

March 30, 2021



PolarityTE Reports Fourth Quarter and Fiscal Year 2020 Results

Fourth Quarter Revenues of \$3.59 million and Full Year 2020 Revenues of \$10.13 million

PolarityTE to host conference call and webcast today, March 30, 2021 at 8:00 a.m. ET

SALT LAKE CITY--(BUSINESS WIRE)-- **PolarityTE, Inc. (Nasdaq: PTE)**, a biotechnology company developing regenerative tissue products and biomaterials, today reported financial results for the fourth quarter and fiscal year ended December 31, 2020.

David Seaburg, Chief Executive Officer, commented, “2020 was a transformational year for PolarityTE as we made the decision to pursue an IND and BLA for SkinTE. If we successfully obtain a BLA for SkinTE, we believe it will create a more valuable asset with a greater likelihood of achieving widespread commercial adoption bolstered by robust clinical data, which should have a positive effect on stockholder value. As a result of this change in direction, we reduced our commercial operations in May 2020 and have realized a substantial reduction in our operating expenses. This cost savings coupled with our recent capital raises means we have the resources to pursue the FDA regulatory process and fund our operations well into 2022. Our team weathered COVID-19’s headwinds to our SkinTE business and leveraged our internal resources to build out our testing business, allowing us to defray expenses and support the public health effort to combat the pandemic. We have also made great progress towards our planned IND submission, which we remain on track to file in the second half of 2021. I am proud of what we have accomplished over the past year, and look forward to what the future holds for PolarityTE and all of our stakeholders.”

Recent Business Highlights

- Raised \$25.67 million of capital (before offering costs) from a single healthcare-dedicated institutional investor in December 2020 and January 2021
- Submitted a Type B Pre-IND meeting request to FDA for SkinTE and received written responses in October 2020
- In February 2021, U.S. Patent No. 10,926,001 issued, and U.S. Application No. 16/165,169 was allowed. The granted and allowed claims pertain to methods of making compositions for regenerating functional skin tissue, and related methods of treatment. The Company’s total number of allowed and granted utility patents is currently ten—eight internationally and two in the U.S.
- Final patient enrolled in our multicenter, randomized controlled trial evaluating SkinTE plus standard of care versus standard of care alone in treatment of diabetic foot ulcers in January 2021, with top-line results expected to be announced at the Symposium on Advanced Wound Care (SAWC) Spring Conference in May 2021

Operating Highlights for the Year Ended December 31, 2020

- Total revenues were \$10.13 million for FY:20 compared to \$5.65 million for FY:19, representing a 79% increase year over year
- SkinTE revenues were \$3.73 million for FY:20 compared to \$2.35 million for FY:19, representing a 59% increase year over year
- Contract services revenues were \$6.40 million for FY:20 compared to \$3.30 million for FY:19, representing a 94% increase year over year
 - Contract services revenues for FY:20 includes \$4.32 million from COVID-19 test processing that began in late May of 2020
- Operational cash burn for FY:20 was \$37.75 million which is a reduction of \$18.89 million from FY:19, representing a 33% decrease year over year

Operating Highlights for the Quarter Ended December 31, 2020

- Total revenues were \$3.59 million in Q4:20 compared to \$3.34 million in Q3:20, representing an 8% increase quarter over quarter
- SkinTE revenues were \$1.20 million in Q4:20 compared to \$1.16 million in Q3:20, representing a 4% increase quarter over quarter
- Contract services revenues were \$2.39 million in Q4:20 compared to \$2.18 million in Q3:20, representing a 9% increase quarter over quarter
 - Contract services revenues for Q4:20 includes \$1.86 million from COVID-19 testing processing
- Operational cash burn for Q4:20 was \$4.82 million, excluding \$0.76 million of offering and warrant repricing expenses, which represents a 70% reduction from Q4:19 and 29% reduction from Q3:20

Financial Results for the Year Ended December 31, 2020

Net revenues increased by 79% to \$10.13 million in 2020. The increase in net revenues for sale of products was the result of a sales strategy adopted in May 2020 to focus on regions and facilities where we had repeat users of SkinTE. For 2020 the average wound size treated with SkinTE was 219 cm² compared to 120 cm² in 2019, which corresponds with the difference in revenue between those years. The increase in net revenues for services was the result of \$4.32 million in new COVID-19 testing services we began to offer through Arches Research at the end of May 2020. In 2019 services net revenues was derived primarily from pre-clinical testing services provided through IBEX Preclinical Research, which were adversely impacted by COVID-19 in 2020.

Total operating costs and expenses decreased to \$51.64 million in 2020 from \$96.57 million in 2019, or 47%. This is the most significant change in our results of operations period over period and is attributable to the 46% reduction in personnel from the end of 2019 to the end of 2020. The reduction in personnel substantially reduced salary and benefit costs across the Company. Salary and benefits totaled \$19.72 million in 2020 compared to \$28.81 million in 2019. In addition, stock-based compensation decreased by 77% from \$31.40 million in 2019 to \$7.26 million in 2020. The decrease in salary and benefits in 2020 accounts for 20% of the decrease in total operating costs and expenses in 2020 compared to 2019. The decrease in stock-based compensation in 2020 accounts for 54% of the decrease in total operating costs and expenses in 2020 compared to 2019. The reduction in personnel also allows us to make incremental reductions in the cost of infrastructure required to support the activities of

employees.

Research and development expenses decreased by 30% in 2020 to \$11.53 million, which is attributable to the reduction in salary and benefits and stock compensation costs from 2019.

General and administrative expenses decreased by 56% in 2020 to \$27.56 million. In addition to reductions in salary and benefits and stock compensation costs from 2019, travel and related costs decreased to \$0.24 million in 2020 from \$1.32 million in 2019. Expenses for our leased facilities were \$2.09 million in 2020.

Sales and marketing expenses decreased by 49% in 2020 to \$8.72 million. In addition to reductions in salary and benefits and stock compensation costs from 2019, promotional consulting and expense was reduced to \$0.83 million in 2020 from \$5.27 in 2019, and travel and related costs decreased to \$0.44 million in 2020 from \$1.44 million in 2019.

Net loss for the year ended December 31, 2020 was \$42.85 million compared with a net loss of \$92.49 million for the year ended December 31, 2019.

Cash and Liquidity as of December 31, 2020

As of December 31, 2020, we had \$25.52 million in cash and cash equivalents. In January 2021, we raised an additional \$17.67 million in gross proceeds before offering expenses in a registered direct offering and through a warrant exercise agreement. Based on currently available information as of the date we file this press release, we believe that our existing cash and cash equivalents will be sufficient to fund our activities through the end of 2021 and into the third quarter of 2022. However, our projections of future cash needs may differ from actual results.

Cash used in operating activities for the three-month period ended December 31, 2020 was approximately \$5.58 million, which included \$0.76 million of offering and repricing costs, or \$4.82 million excluding offering and repricing costs or approximately \$1.61 million per month on average, 70% lower than the \$5.33 million monthly average in the three months ended December 31, 2019 and 29% lower than the \$2.25 million monthly average in the three months ended September 30, 2020.

Conference Call and Webcast Details

The 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 363305 and referencing "PolarityTE Fiscal Year 2020 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 is focused on transforming the lives of patients by discovering, designing, and developing a range of regenerative tissue products and biomaterials for the fields of medicine, biomedical engineering and material sciences. Rather than manufacturing with synthetic and foreign materials within artificially engineered environments, PolarityTE manufactures products from the patient's own tissue and uses the patient's own body to support the regenerative process. From a small piece of healthy autologous tissue, the company creates an easily deployable, dynamic, and self-propagating product designed to regenerate the target tissues. PolarityTE's innovative methods are intended to promote and accelerate growth of the patient's tissues to undergo a form of effective regenerative healing. Learn more at www.PolarityTE.com – Welcome to the Shift®.

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 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. Our actual results could differ materially due to 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).

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

	December 31, 2020	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	\$ 25,522	\$ 10,218
Short-term investments	–	19,022
Accounts receivable, net	3,819	1,731
Inventory	883	252
Prepaid expenses and other current assets	992	1,264
Total current assets	31,216	32,487
Property and equipment, net	10,550	14,911
Operating lease right-of-use assets	2,452	4,590
Intangible assets, net	542	731
Goodwill	278	278
Other assets	472	602
TOTAL ASSETS	\$ 45,510	\$ 53,599

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities			
Accounts payable and accrued expenses	\$	4,148	\$ 7,095
Other current liabilities		2,106	2,338
Current portion of long-term note payable		2,059	528
Deferred revenue		168	98
Total current liabilities		8,481	10,059
Common stock warrant liability		5,975	–
Operating lease liabilities		1,476	2,994
Other long-term liabilities		723	1,630
Long-term notes payable		1,517	–
Total liabilities		18,172	14,683

Commitments and Contingencies (Note 17)

STOCKHOLDERS' EQUITY

Preferred stock – 25,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2020 and 2019		–	–
Common stock - \$.001 par value; 250,000,000 shares authorized; 54,857,099 and 27,374,653 shares issued and outstanding at December 31, 2020 and 2019, respectively		55	27
Additional paid-in capital		505,494	474,174
Accumulated other comprehensive income		–	72
Accumulated deficit		(478,211)	(435,357)
Total stockholders' equity		27,338	38,916
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	45,510	\$ 53,599

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

	For the Year Ended December 31,	
	2020	2019
Net revenues		
Products	\$ 3,730	\$ 2,353
Services	6,396	3,299
Total net revenues	10,126	5,652
Cost of sales		
Products	1,068	1,365
Services	3,356	1,114
Total costs of sales	4,424	2,479
Gross profit	5,702	3,173
Operating costs and expenses		
Research and development	11,532	16,397
General and administrative	27,557	63,189
Sales and marketing	8,719	16,980
Restructuring and other charges	3,834	–
Total operating costs and expenses	51,642	96,566
Operating loss	(45,940)	(93,393)
Other income (expense), net		
Change in fair value of common stock warrant liability	2,914	–
Interest (expense) income, net	(182)	151
Other income, net	354	749
Net loss	\$ (42,854)	\$ (92,493)
Net loss per share attributable to common stockholders		
Basic	\$ (1.11)	\$ (3.70)
Diluted	\$ (1.16)	\$ (3.70)
Weighted average shares outstanding		
Basic	38,779,316	24,966,355

Diluted

39,367,390

24,966,355

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

	For the Year Ended December 31, 2020	For the Year Ended December 31, 2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (42,854)	\$ (92,493)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	7,258	31,402
Depreciation and amortization	3,074	2,992
Change in allowance for doubtful accounts	148	26
Change in fair value of common stock warrant liability	(2,914)	–
Amortization of intangible assets	189	193
Amortization of debt discount	19	49
Change in fair value of contingent consideration	–	(36)
Loss on abandonment of property and equipment and ROU assets	2,806	914
Other non-cash adjustments	(21)	20
Changes in operating assets and liabilities:		
Accounts receivable	(2,236)	(1,045)
Inventory	(631)	84
Prepaid expenses and other current assets	272	193
Operating lease right-of-use assets	1,700	1,651
Other assets/liabilities, net	(200)	(249)
Accounts payable and accrued expenses	(2,761)	1,269
Other current liabilities	35	32
Deferred revenue	70	(72)
Operating lease liabilities	(1,708)	(1,578)
Net cash used in operating activities	<u>(37,754)</u>	<u>(56,648)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(1,339)	(2,773)
Purchase of available-for-sale securities	(14,144)	(40,072)
Proceeds from maturities of available-for-sale securities	16,945	23,327
Proceeds from sale of available-for-sale securities	16,171	3,901
Net cash provided by/(used in) investing activities	<u>17,633</u>	<u>(15,617)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from term note payable and financing arrangements	4,629	–
Principal payments on term note payable and financing arrangements	(1,675)	(534)
Payment of contingent consideration liability	–	(225)
Principal payments on financing leases	(508)	(453)
Net proceeds from the sale of common stock, warrants and pre-funded warrants	32,020	28,073
Proceeds from warrants exercised	1,008	–
Cash paid for tax withholdings related to net share settlement	(155)	(679)
Proceeds from stock options exercised	31	529
Proceeds from ESPP purchase	75	99
Net cash provided by financing activities	<u>35,425</u>	<u>26,810</u>
Net increase/(decrease) in cash and cash equivalents	15,304	(45,455)
Cash and cash equivalents - beginning of period	10,218	55,673
Cash and cash equivalents - end of period	<u>\$ 25,522</u>	<u>\$ 10,218</u>

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