

March 30, 2022



PolarityTE Reports Fiscal Year 2021 Financial Results and Provides Business Update

PolarityTE to host conference call and webcast today, March 30, 2022, at 8:30 a.m. ET

SALT LAKE CITY, March 30, 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 twelve-month period ended December 31, 2021.



Recent Business and Financial Updates

- In the first quarter of 2022, PolarityTE received approval from the U.S. Food and Drug Administration (FDA) for its investigational new drug (IND) application for the evaluation of SkinTE[®] for the treatment of chronic cutaneous ulcers. As of this week, the Company has several clinical trial sites actively identifying patients for enrollment in its first pivotal study under IND, a multi-center, randomized controlled trial evaluating SkinTE in the treatment of Wager 2 diabetic foot ulcers (DFUs) entitled "Closure Obtained with Vascularized Epithelial Regeneration for DFUs with SkinTE," or "COVER DFUs." The company expects to have its first patient treated with SkinTE in April and to have up to 16 sites fully operational by the end of May.
- The Company reported final results from a non-IND randomized controlled trial evaluating treatment of venous leg ulcers (VLU) with its investigational product SkinTE plus standard of care (SOC) vs SOC alone (NCT03881267). The trial met the primary endpoint of wound closure at 12 weeks and secondary endpoint of Percent Area Reduction (PAR) at 4, 6, 8, 10, and 12 weeks.
 - Primary Endpoint: 71% (10/14) of participants receiving SkinTE plus SOC had

wound closure at 12 weeks versus 33% (5/15) of participants receiving SOC alone (p=0.046)

- Secondary Endpoint: Percent Area Reduction (PAR) assessed at 4, 6, 8, 10, and 12 weeks was significantly greater for the SkinTE plus SOC treatment group vs SOC alone (p=0.000035)
- 93% (13/14) of SkinTE plus SOC treated participants received a single application of SkinTE
- PolarityTE raised \$5.0m in gross proceeds through a registered direct offering of preferred stock on March 16, 2022.
- Cash used in operations for the twelve months ended December 31, 2021, was \$22.6 million, or an average of \$1.9 million per month, compared to \$37.8 million of cash used in operations for the twelve months ended December 31, 2020, or an average of \$3.2 million per month.
- Operating loss for the fiscal year ended December 31, 2021, was \$33.7 million, an improvement of 27% from the operating loss of \$45.9 million for 2020.
- The Company had cash and cash equivalents of \$19.4 million and working capital of \$17.7 million at December 31, 2021.

Richard Hague, Chief Executive Officer, commented, "We are pleased to have reached the significant milestone of IND acceptance and look forward to our next crucial milestone of treating patients in our first pivotal study under IND in the near future. In less than one year since announcing we would wind down commercial operations for SkinTE as a 361 HCT/P, we have made substantial progress to position the Company for long-term growth and opportunities by submitting our IND, resolving the CMC issues that FDA identified, and being on track to see SkinTE used in the clinic once again in subjects who are suffering from hard-to-treat wounds. Our confidence in SkinTE's ability to address wounds such as the Wagner 2 DFUs that will be treated in the COVER DFU Phase III pivotal study is borne out of our extensive clinical experience with the product and our steadfast belief that SkinTE can provide meaningful relief to patients with limited treatment options available to them currently."

Financial Results for the Period Ended December 31, 2021

PolarityTE is a clinical stage biotechnology company developing regenerative tissue products and biomaterials. PolarityTE has also historically operated a pre-clinical research business. 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 it pursues an IND and BLA, and PolarityTE expects to seek financing from external sources over the foreseeable future to fund its operations.

Comparison of the twelve months ended December 31, 2021, and the twelve months ended December 31, 2020

Net Revenues. Net revenues decreased \$0.7 million, or 7%, for the year ended December 31, 2021, compared to year ended December 31, 2020.

Products net revenues of \$3.1 million in 2021 were 18% less products net revenues in 2020 due to the cessation of commercial sales of SkinTE at the end of May 2021.

The mix of business activity generating services net revenues changed from a majority of service revenues generated by COVID-19 testing in 2020, to a majority of service revenues generated by pre-clinical research services in 2021. Service revenues generated by our pre-clinical research services business in the year ended December 31, 2021, were substantially higher than in 2020, as this business activity experienced a strong recovery from the poor results in 2020, which we believe was caused by the COVID-19 pandemic. Our COVID-19 testing services were a significant contributor to overall services revenues only in the first three months of 2021, which was offset by the increases from revenues from our pre-clinical research services business. As a result of these developments net revenues from services remained essentially unchanged in fiscal year 2021 compared to fiscal year 2020.

Cost of Revenues. The amount for cost of revenues remained essentially unchanged for the year ended December 31, 2021, compared to year ended December 31, 2020. There was a change, however, in the mix of cost of revenues amounts between products and services. Due to the cessation of SkinTE sales activity at the end of May 2021, products cost of revenues decreased by 58% from \$1.1 million in 2020 to \$0.4 million in 2021. This decrease was largely offset by an increase in services cost of revenues in the amount of \$0.5 million. Services cost of revenues increased from \$3.4 million in 2020 to \$3.9 million in 2021 due to an increase in revenues and resulting cost of sales in our pre-clinical research services, which is a lower margin business than the COVID -19 testing services that was the major component of our services revenues in 2020.

Operating Costs and Expenses. Operating costs and expenses decreased \$12.9 million, or 25%, for the year ended December 31, 2021, compared to the year ended December 31, 2020. The reduction in operating costs and expenses is attributable to reductions in general and administrative expenses, sales and marketing expenses, and restructuring and other charges that were partially offset by increases in research and development expenses.

Research and development expenses increased 23% for the year ended December 31, 2021, compared to the year ended December 31, 2020. The substantial increase in 2021 is primarily attributable to an increase in lab supply costs and consulting services for work on the CMC elements of our IND; re-allocation of costs for manufacturing supplies and compensation following the cessation of SkinTE sales from products cost of goods, general and administrative expenses, and sales and marketing expenses to research and development costs; the costs in our pre-IND clinical trials that we concluded during 2021; and, costs incurred in connection with the planning and initial payments required for the clinical trial we are about to begin under the IND for SkinTE.

We effectuated a reduction in force for our commercial operations in 2021. Consequently, there were reductions in cash compensation, stock compensation, consulting fees, and travel expense. As we reduced and then ended our commercial sales of SkinTE, we also reduced expenses related to a larger operation by terminating our lease for the Utah corporate office in September 2020 and ceasing operations at our manufacturing node in Georgia in the fourth quarter of 2020, from which we recognized the benefits in 2021. 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 partially offset by executive and employee bonus compensation paid or accrued in 2021 at levels higher than bonus compensation paid or accrued in 2020 and professional fees incurred in connection with our pursuit of a strategic transaction that did not materialize. The cost cutting measures and re-allocation of costs described above are the primary causes of a 26% decrease in general and administrative expense period over period for the year ended December 31, 2021, compared to the year ended December 31, 2020.

When we reduced the commercial sales team and related commercial activities, we also took steps to reduce staff and consultants in sales and marketing. With the cessation of SkinTE sales several employees who supported sales and marketing moved into new roles in research and development, so their compensation was allocated to research and development. Consequently, there were significant reductions in cash compensation, stock compensation, consulting fees, and travel expense, which resulted in a 68% decrease in sales and marketing expense for the year ended December 31, 2021, compared to the year ended December 31, 2020.

We realized restructuring and other charges as a result of the transition to a clinical stage company, much of which were recognized in the year ended December 31, 2020. In connection with reducing our commercial sales activity in 2020 we incurred severance charges of \$1.1 million. We abandoned operations at the manufacturing node in Augusta, Georgia, which resulted in the recognition of a charge in the amount of \$1.2 million consisting of equipment, leasehold improvements, and a right of use asset. In 2020 we also decided to abandon equipment in addition to the development of a vivarium research facility at our Salt Lake City location resulting in a charge of \$1.5 million. By contrast, during the 12-month period ended December 31, 2021, we recognized an impairment of property and equipment in the amount of \$0.4 million and severance charges of \$0.6 million, which were offset by a \$0.3 million gain on the termination of Polarity's Augusta node lease. Consequently, there was an 82% decrease in restructuring and other charges for the year ended December 31, 2021, compared to the year ended December 31, 2020.

We recognized an impairment of goodwill and intangible assets pertaining to IBEX for \$0.6 million based on management's judgment regarding the likelihood that IBEX will continue to be a meaningful contributor to the operations of the Company through the remainder of 2022.

Operating Loss and Net Loss. Operating loss decreased \$12.3 million, or 27%, for the year ended December 31, 2021, compared to the year ended December 31, 2020. Net loss decreased \$12.7 million, or 30%, for the year ended December 31, 2021, compared to the year ended December 31, 2020.

Warrants issued in connection with financings we completed in 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 \$5.0 million for the year ended December 31, 2021, compared to a gain of \$2.9 million for the year ended December 31, 2020. For additional information on the change in fair value of common stock warrant liability please see Note 12 to the 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. There was no similar action taken in 2020.

When the PPP Loan was forgiven in June 2021, we recognized a gain on extinguishment of debt in the amount of \$3.6 million. This gain together with the positive change in fair value of common stock warrant liability was offset by the inducement loss of \$5.2 million recognized in January 2021, which, primarily accounts for the difference of \$3.5 million between our operating loss and net loss for the year ended December 31, 2021.

Cash and Liquidity as of December 31, 2021

As of December 31, 2021, we had \$19.4 million in cash and cash equivalents and working capital of approximately \$17.7 million. We do not expect that our cash and cash equivalents of \$19.4 million as of December 31, 2021, would 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 annual financial statements. We plan to address this condition by raising additional capital to finance our operations.

Conference Call and Webcast Details

The March 30, 2022 8:30am ET conference call can be accessed by calling 1-800-581-5838 (U.S. and Canada) or +44 (0)330 336 9104 (International) with confirmation code 361897 and referencing "PolarityTE Fiscal Year 2021 Earnings Call". A webcast of the conference call can be accessed by using the link below.

[Earnings Call Webcast – CLICK HERE](#)

A replay of the earnings conference call will be available for 30 days, beginning approximately one hour after the conclusion of the call and can be found by visiting PolarityTE's website at <https://www.polarityte.com/news-media/events>, or by clicking on the link above.

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 expected pivotal studies on SkinTE® needed to support a biologics license application (BLA) for a chronic cutaneous ulcer indication. 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.

POLARITYTE, the POLARITYTE logo, SKINTE, WHERE SELF REGENERATES SELF and WELCOME TO THE SHIFT are registered trademarks of PolarityTE, Inc.

CONTACTS

Investors:

PolarityTE Investor Relations
ir@PolarityTE.com
 385-831-5284

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

	<u>December 31, 2021</u>	<u>December 31, 2020</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 19,375	\$ 25,522
Accounts receivable, net	978	3,819
Inventory	—	883
Assets held for sale	441	—
Prepaid expenses and other current assets	1,595	992
Total current assets	<u>22,389</u>	<u>31,216</u>
Property and equipment, net	6,923	10,550
Operating lease right-of-use assets	1,146	2,452
Intangible assets, net	—	542
Goodwill	—	278
Other assets	720	472
TOTAL ASSETS	<u>\$ 31,178</u>	<u>\$ 45,510</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 3,115	\$ 4,148
Other current liabilities	1,520	2,106
Current portion of long-term note payable	—	2,059
Deferred revenue	74	168
Total current liabilities	<u>4,709</u>	<u>8,481</u>
Common stock warrant liability	6,844	5,975
Operating lease liabilities	43	1,476
Other long-term liabilities	338	723
Long-term notes payable	—	1,517
Total liabilities	<u>11,934</u>	<u>18,172</u>

Commitments and Contingencies (Note 16)

STOCKHOLDERS' EQUITY

Preferred stock – 25,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2021 and 2020

Common stock - \$.001 par value; 250,000,000 shares authorized; 82,484,462 and 54,857,099 shares issued and outstanding at December 31, 2021 and 2020, respectively

Additional paid-in capital

Accumulated deficit

Total stockholders' equity

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY

	-	-
	82	55
	527,560	505,494
	(508,398)	(478,211)
	<u>19,244</u>	<u>27,338</u>
	<u>\$ 31,178</u>	<u>\$ 45,510</u>

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

	For the Year Ended December	
	31,	
	2021	2020
Net revenues		
Products	\$ 3,076	\$ 3,730
Services	6,328	6,396
Total net revenues	<u>9,404</u>	<u>10,126</u>
Cost of revenues		
Products	448	1,068
Services	3,868	3,356
Total costs of revenues	<u>4,316</u>	<u>4,424</u>
Gross profit	<u>5,088</u>	<u>5,702</u>
Operating costs and expenses		
Research and development	14,182	11,532
General and administrative	20,476	27,557
Sales and marketing	2,808	8,719
Restructuring and other charges	678	3,834
Impairment of goodwill and intangible assets	630	-
Total operating costs and expenses	<u>38,774</u>	<u>51,642</u>
Operating loss	<u>(33,686)</u>	<u>(45,940)</u>
Other income (expense), net		
Gain on extinguishment of debt	3,612	-
Change in fair value of common stock warrant liability	4,995	2,914
Inducement loss on sale of liability classified warrants	(5,197)	-
Interest (expense) income, net	(127)	(182)
Other income, net	216	354
Net loss	<u>\$ (30,187)</u>	<u>\$ (42,854)</u>
Net loss per share attributable to common stockholders		
Basic	\$ (0.38)	\$ (1.11)
Diluted	\$ (0.38)	\$ (1.16)
Weighted average shares outstanding		
Basic	80,014,014	38,779,316
Diluted	80,014,014	39,367,390

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

	For the Year Ended December	
	31,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (30,187)	\$ (42,854)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	5,381	7,258
Depreciation and amortization	2,652	3,074
Impairment of goodwill and intangible assets	630	-

Amortization of intangible assets	190	189
Amortization of debt discount	–	19
Bad debt expense	75	148
Inventory write-off	747	–
Gain on extinguishment of debt – PPP loan	(3,612)	–
Change in fair value of common stock warrant liability	(4,995)	(2,914)
Inducement loss on sale of liability classified warrants	5,197	–
Loss on restructuring and other charges	321	–
Loss on sale of property and equipment and ROU assets	12	2,806
Loss on abandonment of property and equipment	209	–
Other non-cash adjustments	(45)	(21)
Changes in operating assets and liabilities:		
Accounts receivable	2,766	(2,236)
Inventory	136	(631)
Prepaid expenses and other current assets	(603)	272
Operating lease right-of-use assets	1,318	1,700
Other assets/liabilities, net	(248)	(200)
Accounts payable and accrued expenses	(1,047)	(2,761)
Other current liabilities	(29)	35
Deferred revenue	(94)	70
Operating lease liabilities	(1,404)	(1,708)
Net cash used in operating activities	<u>(22,630)</u>	<u>(37,754)</u>
CASH FLOWS FROM (USED IN) INVESTING ACTIVITIES		
Purchase of property and equipment	(123)	(1,339)
Proceeds from sale of property and equipment	27	–
Purchase of available-for-sale securities	–	(14,144)
Proceeds from maturities of available-for-sale securities	–	16,945
Proceeds from sale of available-for-sale securities	–	16,171
Net cash provided by/(used in) investing activities	<u>(96)</u>	<u>17,633</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from term note payable and financing arrangements	1,028	4,629
Principal payments on term note payable and financing arrangements	(1,054)	(1,675)
Principal payments on financing leases	(555)	(508)
Net proceeds from the sale of common stock, warrants and pre-funded warrants	9,884	32,020
Proceeds from the sale of new warrants	1,002	–
Proceeds from warrants exercised	6,671	1,008
Proceeds from pre-funded warrants exercised	8	–
Cash paid for tax withholdings related to net share settlement	(463)	(155)
Proceeds from stock options exercised	3	31
Proceeds from ESPP purchase	55	75
Net cash provided by financing activities	<u>16,579</u>	<u>35,425</u>
Net increase (decrease) in cash and cash equivalents	<u>(6,147)</u>	<u>15,304</u>
Cash and cash equivalents - beginning of period	25,522	10,218
Cash and cash equivalents - end of period	<u>\$ 19,375</u>	<u>\$ 25,522</u>

View original content to download multimedia <https://www.prnewswire.com/news-releases/polarityte-reports-fiscal-year-2021-financial-results-and-provides-business-update-301513448.html>

SOURCE PolarityTE, Inc.