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**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION**

<p>In re:</p> <p>PolarityTE, Inc., a Delaware corporation</p> <p style="text-align: center;">Debtor</p>	<p>Case No. 23-bk-22358-KRA</p> <p>Case No. 23-bk-22360-KRA</p> <p>Case No. 23-bk-22361-KRA</p>
<p>In re:</p> <p>PolarityTE, MD Inc., a Nevada corporation</p> <p style="text-align: center;">Debtor</p>	<p>Chapter 11</p> <p>Judge Kevin R. Anderson</p>
<p>In re:</p> <p>PolarityTE, Inc., a Nevada corporation</p> <p style="text-align: center;">Debtor</p>	<p style="text-align: center;">THIS FILING RELATES TO ALL DEBTORS¹</p>

¹ The Debtors in these jointly administered chapter 11 cases, along with the last four digits of each Debtor’s federal tax identification number, are PolarityTE, Inc. (9524); PolarityTE MD, Inc. (1555); and PolarityTE, Inc. (6882). The location of the Debtors’ service address is 1960 S. 4250 W., Salt Lake City, UT 84104.



**DEBTORS' EX PARTE MOTION FOR ORDER SHORTENING
TIME FOR HEARING ON DEBTORS' MOTION FOR AN ORDER
AUTHORIZING, BUT NOT REQUIRING, THE DEBTORS TO
PAY CERTAIN NECESSARY PAYMENTS, INCLUDING
PREPETITION AMOUNTS, TO CRITICAL VENDOR ALIRA
HEALTH**

By this ex parte motion (the “**Ex Parte Motion**”), the above captioned debtors and debtors in possession PolarityTE, Inc., a Delaware corporation (“**PTE**”), PolarityTE MD, Inc., a Nevada corporation (“**PTE MD**”), and PolarityTE, Inc., a Nevada corporation (“**PTE NV**” and, together with PTE and PTE MD, the “**Debtors**” or each a “**Debtor**”), request expedited consideration and approval of Debtors’ Motion (the “**Motion**”) for entry of an order authorizing but not requiring the Debtors to pay certain prepetition amounts due to Alira Health (“**Alira**”) as described in the Motion. In support of their Ex Parte Motion, the Debtors respectfully represent as follows:

I. JURISDICTION

1. The Bankruptcy Court has jurisdiction over this matter under 28 U.S.C. §§ 157 and 1334. This matter is a core proceeding within the meaning of 28 U.S.C. § 157(b)(2).
2. The Debtors’ principal offices and principal place of business are in Salt Lake City, Utah, within the District of Utah, and, therefore, venue is proper in this District under 28 U.S.C. §§ 1408(1) and 1409.
3. The bases for the relief requested herein are sections 105, 363, and 364 of Title 11 of the United States Code (the “**Bankruptcy Code**”) and rules 9006(c) of the Federal Rules of Bankruptcy Procedure (the “**Bankruptcy Rules**”).
4. No trustee, examiner, or creditors’ committee has been appointed in the Debtors’ chapter 11 cases.

II. GENERAL BACKGROUND

5. PTE MD and PTE NV are each wholly owned subsidiaries of PTE, a publicly traded company.

6. The Debtors are a clinical stage biotechnology company with a promising product, SkinTE (“**SkinTE**”). SkinTE is a human cellular and tissue-based product derived and grown from a patient’s own skin to regenerate full-thickness skin with all its layers (epidermis, dermis and hypodermis) and appendages (hair follicles and glands). SkinTE has been used to treat complex wounds, including both acute and chronic wounds, and can be used in addition to and/or in place of split-thickness skin grafting, full-thickness grafting, temporizing skin coverage and/or skin substitute products.

7. Previously the Debtors were selling SkinTE under the U.S. Food and Drug Administration’s (“**FDA**”) 361 HCT/P pathway governed by 21 C.F.R. 1271. SkinTE was earning revenue, which partially offset its operating expenses. However, based on FDA guidance, since May 2021, the Debtors have been conducting the first of two more-rigorous clinical trials under the FDA’s 351 Biologic pathway, from which they derive no revenue. On this pathway, the Debtors’ business will not be generating revenue again until obtaining FDA approval, which it anticipates in 2026.

8. The Debtors cannot suspend their current clinical trial regime, including that being conducted by Alira, without jeopardizing FDA approval. But the Debtors are unable to continue to fund the clinical trials and will shortly run out of cash.

9. Rather than abandon the clinical trials and their promising product, on the Petition Date, each of the Debtors filed a petition for relief under chapter 11 of the Bankruptcy Code (the “**Chapter 11 Cases**”) in the United States Bankruptcy Court for the District of Utah (the “**Bankruptcy Court**”). The Debtors will seek to sell their assets, including the ongoing clinical

trials, to the highest bidder who can maximize the value of the assets and, presumably, will have funding to allow the clinical trials to go forward and eventually monetize the SkinTE product. Without this relief, the Debtors will be forced to close the clinical trials due to lack of funding, which will greatly reduce the potential value of their assets and delay, perhaps for years, the availability of the SkinTE product.

III. BACKGROUND SPECIFIC TO THIS MOTION

10. Alira Health is a research organization engaged in providing clinical trial, regulatory, contract clinical, technical, and other related services to developers of pharmaceutical products, medical devices, medical foods, and food supplements.

11. In June 2021, Defendants engaged Alira to conduct a thirty-two-month clinical trial evaluating the effects of SkinTE.

12. At the time of filing, Alira has conducted approximately twenty-four months of the thirty-two-month clinical trial of SkinTE.

13. In February and March 2022, Defendants expanded their contract with Alira to receive general consulting, ongoing regulatory support, and clinical support for all PolarityTE products. These services include general consulting for PolarityTE products, FDA inspection training, a mock FDA inspection, and a post-mock inspection report for SkinTE.

14. Defendants estimate the total cost of Alira's thirty-two-month clinical trial regime to be approximately \$5,000,000.

15. Defendants estimate the total cost of Alira's ongoing regulatory and clinical support to be approximately \$27,000.

16. Alira has an outstanding balance of \$358,835.53, of which \$84,491.07 is currently due, all of which relates to the prepetition period. The outstanding balance total does not include

the invoice for Alira's services during June 2023, which Defendants anticipate receiving in the next two weeks.

17. Defendants are negotiating a reduction in the remaining \$274,344.46 outstanding but must pay the currently due \$84,491.07 to continue engaging Alira's clinical trial services and must pay the amounts ultimately settled upon, including, up to \$358,835.53 to avoid shut down of the clinical trials, which would irrevocably harm the estates.

IV. ARGUMENTS AND AUTHORITIES

The Debtor seeks an expedited hearing on or before July 13, 2023 or as soon as practicable to hear and consider the Motion. Bankruptcy Rule 9006(c)(1) and (d) allow the Court to reduce the time for a hearing. Bankruptcy Rule 9006(d) permits parties to submit an ex parte motion shorten time for a hearing for cause. Local Rule 4001-1 allows the Court to grant relief in the absence of any objection.

V. NOTICE

The Debtors will provide immediate notice of this Ex Parte Motion, upon filing, by email to (a) the Office of the United States Trustee for the District of Utah, Attn: Melinda Wilden; (b) all ECF notice parties; (c) all parties that have appeared and requested notice in this case. The Debtors submit that this notice is sufficient under the Local Rules under the circumstances of this Ex Parte Motion. The Debtor respectfully submits that no further notice is necessary.

VI. CONCLUSION

WHEREFORE, for the reasons set forth above, the Debtors respectfully request that the Court enter the Order submitted herewith granting the Ex Parte Motion.

DATED July 6, 2023.

PARSONS BEHLE & LATIMER

/s/ Brian M. Rothschild

J. Thomas Beckett

Brian M. Rothschild

Darren Neilson

Attorneys for the Debtors.

CERTIFICATE OF SERVICE

I hereby certify that on July 6, 2023, I caused a true and correct copy of **DEBTORS' EX PARTE MOTION FOR ORDER SHORTENING TIME FOR HEARING ON DEBTORS' MOTION FOR AN ORDER AUTHORIZING, BUT NOT REQUIRING, THE DEBTORS TO PAY CERTAIN NECESSARY PAYMENTS, INCLUDING PREPETITION AMOUNTS, TO CRITICAL VENDOR ALIRA HEALTH** to be served by electronic mail to:

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/s/ Brian M. Rothschild

Brian M. Rothschild