

August 12, 2021



PolarityTE Reports Second Quarter Financial Results and Provides Business Update

PolarityTE to host conference call and webcast today, August 12, 2021, at 4:30 p.m. ET

SALT LAKE CITY--(BUSINESS WIRE)-- **PolarityTE, Inc. (Nasdaq: PTE)**, a biotechnology company developing regenerative tissue products and biomaterials, today provided a business update and reported financial results for the second quarter ended June 30, 2021.

Recent Business Updates

- Submitted an Investigational New Drug application (IND) for SkinTE® on July 23, 2021, for the proposed indication of treatment of chronic cutaneous ulcers
- Reported SkinTE met primary and secondary endpoints in final analysis from Diabetic Foot Ulcer (DFU) trial
- Received notice of allowance for additional patent, bringing the Company's total number of allowed and granted utility patents worldwide to 12 – 10 abroad and 2 in the United States

In response to the IND submission the Company recently received requests from the FDA's Clinical and CMC reviewers for additional information and the Company provided initial responses to those requests. The Company appreciates the FDA's feedback and believes it is generally in line with what the Company anticipated following its pre-IND interactions with the FDA.

Financial Updates for the Quarter Ended June 30, 2021

- Total revenues were \$2.54 million in Q2:21 compared to \$4.71 million in Q1:21
- SkinTE revenues were \$1.20 million in Q2:21 (April 1, 2021 through cessation of SkinTE sales on May 31, 2021) compared to \$1.73 million in Q1:21
- Contract services revenues were \$1.34 million in Q2:21 compared to \$2.98 million in Q1:21
- Cash used in operations for Q2:21 was \$4.1 million, or an average of \$1.4 million per month, representing a 38% reduction from Q1:21

Transition to a Clinical Stage Biotech Company

As part of the transition to a clinically focused biotech company and consistent with the conclusion of FDA's enforcement discretion for certain human cells, tissues, and cellular and tissue-based products under Section 361 of the Public Health Service Act (361 HCT/PS), the

Company ceased commercial sales of SkinTE on May 31, 2021, and has made substantial reductions in costs associated with its commercial operations. The Company previously provided guidance for an IND submission in the second half of 2021 and on July 23, 2021 the Company submitted to the FDA an IND for SkinTE for the treatment of chronic cutaneous ulcers.

David Seaburg, Chief Executive Officer, commented, “We have made great strides to position the Company for the future, most recently with the submission of an IND, and I could not be more impressed by the organization’s commitment to this achievement. We are also incredibly encouraged by the recent outreach and support from physicians and patients after ceasing sales of SkinTE, and we will work expeditiously in the pursuit of a Biologic License Application (BLA).” Mr. Seaburg continued, “The second quarter includes the final two months of SkinTE sales prior to the end of FDA’s enforcement discretion and further solidifies our view that there is sizable market opportunity for SkinTE.”

Financial Results for the Quarter Ended June 30, 2021

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

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

As a result of the foregoing developments, the Company made a number of changes to its operations that impacted results of operations. These included reductions in the Company’s work force in March and May 2020 and on June 1, 2021, and reducing the services and infrastructure needed to support a larger work force and commercial sales effort.

Net revenues increased \$4.0 million, or 127%, for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, and \$0.3 million, or 12%, for the three months ended June 30, 2021, compared to the same period in 2020. The Company effectuated a substantial reduction in force for commercial operations in May 2020, which together with the effect of COVID-19 on selling product to healthcare institutions caused the Company to adopt a sales strategy in May 2020 that focused on regions and facilities where there were repeat users of SkinTE. As a result of this strategy, product net revenues increased by 27% for the three-months ended June 30, 2021, compared to the same period in 2020, even though the Company ceased product sales at the end of May 2021. Net revenues from services remained essentially unchanged for the three months ended June 30, 2021, compared to the same period in 2020, but the mix of business activity generating those revenues changed from a majority of service revenues generated by COVID-19 testing in the second quarter of 2020 to a majority of service revenues generated by pre-clinical research services in 2021.

Cost of sales increased \$1.7 million, or 121%, for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, and \$0.04 million, or 5%, for the three months ended June 30, 2021, compared to the same period in 2020. Cost of sales for products revenues decreased 27% period over period for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, and decreased 25% period over period for the three months ended June 30, 2021, compared to the three months ended June 30, 2020, even though revenues were higher in 2021 for both the six and three-month periods, which is attributable to the economies of scale the Company achieved by selling product for larger wound sizes in 2021 compared to 2020. Cost of sales for services revenues increased 237% period over period for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, and increased 18% period over period for the three months ended June 30, 2021, compared to the three months ended June 30, 2020, which is primarily attributable to the cost of sales pertaining to the COVID-19 testing service that only began in the last week of May 2020, including a write-off of inventory for the COVID-19 testing business in the first quarter of 2021 due to the substantial decrease in that business during the quarter.

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

Operating loss decreased \$12.0 million, or 42%, for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, and \$2.5 million, or 22%, for the three months ended June 30, 2021, compared to the same period in 2020. Net loss decreased \$5.1 million, or 20%, for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, and \$9.5 million, or 75%, for the three months ended June 30, 2021, compared to the same period in 2020. When the Company's PPP Loan was forgiven in June 2021, it recognized a gain on extinguishment of debt in the amount of \$3.6 million. For the six months ended June 30, 2021, this gain was offset by a day one loss on warrants issued in January 2021 of \$5.2 million plus a loss on the change in fair value of common stock warrant liability of \$2.2 million, which are primarily responsible for other expense of \$3.8 million for the six months ended June 30, 2021, and the \$3.8 million difference between the Company's operating loss and net loss for the six months ended June 30, 2021.

The table below details 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. The Company believes this measure is useful to investors because it eliminates the effect of non-operating items that can significantly fluctuate from period to period due to fair value remeasurements. For purposes of calculating non-GAAP per share metrics, the same denominator is used as that which was used in calculating net loss per share under GAAP.

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
GAAP Net Loss	\$ (3,188)	\$ (12,677)	\$ (20,598)	\$ (25,717)
Change in fair value of common stock warrant liability	(1,807)	1,591	2,220	(2,941)

Inducement loss on sale of liability classified warrants		–	–	5,197	–
Non-GAAP adjusted net loss attributable to common stockholders - basic	\$	(4,995)	\$ (11,086)	\$ (13,181)	\$ (28,658)
Gain from change in fair value of warrant liabilities		(107)	–	–	–
Non-GAAP adjusted net loss attributable to common stockholders - diluted	\$	(5,102)	\$ (11,086)	\$ (13,181)	\$ (28,658)
GAAP net loss per share attributable to common stockholders					
Basic	\$	(0.04)	\$ (0.33)	\$ (0.26)	\$ (0.72)
Diluted	\$	(0.04)	\$ (0.33)	\$ (0.26)	\$ (0.72)
Non-GAAP adjusted net loss per share attributable to common stockholders					
Basic	\$	(0.06)	\$ (0.29)	\$ (0.17)	\$ (0.80)
Diluted	\$	(0.06)	\$ (0.29)	\$ (0.17)	\$ (0.80)

Cash and Liquidity as of June 30, 2021

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

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 210912 and referencing "PolarityTE Second Quarter 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 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.

PolarityTE's products, including SkinTE, are in the development stage, and are not approved or available for clinical use. 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, 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)

	June 30, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	\$ 32,614	\$ 25,522
Accounts receivable, net	2,042	3,819
Inventory	76	883
Prepaid expenses and other current assets	2,286	992
Total current assets	37,018	31,216
Property and equipment, net	8,684	10,550
Operating lease right-of-use assets	1,756	2,452
Intangible assets, net	447	542
Goodwill	278	278
Other assets	227	472
TOTAL ASSETS	\$ 48,410	\$ 45,510
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 3,924	\$ 4,148
Other current liabilities	2,509	2,106
Current portion of long-term notes payable	–	2,059
Deferred revenue	86	168
Total current liabilities	6,519	8,481
Common stock warrant liability	14,059	5,975
Operating lease liabilities	550	1,476
Other long-term liabilities	514	723
Long-term notes payable	–	1,517
Total liabilities	21,642	18,172

Commitments and Contingencies (Note 14)

STOCKHOLDERS' EQUITY

Preferred stock - 25,000,000 shares authorized, 0 shares issued and outstanding at June 30, 2021 and December 31, 2020	-	-
Common stock – \$.001 par value; 250,000,000 shares authorized; 80,742,443 and 54,857,099 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	81	55
Additional paid-in capital	525,496	505,494
Accumulated deficit	(498,809)	(478,211)
Total stockholders' equity	<u>26,768</u>	<u>27,338</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 48,410</u>	<u>\$ 45,510</u>

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Net revenues				
Products	\$ 1,195	\$ 944	\$ 2,924	\$ 1,372
Services	1,342	1,322	4,322	1,827
Total net revenues	<u>2,537</u>	<u>2,266</u>	<u>7,246</u>	<u>3,199</u>
Cost of sales				
Products	207	275	448	615
Services	717	607	2,641	783
Total cost of sales	<u>924</u>	<u>882</u>	<u>3,089</u>	<u>1,398</u>
Gross profit	<u>1,613</u>	<u>1,384</u>	<u>4,157</u>	<u>1,801</u>
Operating costs and expenses				
Research and development	4,190	3,164	6,621	6,537
General and administrative	4,941	5,211	11,312	15,816
Sales and marketing	1,099	2,024	2,625	5,718
Restructuring and other charges	11	2,084	436	2,536
Total operating costs and expenses	<u>10,241</u>	<u>12,483</u>	<u>20,994</u>	<u>30,607</u>
Operating loss	<u>(8,628)</u>	<u>(11,099)</u>	<u>(16,837)</u>	<u>(28,806)</u>
Other income (expenses)				
Gain on extinguishment of debt	3,612	-	3,612	-
Change in fair value of common stock warrant liability	1,807	(1,591)	(2,220)	2,941
Inducement loss on sale of liability classified warrants	-	-	(5,197)	-
Interest expense, net	(39)	(65)	(77)	(77)
Other income, net	60	78	121	225
Net loss	<u>\$ (3,188)</u>	<u>\$ (12,677)</u>	<u>\$ (20,598)</u>	<u>\$ (25,717)</u>
Net loss per share attributable to common stockholders				
Basic	\$ (0.04)	\$ (0.33)	\$ (0.26)	\$ (0.72)
Diluted	\$ (0.04)	\$ (0.33)	\$ (0.26)	\$ (0.72)
Weighted average shares outstanding				
Basic	80,602,931	38,428,289	78,392,881	35,724,141
Diluted	81,162,256	38,428,289	78,392,881	35,724,141

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

	For the Six Months Ended June 30,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (20,598)	\$ (25,717)

Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	3,124	3,784
Depreciation and amortization	1,437	1,549
Amortization of intangible assets	95	95
Amortization of debt discount	–	13
Bad debt expense	134	–
Inventory write-off	697	–
Gain on extinguishment of debt – PPP loan	(3,612)	–
Change in fair value of common stock warrant liability	2,220	(2,941)
Inducement loss on sale of liability classified warrants	5,197	–
Loss on restructuring and other charges	269	–
Loss on abandonment of property and equipment	–	1,529
Loss on sale of property and equipment	7	–
Other non-cash adjustments	–	(21)
Changes in operating assets and liabilities:		
Accounts receivable	1,643	(384)
Inventory	110	(29)
Prepaid expenses and other current assets	(1,294)	(1,189)
Operating lease right-of-use assets	666	899
Other assets	245	3
Accounts payable and accrued expenses	(221)	(2,109)
Other current liabilities	(14)	9
Deferred revenue	(82)	(1)
Operating lease liabilities	(728)	(903)
Net cash used in operating activities	(10,705)	(25,413)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(18)	(1,170)
Proceeds from sale of property and equipment	10	–
Purchase of available-for-sale securities	–	(14,144)
Proceeds from maturities of available-for-sale securities	–	16,945
Proceeds from sale of available-for-sale securities	–	16,171
Net cash (used in) provided by investing activities	(8)	17,802
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from term note payable and financing arrangements	1,028	4,629
Principal payments on term note payable and financing arrangements	(359)	(830)
Principal payments on financing leases	(272)	(243)
Net proceeds from the sale of common stock and warrants	–	24,276
Net proceeds from the sale of common stock, warrants and pre-funded warrants	9,884	–
Proceeds from the sale of new warrants	1,002	–
Proceeds from warrants exercised	6,671	–
Proceeds from pre-funded warrants exercised	8	–
Cash paid for tax withholdings related to net share settlement	(188)	(6)
Proceeds from stock options exercised	3	31
Proceeds from ESPP purchase	28	40
Net cash provided by financing activities	17,805	27,897
Net increase in cash and cash equivalents	7,092	20,286
Cash and cash equivalents - beginning of period	25,522	10,218
Cash and cash equivalents - end of period	\$ 32,614	\$ 30,504

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