

November 10, 2022



PolarityTE Reports Third Quarter 2022 Financial Results and Provides Business Update

SALT LAKE CITY, Nov. 10, 2022 /PRNewswire/ -- **PolarityTE, Inc.** (Nasdaq: PTE) a biotechnology company developing regenerative tissue products and biomaterials, today provided a business update and reported financial results for the quarterly period ended September 30, 2022.



Recent Business and Financial Updates

- At the end of April 2022, PolarityTE began enrollment in its Phase III randomized controlled trial (RCT), which is a pivotal study under its open IND for SkinTE[®]. The Company estimates that it may be able to complete enrollment of 100 subjects sometime in the first six months of 2024. Additionally, there is an interim analysis planned for the first 50 patients and we believe that data will be available in the fourth calendar quarter of 2023.
- In May 2022, the U.S Food and Drug Administration (FDA) granted PolarityTE's request for SkinTE to be designated as a Regenerative Medicine Advanced Therapy (RMAT). As a result of the RMAT designation the Company was able to engage in an expedited dialogue with the FDA on the tasks that are likely to be necessary to support a Biologics License Application (BLA) for SkinTE. Based on that dialogue the Company plans to run a second multi-center RCT under its current IND to support approval of a broad diabetic foot ulcer (DFU) indication for SkinTE, and the Company will be communicating with the FDA regarding the design and implementation of the second clinical trial.
- The Company had cash and cash equivalents of \$16.1 million and working capital of \$15.7 million at September 30, 2022.

- For the three-month period ended September 30, 2022, cash used in operating activities was \$4.0 million, or an average of \$1.3 million per month, compared to \$4.6 million of cash used in operating activities, or an average of \$1.5 million per month, for the three-month period ended September 30, 2021.

Richard Hague, President and CEO of PolarityTE, commented, "We remain firmly focused on enrolling our Phase III pivotal study in Wagner 2 DFUs for SkinTE, which we believe represents both a significant unmet medical need and a substantial market opportunity. We are very pleased that FDA granted SkinTE a Regenerative Medicine Advanced Therapy (RMAT) for DFUs and VLUs. The RMAT designation is reserved for products that FDA believes has the potential to treat, modify, reverse or cure a serious or life threatening condition. As we work to generate the data necessary for an eventual BLA submission, we will continue to exercise financial discipline and look to reduce operating expenses wherever possible."

Financial Results for the Period Ended September 30, 2022

There have been significant changes in the Company's operations affecting its results of operations for the nine-month period ended September 30, 2022, compared to the nine-month period ended September 30, 2021.

On July 23, 2021, the Company submitted an IND for SkinTE to the FDA through its subsidiary 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 the Company identifying certain issues that needed to be addressed before the IND could be approved. The Company provided responses to the FDA, and on January 14, 2022, the FDA sent correspondence informing the Company that the clinical hold had been removed. Acceptance of the IND by the FDA enables the Company to commence the first of two expected pivotal studies needed to support a BLA for SkinTE. The Company 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 regenerative medicine therapies, such as SkinTE, came to an end, and the Company does not expect to be able to commercialize SkinTE until its BLA is approved, which the Company believes will take at least three to four years. Consequently, the Company recognized products net revenues in the nine months of 2021, and did not have any such revenues in the first nine months of 2022.

The Company's 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 the Company's 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, the Company's COVID-19 testing revenues declined substantially, and in August 2021, the Company decided to cease COVID-19 testing. Arches focused its research and development resources on supporting the Company's IND and clinical trial efforts for the remainder of 2021 and continued in that role in 2022. However, the Company does not expect it will have the same need for research and development staff associated with product development and, as a result, the Company reduced research and development staff in April 2022, and began to eliminate or sell certain

items of equipment that had been leased or purchased for research and development activity.

At the beginning of May 2018, the Company acquired a preclinical research and veterinary sciences business, which the Company operated through its indirect subsidiary, IBEX Preclinical Research, Inc. ("IBEX"). Utah CRO Services, Inc., a Nevada corporation ("Utah CRO"), is the Company's direct subsidiary and held all the outstanding capital stock of IBEX (the "IBEX Shares"). Utah CRO also held 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 28, 2022, Utah CRO sold all the IBEX Shares to an unrelated third party in exchange for a promissory note in the principal amount of \$0.4 million 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. On the same day IBEX Property closed the sale of the Property to an affiliate of the same party that purchased the IBEX Shares and the Company realized net cash proceeds of \$2.3 million, after deducting closing costs and advisory fees. Prior to April 2022, while the Company was 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 nine months of 2022 compared to the first nine months of 2021. Accordingly, the Company's services net revenues were nominal from the beginning of 2022 through the sale of IBEX and the IBEX Property completed at the end of April 2022, and services net revenues generated by IBEX ended permanently after the sale.

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

Comparison of the nine months and three months ended September 30, 2022, to the nine months and three months ended September 30, 2021

Net Revenues and Gross Profit. The Company ceased commercial sales of SkinTE in the second calendar quarter of 2021 and sold the IBEX services business at the end of April 2022, so the Company was not engaged in any revenue generating business activity at September 30, 2022, and does not expect to generate operating revenues from any business activity for the foreseeable future. The decreases in revenues, cost of revenues, and gross profit for the nine-month and three-month periods ended September 30, 2022, compared to the same periods in 2021 are consistent with the Company's cessation of revenue-generating business activity.

Operating Costs and Expenses. Operating costs and expenses decreased \$7.7 million, or 27%, for the nine-month period ended September 30, 2022, compared to the nine-month period ended September 30, 2021, and decreased \$2.5 million, or 32%, for the three-month period ended September 30, 2022, compared to the three-month period ended September 30, 2021.

Research and development expenses decreased 19% for the nine-month period ended September 30, 2022, compared to the nine-month period ended September 30, 2021, and decreased 34%, for the three-month period ended September 30, 2022, compared to the three-month period ended September 30, 2021. The decrease is primarily attributable to costs in the nine-month period ended September 30, 2021, for completing the Company's pre-IND diabetic foot ulcers trial, lab supplies for work on preparing the technical items for its IND, and consulting services for preparing its IND that did not recur in the nine-month period ended September 30, 2022, which was partially offset by an increase primarily attributable to the SkinTE manufacturing and overhead personnel redirecting their efforts following the cessation of SkinTE sales to research and development activities, manufacturing costs for SkinTE produced for use in the COVER DFUs Trial, and increased costs related to quality control supplies and infrastructure implemented for the COVER DFUs Trial.

The amount of general and administrative expenses decreased 17% for the nine-month period ended September 30, 2022, compared to the nine-month period ended September 30, 2021, and decreased 27%, for the three-month period ended September 30, 2022, compared to the three-month period ended September 30, 2021. The Company effectuated a reduction in force for its 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 the Company 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 the Company's pursuit of a strategic transaction that did not materialize, and investment banking fees paid in connection with an at-the-market offering the Company terminated in the first quarter of 2022.

In the first nine months of 2021, the Company incurred sales and marketing costs related to its commercial sales effort that did not recur in the first nine months of 2022. In connection with terminating commercial sales of SkinTE, the Company realized as a restructuring charge a loss on impairment of property and equipment in the amount of \$0.4 million and a charge of \$0.6 million for employee severance and revaluing of equity awards related to severance, which was offset by a gain of \$0.3 million from early termination of an office/laboratory lease in Augusta, Georgia. In the first nine months of 2022 the Company realized a charge of \$0.2 million from impairment of equipment to be sold and a nominal amount of restructuring charges on employee severance.

Operating Loss and Net Loss. Operating loss decreased \$3.2 million, or 13%, for the nine-month period ended September 30, 2022, compared to the nine-month period ended September 30, 2021, and decreased \$2.0 million, or 27%, for the three-month period ended September 30, 2022, compared to the three-month period ended September 30, 2021.

Net loss decreased \$14.4 million, or 67%, for the nine-month period ended September 30, 2022, compared to the nine-month period ended September 30, 2021, and increased \$2.4 million, or 233%, for the three-month period ended September 30, 2022, compared to the three-month period ended September 30, 2021. Warrants issued in connection with financings the Company 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, the Company recorded a gain for change in fair value of common stock warrant liability of \$13.7 million for the nine-month period ended September 30, 2022,

compared to a gain of \$4.1 million for the nine-month period ended September 30, 2021, and a gain for change in fair value of common stock warrant liability of \$2.0 million for the three-month period ended September 30, 2022, compared to a gain of \$6.4 million for the three-month period ended September 30, 2021. The Company 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, the Company recognized an inducement loss of \$5.2 million for the nine-month period ended September 30, 2021. There was no similar inducement loss in the first nine months 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 the Company's common stock warrant liability and warrant inducement loss, to GAAP net loss. The Company believes 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 the Company does. Adjusted net loss has limitations as an analytical tool and investors should not consider adjusted net loss in isolation or as a substitute for the Company's 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 September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
GAAP Net Loss	\$ (3,400)	\$ (1,021)	\$ (7,239)	\$ (21,619)
Change in fair value of common stock warrant liability	(1,984)	(6,354)	(13,719)	(4,134)
Inducement loss on sale of liability classified warrants	-	-	-	5,197
Non-GAAP adjusted net loss attributable to common stockholders – basic & diluted	<u>\$ (5,384)</u>	<u>\$ (7,375)</u>	<u>\$ (20,958)</u>	<u>\$ (20,556)</u>
GAAP net loss per share attributable to common stockholders				
Basic*	\$ (0.47)	\$ (0.31)	\$ (1.08)	\$ (6.81)
Diluted*	\$ (0.47)	\$ (0.37)	\$ (1.54)	\$ (6.81)
Non-GAAP adjusted net loss per share attributable to common stockholders				
Basic and diluted*	\$ (0.75)	\$ (2.27)	\$ (3.12)	\$ (6.47)

About PolarityTE®

PolarityTE, Inc., headquartered in Salt Lake City, Utah, is a biotechnology company developing regenerative tissue products. PolarityTE's first regenerative tissue product is SkinTE®. PolarityTE has an open investigational new drug application (IND) for SkinTE® with the U.S. Food and Drug Administration (FDA) and is now pursuing the first of two pivotal studies on SkinTE® needed to support a biologics license application (BLA). SkinTE® is available for investigational use only. Learn more at www.PolarityTE.com.

Forward Looking Statements

Certain statements contained in this release are "forward-looking statements" within the

meaning of the Private Securities Litigation Reform Act of 1995. They are generally identified by words such as "believes," "may," "expects," "anticipates," "intend," "plan," "will," "would," "should" and similar expressions. Readers should not place undue reliance on such forward-looking statements, which are based upon the Company's beliefs and assumptions as of the date of this release. The Company's actual results could differ materially due to the impact of the COVID-19 pandemic, future clinical studies, and FDA regulatory matters, which cannot be predicted, and the risk factors and other items described in more detail in the "Risk Factors" section of the Company's Annual Reports and other filings with the SEC (copies of which may be obtained at www.sec.gov). Subsequent events and developments may cause these forward-looking statements to change. The Company specifically disclaims any obligation or intention to update or revise these forward-looking statements as a result of changed events or circumstances that occur after the date of this release, except as required by applicable law.

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

	September 30, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	\$ 16,094	\$ 19,375
Accounts receivable, net	–	978
Assets held for sale	916	441
Prepaid expenses and other current assets	1,479	1,595
Total current assets	18,489	22,389
Property and equipment, net	2,499	6,923
Operating lease right-of-use assets	246	1,146
Other assets	911	720
TOTAL ASSETS	\$ 22,145	\$ 31,178
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 1,895	\$ 3,115
Other current liabilities	904	1,520
Deferred revenue	–	74
Total current liabilities	2,799	4,709
Common stock warrant liability	2,238	6,844
Operating lease liabilities	52	43
Other long-term liabilities	113	338
Total liabilities	5,202	11,934

Commitments and Contingencies (Note 16)

STOCKHOLDERS' EQUITY

Preferred stock – 25,000,000 shares authorized, 0 shares issued and outstanding at September 30, 2022 and December 31, 2021

Common stock - \$.001 par value; 250,000,000 shares authorized; 7,219,974 and 3,299,379 shares

issued and outstanding at September 30, 2022 and December 31, 2021, respectively*

Additional paid-in capital	532,573	527,639
Accumulated deficit	(515,637)	(508,398)
Total stockholders' equity	<u>16,943</u>	<u>19,244</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 22,145</u>	<u>\$ 31,178</u>

* Giving retroactive effect to the 1-for-25 reverse stock split effectuated on May 16, 2022

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

	<u>2022</u>		<u>2021</u>	
	For the Three Months		For the Nine Months	
	Ended		Ended	
	September 30,		September 30,	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Net revenues				
Products	\$ –	\$ –	\$ –	\$ 2,924
Services	–	1,116	814	5,438
Total net revenues	<u>–</u>	<u>1,116</u>	<u>814</u>	<u>8,362</u>
Cost of revenues				
Products	–	–	–	448
Services	–	634	616	3,275
Total costs of revenues	<u>–</u>	<u>634</u>	<u>616</u>	<u>3,723</u>
Gross profit	<u>–</u>	<u>482</u>	<u>198</u>	<u>4,639</u>
Operating costs and expenses				
Research and development	2,551	3,870	8,489	10,491
General and administrative	2,685	3,687	12,456	14,999
Sales and marketing	–	93	–	2,718
Restructuring and other charges	–	242	38	678
Impairment of assets held for sale	169	–	223	–
Total operating costs and expenses	<u>5,405</u>	<u>7,892</u>	<u>21,206</u>	<u>28,886</u>
Operating loss	<u>(5,405)</u>	<u>(7,410)</u>	<u>(21,008)</u>	<u>(24,247)</u>
Other income (expense), net				
Gain on extinguishment of debt	–	–	–	3,612
Change in fair value of common stock warrant liability	1,984	6,354	13,719	4,134
Inducement loss on sale of liability classified warrants	–	–	–	(5,197)
Interest expense, net	(4)	(29)	(33)	(106)
Other income, net	25	64	83	185
Net loss and comprehensive loss	<u>\$ (3,400)</u>	<u>\$ (1,021)</u>	<u>\$ (7,239)</u>	<u>\$ (21,619)</u>
Net loss per share attributable to common stockholders				
Basic*	\$ (0.47)	\$ (0.31)	\$ (1.08)	\$ (6.81)
Diluted*	\$ (0.47)	\$ (0.37)	\$ (1.54)	\$ (6.81)
Weighted average shares outstanding				
Basic*	7,215,898	3,251,387	6,724,876	3,174,697
Diluted*	7,215,898	3,270,188	7,505,128	3,176,787

* Giving retroactive effect to the 1-for-25 reverse stock split effectuated on May 16, 2022

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

<u>2022</u>	<u>2021</u>
For the Nine Months Ended September 30,	

	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (7,239)	\$ (21,619)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,589	4,389
Depreciation and amortization	1,231	2,083
Impairment of assets held for sale	223	-
Amortization of intangible assets	-	142
Bad debt expense	-	99
Inventory write-off	-	747
Gain on extinguishment of debt – PPP loan	-	(3,612)
Change in fair value of common stock warrant liability	(13,719)	(4,134)
Inducement loss on sale of liability classified warrants	-	5,197
Loss on restructuring and other charges	-	321
Loss on sale of property and equipment	37	7
Gain on sale of subsidiary and property	(32)	-
Loss on disposal of property and equipment	3	-
Changes in operating assets and liabilities:		
Accounts receivable	396	2,534
Inventory	-	136
Prepaid expenses and other current assets	326	(1,392)
Operating lease right-of-use assets	900	1,011
Other assets/liabilities, net	(1)	247
Accounts payable and accrued expenses	(1,064)	(456)
Other current liabilities	-	(29)
Deferred revenue	(51)	87
Operating lease liabilities	(898)	(1,082)
Net cash used in operating activities	(18,299)	(15,324)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(37)	(18)
Proceeds from sale of property and equipment	195	23
Proceeds from sale of subsidiary and property, net of selling expenses and cash sold	2,327	-
Net cash provided by investing activities	2,485	5
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from insurance financing arrangements	1,027	1,028
Principal payments on term note payable and financing arrangements	(699)	(708)
Principal payments on financing leases	(256)	(413)
Net proceeds from the sale of common stock, warrants and pre-funded warrants	7,823	9,884
Proceeds from the sale of warrants	-	1,002
Proceeds from warrants exercised	-	6,671
Proceeds from pre-funded warrants exercised	3	8
Net proceeds from the sale of preferred stock and warrants	4,814	-
Cash paid for tax withholdings related to net share settlement	(181)	(355)
Proceeds from stock options exercised	-	3
Proceeds from ESPP purchase	2	28
Net cash provided by financing activities	12,533	17,148
Net (decrease) increase in cash and cash equivalents	(3,281)	1,829
Cash and cash equivalents - beginning of period	19,375	25,522
Cash and cash equivalents - end of period	\$ 16,094	\$ 27,351
Supplemental cash flow information:		
Cash paid for interest	\$ 56	\$ 96
Supplemental schedule of non-cash investing and financing activities:		
Fair value of placement agent warrants issued in connection with offerings	\$ 417	\$ 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 proceeds to warrant liability	\$ 9,113	\$ 8,629
Deferred and accrued offering costs	\$ 98	\$ 400
Sale of assets held for sale in exchange for a note receivable	\$ 400	\$ -
Reclassification of lease deposit to short term	\$ 210	\$ -

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SOURCE PolarityTE, Inc.