we recognized an inducement loss of $5.2 million for the three-month period ended March 31, 2021. There was no similar inducement loss in the first quarter of 2022.

Non-GAAP Financial Measure

The table below provides a reconciliation of 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, to GAAP net loss. We believe adjusted net loss 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. Other companies may calculate adjusted net loss differently than we do. Adjusted net loss has limitations as an analytical tool and you should not consider adjusted net loss in isolation or as a substitute for our financial results prepared in accordance with GAAP.

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

	For the Three Months Ended March 31,	
	2022	**2021**
GAAP Net loss	$ (3,771)	$ (17,410)
Change in fair value of common stock warrant liability	(5,105)	4,027
Inducement loss on sale of liability classified warrants	–	5,197
Non-GAAP adjusted net loss attributable to common stockholders – basic & diluted	$ (8,876)	$ (8,186)
GAAP net loss per share attributable to common stockholders		
Basic	$ (0.04)	$ (0.23)
Diluted	$ (0.09)	$ (0.24)
Non-GAAP adjusted net loss per share attributable to common stockholders		
Basic	$ (0.11)	$ (0.11)
Diluted	$ (0.10)	$ (0.11)

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. Our management believes that this method provides a faithful depiction of the transfer of services over the term of the performance obligation based on the remaining services needed to satisfy the obligation. This requires 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 Annual 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 Annual 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:

- our ability to raise capital to fund our operations;
- 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 in the near and long term, which raises doubt about our ability to continue as a going concern;
- 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 need for, and ability to obtain, additional financing in the future;
- the ability to comply with regulations applicable to the development of SkinTE;
- the timing and requirements associated with obtaining FDA acceptance of our second clinical trial;
- the ability to obtain subject enrollment in our trials at a pace that allows the trials to progress on the schedules we have established with our CRO;
- unexpected delays in the progress of our clinical trials;
- 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;
- general economic conditions;
- inaccuracies in estimates of our expenses, future revenues, and capital requirements;
- future accounting pronouncements; and
- unauthorized access to confidential information and data on our information technology systems and security and data breaches.

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 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 may also contain 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 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 March 31, 2022, 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 March 31, 2022.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

For a description of our material pending legal proceedings, see Note 16, "Commitments and Contingencies—Contingencies" in the condensed consolidated financial statements included in this report.

Item 1A. Risk Factors

You should carefully consider the factors discussed below in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, which could materially affect our business, financial position, or future results of operations. The risks described below in our 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 we may be unable to raise capital when needed, which would force us to delay, reduce, eliminate, or abandon our product development program.

We reported an operating loss of $8.9 million for the three-month period ended March 31, 2022, and on that date we had had an accumulated deficit of $512.2 million. We believe our cash and cash equivalents at March 31, 2022, will fund our current business plan including related operating expenses and capital expenditure requirements into the fourth calendar quarter of 2022. Accordingly, there is substantial doubt about our ability to continue as a going concern beyond that time unless we can raise additional capital from external sources.

We expect to incur significant operating costs in the near term as we pursue the regulatory process for SkinTE with the FDA, conduct clinical trials and studies, and pursue product research, all while operating our business and incurring continuing fixed costs related to the maintenance of our assets and business. 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. As a result of the disposition of IBEX in April 2022, we are no longer engaged in any revenue generating activity that would contribute to defraying our operating costs in future periods, which will make us entirely dependent on capital obtained from external sources to fund our operations. The impact of COVID-19, inflation, and other macroeconomic issues have and may continue to adversely affect capital markets and could limit our ability to obtain the capital we need to operate our business.

We may not be able to obtain necessary capital in sufficient amounts, on terms favorable to us, or at all. If adequate funds are not available for our business in the future, we may be required to delay, reduce the scope of, or eliminate the plans for obtaining regulatory licensure or 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, results of operation, and the value of an investment in us.

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

During the three-month period ended March 31, 2022, 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
January 2022	155,562	$ 0.72	N/A	N/A
February 2022	29,481	$ 0.48	N/A	N/A
March 2022	–	$ –	N/A	N/A
Total	185,043	$ 0.68		

Item 6. Exhibits

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

3.1	Restated Certificate of Incorporation of PolarityTE, Inc. (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on October 1, 2021).
3.2	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K filed on March 17, 2022)
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K filed on March 17, 2022)
4.1	Form of Common Warrant – March 2022 (incorporated by reference to Exhibit 4.1 to our Form 8-K filed with the SEC on March 17, 2022)
4.2	Form of Placement Agent Warrant – March 2022 (incorporated by reference to Exhibit 4.2 to our Form 8-K filed with the SEC on March 17, 2022)
10.1	Purchase and Sale Agreement between PolarityTE, Inc., and Adcomp LLC (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the SEC on March 15, 2022)
10.2	Amendment No. 1 to Purchase and Sale Agreement between PolarityTE, Inc., and BCG Acquisitions LLC (incorporated by reference to Exhibit 10.4 to our Form 8-K filed with the SEC on March 15, 2022)
10.3	Form of Securities Purchase Agreement dated March 15, 2022 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on March 17, 2022)
10.4	Form of Warrant Amendment Agreement dated March 15, 2022 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the SEC on March 17, 2022)
10.5	Stock Purchase Agreement between Utah CRO Services, Inc., and JP Lawrence Biomedical, Inc., dated April 14, 2022 (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on April 18, 2022)
10.6	Real Estate Purchase and Sale Agreement between IBEX Property LLC, and JP Lawrence Land and Building LLC, dated April 14, 2022 (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the SEC on April 18, 2022)
10.7	Promissory Note in the Principal Amount of $400,000 dated April 28, 2022 (incorporated by reference to Exhibit 10.3 to our Form 8-K filed with the SEC on May 2, 2022)
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	Inline 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	Inline XBRL Schema Document
101.CAL	Inline XBRL Calculation Linkbase Document
101.DEF	Inline XBRL Definition Linkbase Document
101.LAB	Inline XBRL Label Linkbase Document
101.PRE	Inline 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: May 16, 2022

/s/ Richard Hague

Richard Hague
Chief Executive Officer
Duly Authorized Officer

Date: May 16, 2022

/s/ Jacob Patterson

Jacob Patterson
Chief Financial Officer
Chief Accounting Officer

EXHIBIT 31.1

CERTIFICATION

I, Richard Hague, certify that:

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

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

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

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15 (f) and 15 d-15(f)) for the registrant and we have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: May 16, 2022

/s/ Richard Hague

Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Jacob Patterson, certify that:

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

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

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

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15 (f) and 15 d-15(f)) for the registrant and we have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: May 16, 2022

/s/ Jacob Patterson

Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

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

The Quarterly Report on Form 10-Q for the period ending March 31, 2022 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 16, 2022

/s/ Richard Hague

Richard Hague
Chief Executive Officer

/s/ Jacob Patterson

Jacob Patterson
Chief Financial Officer