

August 8, 2019



## PolarityTE Reports Second Calendar Quarter 2019 Results

SALT LAKE CITY, Aug. 8, 2019 /PRNewswire/ -- PolarityTE, Inc. (Nasdaq: PTE), a biotechnology company developing and commercializing regenerative tissue products and biomaterials, today reported financial results for the second calendar quarter of 2019.

PolarityTE will host a conference call and webcast today, August 8, 2019 at 8:00am ET. Please see details below.



### Highlights

- Total Q2:19 Revenue of \$1.326 million
- SkinTE Q2:19 Revenue of \$504 thousand vs \$297 thousand in Q1:19 (70% increase quarter over quarter)
- Cash burn from operations in Q2:19 decreased 26% from Q1:19; a result of new management's focus on fiscal discipline
- 46 total paid cases in Q2:19 vs. 41 paid cases in Q1:19
- 14 SkinTE abstracts presented in Q2 2019 (9 posters and 5 podium presentations)

### Financial Results for the Three and Six Months Ended June 30, 2019

Total revenue for the six months ended June 30, 2019 was \$2.791 million, of which \$801 thousand was from sales of SkinTE and \$1.990 million was associated with PolarityTE's contract research operations.

Total revenue for the three months ended June 30, 2019 was \$1.326 million, of which \$504 thousand was from sales of SkinTE and \$822 thousand was associated with PolarityTE's contract research operations.

Research and development expenses for the six months ended June 30, 2019 were

approximately \$10.116 million versus \$8.488 million for the six months ended June 30, 2018. Research and development expenses for the six months ended June 30, 2019 included \$2.565 million of stock-based compensation which is a non-cash charge.

Research and development expenses for the three months ended June 30, 2019 were approximately \$4.764 million versus \$2.915 million for the three months ended June 30, 2018. Research and development expenses for the three months ended June 30, 2019 included \$1.481 million of stock-based compensation which is a non-cash charge, versus \$1.309 million for the three months ended June 30, 2018.

General and administrative expenses for the six months ended June 30, 2019 were \$32.255 million versus \$18.863 million for the six months ended June 30, 2018. General and administrative expenses for the six months ended June 30, 2019 included \$15.929 million of stock-based compensation which is a non-cash charge, versus \$12.807 million for the six months ended June 30, 2018.

General and administrative expenses for the three months ended June 30, 2019 were \$15,060 million versus \$11.290 million for the three months ended June 30, 2018. General and administrative expenses for the three months ended June 30, 2019 included \$6.892 million of stock-based compensation which is a non-cash charge, versus \$7.035 million for the three months ended June 30, 2018.

Sales and marketing expenses for the six months ended June 30, 2019 were \$7.934 million, of which \$0.413 million was non-cash charges for stock-based compensation related to recent new hires.

Sales and marketing expenses for the three months ended June 30, 2019 were \$3.981 million, of which \$0.245 million was non-cash charges for stock-based compensation related to recent new hires.

Net loss for the six months ended June 30, 2019 was \$48.365 million compared with a net loss of \$33.723 million for the six months ended June 30, 2018. Net loss for the three months ended June 30, 2019 was \$22.792 million compared with a net loss of \$14.000 million for the three months ended June 30, 2018.

### **Cash and Liquidity as of June 30, 2019**

As of June 30, 2019, our cash, cash equivalents and short-term investments balance was approximately \$58.2 million and our working capital was approximately \$52.6 million, compared to cash and cash equivalents and short-term investments of \$61.8 million and working capital of \$56.8 million at December 31, 2018.

Cash used in operating activities for the six-month period ended June 30, 2019, was approximately \$28.8 million. Approximately \$10.8 million of cash was used in operating activities for the six-month period ended June 30, 2018. In the three months ended June 30, 2019, cash used in operations was \$12.2 million, or approximately \$4.1 million per month, 26% lower than cash used in operations during the quarter ended March 31, 2019.

Based on product development and commercialization plans, the Company believes existing cash, cash equivalents and short-term investments will be adequate to meet capital needs

for at least the next 12 months.

## **Commercial and Operational Updates**

In the second quarter of 2019, there were 46 paid cases vs 41 paid cases in the first quarter of 2019. The number of paid cases in the second quarter of 2019 resulted in approximately 70% more SkinTE revenues when compared to SkinTE revenues generated in the first quarter of 2019. There were 14 repeat physician users in the second quarter of 2019 vs 9 repeat physician users in the first quarter of 2019 and 14 new physician users in the second quarter of 2019 vs 18 new physician users in the first quarter of 2019.

*Note: We define repeat users as physicians who have performed multiple paid cases. We define a new user as a physician who has performed their first paid case.*

## **Clinical Updates**

There are currently five ongoing or completed clinical trials or pilot evaluation trials for SkinTE:

- Diabetic Foot Ulcer Multi-Center Randomized Clinical Trial: Currently enrolling and expect to hit interim enrollment of 50 patients by the end of the year or Q1 of 2020, with results expected in the spring conference cycle.
- Venous Leg Ulcer Multi-Center Randomized Clinical Trial: Currently enrolling and expect to reach interim enrollment of 50 patients in 2020 with expected results later in 2020.
- Head-to-Head Trial Evaluating SkinTE for the Treatment of Burns: No observed adverse reactions to date. We plan to conclude this trial and present interim results at a regional conference later this year. We are working with our burn investigators to commence a prospective burn trial focused on evaluating the treatment of large burn wounds with SkinTE.
- Venous Leg Ulcer Pilot Evaluation Trial: Completed enrollment. Final data expected to be presented later this year at a medical conference.
- Diabetic Foot Ulcer Pilot Evaluation Trial: 10 of the 11 patients achieved complete closure within 12 weeks with a single application of SkinTE, and one patient was excluded due to an unrelated infection of previously-placed foot hardware.

## **Conference Call Information**

Today, August 8, 2019 at 8:00am Eastern Time, the Company will host a conference call and webcast with Q&A. The conference call can be accessed by calling 1- 888-394-8218 (U.S. and Canada) or +44 (0)330 336 9105 (International), with confirmation code 1393700 and referencing "PolarityTE Second Quarter 2019 Earnings Call". A webcast of the conference call can be accessed by using the link below.

[Link to Webcast](#)

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 method is 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](http://www.PolarityTE.com) – Welcome to the Shift®.

## **About SkinTE™**

SkinTE is a human cellular and tissue-based product derived from a patient's own skin intended for the repair, reconstruction, and replacement of skin tissue.

SkinTE is intended to be used by physicians or other appropriate healthcare providers for homologous uses of skin tissues/integument. Patients who have suffered from an event, disease, process or acquired deficit that results in the functional loss or void of skin/integument systems can receive SkinTE as an adjunct and/or in place of split-thickness skin grafting, full-thickness grafting, temporizing skin coverage and/or skin substitute products. SkinTE is for autologous use only. Aseptic technique during harvest and deployment of SkinTE is mandatory. SkinTE is marketed as an HCT/P regulated by the FDA solely under Section 361 of the Public Health Service Act and 21 CFR 1271.

## **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 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](http://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](http://www.sec.gov)).

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

	<b>June 30, 2019</b>	<b>December 31, 2018</b>
	<b>(Unaudited)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 45,887	\$ 55,673
Short-term investments	12,342	6,162
Accounts receivable	1,336	712
Inventory	362	336
Prepaid expenses and other current assets	1,918	1,432
Total current assets	61,845	64,315
Non-current assets:		
Property and equipment, net	16,200	13,736
Operating lease right-of-use assets	5,454	-
Intangible assets, net	825	924
Goodwill	278	278
Other assets	353	913
Total non-current assets	23,110	15,851
<b>TOTAL ASSETS</b>	<b>\$ 84,955</b>	<b>\$ 80,166</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,977	\$ 6,508
Other current liabilities	2,646	316
Current portion of long-term note payable	538	529
Deferred revenue	44	170
Total current liabilities	9,205	7,523
Long-term note payable, net	236	479
Operating lease liabilities	3,833	-
Other long-term liabilities	1,315	131
Total liabilities	14,589	8,133

**Commitments and Contingencies****STOCKHOLDERS' EQUITY:**

Preferred stock - 25,000,000 shares authorized, 0 shares issued and outstanding at June 30, 2019 and December 31, 2018	-	-
Common stock - \$.001 par value; 250,000,000 shares authorized; 25,218,606 and 21,447,088 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	25	21
Additional paid-in capital	461,491	414,840
Accumulated other comprehensive income	79	36
Accumulated deficit	(391,229)	(342,864)
Total stockholders' equity	<u>70,366</u>	<u>72,033</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b><u>\$ 84,955</u></b>	<b><u>\$ 80,166</u></b>

**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,	
	2019	2018	2019	2018
<b>Net revenues</b>				
Products	\$ 504	\$ 189	\$ 801	\$ 192
Services	822	131	1,990	131
Total net revenues	<u>1,326</u>	<u>320</u>	<u>2,791</u>	<u>323</u>
<b>Cost of sales</b>				
Products	342	125	615	126
Services	254	41	757	41
Total cost of sales	<u>596</u>	<u>166</u>	<u>1,372</u>	<u>167</u>
<b>Gross profit</b>	<u>730</u>	<u>154</u>	<u>1,419</u>	<u>156</u>
<b>Operating costs and expenses</b>				
Research and development	4,764	2,915	10,116	8,488
General and administrative	15,060	11,290	32,255	18,863
Sales and marketing	3,981	-	7,934	-
Total operating costs and expenses	<u>23,805</u>	<u>14,205</u>	<u>50,305</u>	<u>27,351</u>
<b>Operating loss</b>	<u>(23,075)</u>	<u>(14,051)</u>	<u>(48,886)</u>	<u>(27,195)</u>
<b>Other income (expenses)</b>				
Interest income, net	29	51	99	88
Other income, net	254	-	422	-
Change in fair value of derivatives	-	-	-	1,850
Loss on extinguishment of warrant liability	-	-	-	(520)
<b>Net loss</b>	<u>(22,792)</u>	<u>(14,000)</u>	<u>(48,365)</u>	<u>(25,777)</u>
Deemed dividend – accretion of discount on Series F preferred stock	-	-	-	(698)
Deemed dividend – exchange of Series F preferred stock	-	-	-	(7,057)
Cumulative dividends on Series F preferred stock	-	-	-	(191)
<b>Net loss attributable to common stockholders</b>	<u>\$ (22,792)</u>	<u>\$ (14,000)</u>	<u>\$ (48,365)</u>	<u>\$ (33,723)</u>
<b>Net loss per share, basic and diluted:</b>				
Net loss	\$ (0.92)	\$ (0.74)	\$ (2.09)	\$ (1.82)
Deemed dividend – accretion of discount on Series F preferred stock	-	-	-	(0.05)
Deemed dividend – exchange of Series F preferred stock	-	-	-	(0.50)
Cumulative dividends on Series F preferred stock	-	-	-	(0.01)
<b>Net loss attributable to common stockholders</b>	<u>\$ (0.92)</u>	<u>\$ (0.74)</u>	<u>\$ (2.09)</u>	<u>\$ (2.38)</u>
<b>Weighted average shares outstanding, basic and diluted:</b>	<u>24,768,453</u>	<u>18,944,964</u>	<u>23,190,343</u>	<u>14,187,518</u>

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

	For the six months ended June 30,	
	2019	2018
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (48,365)	\$ (25,777)
Adjustments to reconcile net loss to net cash used in operating activities:		

Stock based compensation expense	18,907	15,789
Change in fair value of derivatives	–	(1,850)
Depreciation and amortization	1,446	672
Loss on extinguishment of warrant liability	–	520
Amortization of intangible assets	99	33
Amortization of debt discount	28	11
Change in fair value of contingent consideration	(48)	20
Other non-cash adjustments	30	–
Changes in operating assets and liabilities:		
Accounts receivable	(624)	(332)
Inventory	(26)	(249)
Prepaid expenses and other current assets	(486)	2
Operating lease right-of-use assets	791	–
Other assets	25	(137)
Accounts payable and accrued expenses	(17)	448
Other current liabilities	367	–
Deferred revenue	(126)	–
Operating lease liabilities	(670)	–
Other long-term liabilities	(120)	89
Net cash used in operating activities	<u>(28,789)</u>	<u>(10,761)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of property and equipment	(2,110)	(4,163)
Purchase of available-for-sale securities	(15,445)	–
Proceeds from maturities of available-for-sale securities	9,278	–
Acquisition of IBEX	–	(2,258)
Net cash used in investing activities	<u>(8,277)</u>	<u>(6,421)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Net proceeds from the sale of common stock	27,948	92,676
Proceeds from stock options exercised	529	64
Proceeds from ESPP purchase	35	–
Cash paid for tax withholdings related to net share settlement	(636)	–
Payment of contingent consideration liability	(109)	–
Principal payments on financing leases	(225)	–
Principal payments on term note payable	(262)	–
Net cash provided by financing activities	<u>27,280</u>	<u>92,740</u>
Net (decrease) increase in cash and cash equivalents	(9,786)	75,558
Cash and cash equivalents - beginning of period	55,673	12,517
Cash and cash equivalents - end of period	<u>\$ 45,887</u>	<u>\$ 88,075</u>

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