J. Thomas Beckett, USB #5587
Brian M. Rothschild, USB #15316
Darren Neilson, USB #15005
PARSONS BEHLE & LATIMER
201 South Main Street, Suite 1800
Salt Lake City, Utah 84111
Telephone: 801.532.1234
Facsimile: 801.536.6111
TBeckett@parsonsbehle.com
BRothschild@parsonsbehle.com
DNeilson@parsonsbehle.com
ecf@parsonsbehle.com

Attorneys for the Debtors

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

In re: PolarityTE, Inc., a Delaware corporation Debtor	Case No. 23-bk-22358-KRA Case No. 23-bk-22360-KRA Case No. 23-bk-22361-KRA
In re: PolarityTE, MD Inc., a Nevada corporation Debtor	Chapter 11 Judge Kevin R. Anderson
In re: PolarityTE, Inc., a Nevada corporation Debtor	**THIS FILING RELATES TO ALL DEBTORS**[1]

MOTION FOR ORDER AUTHORIZING, BUT NOT REQUIRING, THE DEBTORS TO PAY CERTAIN NECESSARY PAYMENTS, INCLUDING PREPETITION AMOUNTS, TO CRITICAL VENDOR ALIRA HEALTH

[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.

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By this motion (the "**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**"), hereby move the Court for entry of an order in the form attached hereto as Exhibit A, authorizing but not requiring the Debtors to pay certain prepetition amounts due to Alira Health ("**Alira**") as described below. In support of their Motion, the Debtors respectfully represent as follows:

MEMORANDUM OF POINTS AND AUTHORITIES

I. SUMMARY OF RELIEF REQUESTED

The Debtors seek an order authorizing, but not requiring, the Debtors to (a) pay or honor prepetition obligations outstanding in relation to Alira's prepetition administration of the Debtors' ongoing clinical trials and (b) continue to maintain and administer their contract with Alira pending the sale order currently before this Court. The payments are necessary and urgent so that Alira does not discontinue the ongoing clinical trials, which would endanger the proposed sale of the Debtors' assets under section 363. Further, since the proceeds from the proposed sale are likely to pay all creditors in full, no party will be harmed or unfairly preferred by advancing the payments to Alira.

II. 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, 364, and 365 of Title 11 of the United States Code (the "**Bankruptcy Code**") and rules 6003 and 6004 of the Federal Rules of Bankruptcy Procedure (the "**Bankruptcy Rules**").

III. GENERAL BACKGROUND

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

5. 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.

6. 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.

7. 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.

8. 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 Case**s") 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.

IV. BACKGROUND SPECIFIC TO THIS MOTION

9. 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.

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

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

12. 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.

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

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

15. 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.

16. 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.

V. ARGUMENTS AND AUTHORITIES

Payment of Alira's outstanding invoice is warranted because the harm to the estate that will result from not paying the invoice will exceed the amount of the invoice itself. Further, since the proceeds from the proposed sale are likely to pay all creditors in full, no party will be harmed or unfairly preferred by advancing the payments to Alira. As discussed above, Alira's services are essential to the Debtors' operations and ability to proceed in the sale of the Debtors' assets to Grander Acquisition LLC.

Section 1107(a) of the Bankruptcy Code, which provides that a debtor-in-possession shall perform all the functions and duties of a trustee, contains an implied duty that a debtor-in-possession act as a fiduciary "to protect and preserve the estate, including an operating business's going-concern value," on behalf of the debtor's creditors and other parties-in-interest. *In re CEI Roofing, Inc.*, 315 B.R. 50, 59 (Bankr. N.D. Tex. 2004) (quoting *In re CoServ, L.L.C.*, 273 B.R. 487, 497 (Bankr. N.D. Tex. 2002)).

Under section 105(a) of the Bankruptcy Code, "[t]he [C]ourt may issue any order, process, or judgment that is necessary or appropriate to carry out the provisions of [the Bankruptcy Code]." 11 U.S.C. § 105(a). The purpose of section 105(a) is to "assure the bankruptcy court's power to take whatever action is appropriate or necessary in aid of the exercise of its jurisdiction." 1 COLLIER ON BANKRUPTCY ¶ 105.01 (15th ed. rev. 2007). Section 105(a) of the Bankruptcy Code thus empowers the Court to issue any order "necessary or appropriate" to allow a debtor in possession to fulfill its duty to preserve the going-concern value of the business, including an order authorizing payment in full or in part of certain prepetition claims of unsecured creditors prior to confirmation of a plan. See *CoServ*, 273 B.R. at 496-97; see also *In re Mirant Corp., et al.*, 296 B.R. 427, 429-30 (Bankr. N.D. Tex. 2003).

The Court may use its power under section 105(a) to authorize the critical payments of prepetition obligations under the "doctrine of necessity." The United States Court of Appeals for the Third Circuit recognized the doctrine of necessity in *In re Lehigh & New England Railway Co.*, 657 F.2d 570, 581 (3d Cir. 1981). The Third Circuit held that a court may authorize the payment of prepetition claims if the payment was essential to the continued operation of the debtor. *Id.* (stating that courts may authorize payment of prepetition claims when there "is the possibility that the creditor will employ an immediate economic sanction, failing such payment"); see also *In re Penn Cent. Transp. Co.*, 467 F.2d 100, 102 n. 1 (3d Cir. 1972) (recognizing that the doctrine of necessity permits "immediate payment of claims of creditors where those creditors will not supply services or material essential to the conduct of the business until their pre-reorganization claims shall have been paid"); *In re Boston & ME. Corp.*, 634 F.2d 1359, 1382 (1st Cir. 1980) (recognizing the existence of a judicial power to authorize trustees to pay claims for goods and services that are indispensably necessary to the debtor's continued operation); *CoServ*, 273 B.R.

at 497 (noting that "it is only logical that the bankruptcy court be able to use section 105(a) of the Code to authorize satisfaction of the prepetition claim in aid of preservation or enhancement of the estate").

The Court's exercise of its authority under the "doctrine of necessity" is appropriate to carry out specific statutory provisions of chapter 11, specifically Section 503(b)(1), which authorizes the Court to allow a debtor to pay any "actual, necessary costs and expenses of preserving the estate." 11 U.S.C. § 503(b)(1).

The court in *CoServ* noted that there are occasions when a debtor in possession's duty to preserve the business "can only be fulfilled by the preplan satisfaction of a prepetition claim." 273 B.R. at 497. Rather, payment of prepetition claims is necessary, and may be authorized, whenever it is established that (1) it is critical the debtor deal with the claimant, (2) a failure to deal with the claimant risks probable harm or eliminates an economic advantage disproportionate to the amount of the claim, and (3) there is no practical or legal alternative to payment of the claim (the "**CoServ Test**"). *Id.* at 498.

In the present case, all elements of the CoServ Test are met. It is critical the Debtors pay Alira's claims because Alira administers the Debtors' clinical trial. If Alira's pre-petition services are not paid, Alira will end their administration of the clinical trial.

If the Debtors fail to pay Alira's pre-petition claim they will suffer economic damage disproportionate to the amount of the claim. Alira has a claim in the amount of $358,835.53 of which $84,491.07 is currently due. The Debtors filed their Chapter 11 Cases to sell their assets, which predominantly consist of their rights under the ongoing clinical trials. The ongoing clinical trials are central to the asset purchase agreement and Sale Motion before this Court. If the Debtors cannot pay Alira's current $84,491.07 claim, the entire value of the Debtors' estate comprised of

the clinical trials would be eliminated. Furthermore, the Debtors' ability to sell their assets at all will be endangered as the ongoing clinical trials performed by Alira are the Debtors' primary asset. Such harm far outweighs the cost of honoring the Debtors' prepetition obligation to Alira.

There is no practical or legal alternative to paying Alira's prepetition claims at this time. Alira's obligations will, in all likelihood, be paid in full after the sale because the Debtors expect that all of their creditors will be paid in full following the sale. In addition, to the extent that Debtors or the purchasers in Chapter 11 choose to assume their contracts with Alira, the Debtors would be required to cure any existing default. In essence, authorization to make payments to Alira now is merely an issue of timing. The Debtors must pay Alira to maintain the clinical trials, which comprise a substantial part of the value of their assets. That payment will occur and be the same regardless of whether it is paid now in connection with this motion, in connection with assumption and assignment of the Alira contract in connection with the Sale Motion, or under a plan of liquidation. Denying the Debtors' Motion and requiring the Debtors to default on their contract with Alira until the settlement of the estate in Chapter 11 is impractical as it will reduce the value of the estate to almost nothing.

Because the value of the clinical trials make up the majority of the Debtors' estates, the Debtors cannot fulfil their fiduciary duty to preserve their assets unless they are authorized to pay Alira. Authorization to pay Alira's prepetition claims will avoid immediate and irreparable harm and will serve the best interest of the Debtors' estates, creditors, and all parties in interest.

Courts frequently authorize debtors to pay prepetition claims when doing so does not disrupt the priority scheme of the Bankruptcy Code and will reasonably benefit the debtor's estate. *See, e.g., In re Tusa-Expo Holdings, Inc.*, *et al.*, Case No. 08-45057 (DML) (Bankr. N.D. Tex. Nov. 7, 2008) [Docket No. 21] (authority to pay prepetition employee wages and benefits); *In re*

Mirant Corp., *et al.*, Case No. 03-46950 (Bankr. N.D. Tex. July 16, 2003) [Docket No. 28] (same). In addition, courts in this district and in others frequently grant authority to pay certain prepetition claims of parties deemed essential to the debtor's ability to continue operating its business. *See, e.g., In re Mirant Corp., et al.*, Case No. 03-46590 (DML) (Bankr. N.D. Tex. July 16, 2003) [Docket No. 32] (authorization to pay "critical" vendors); *In re Bombay Company, Inc., et al.*, Case No. 07-44084 (Bankr. N.D. Tex. 2007) (authorization to pay shippers and critical overseas vendors) [Docket No. 58]; *see also In re Syntax-Brillian Corp., et al.*, Case No. 08-11407 (BLS) (Bankr. D. Del. July 9, 2008) [Docket No. 50]; *In re JHT Holdings, Inc., et al.*, Case No. 08-11267 (BLS) (Bankr. D. Del. June 25, 2008) [Docket No. 48]; *In re American Home Mortgage Holdings, Inc.*, Case No. 07-11047 (CSS) (Bankr. D. Del. Aug. 7, 2007) [Docket No. 64]; *In re Werner Holding Co. (DE) Inc., et al.*, Case No. 06-10578 (KJC) (Bankr. D. Del. June 13, 2006) [Docket No. 54]; *In re Pliant Corp., et al.*, Case No. 06-10001 (MFW) (Bankr. D. Del. Jan. 4, 2006) [Docket No. 26]; *In re Meridian Auto. Sys.-Composite Operations, et al*., Case No. 05 11168 (MFW) (Bankr. D. Del. May 27, 2005) [Docket No. 183]; *In re Maxide Acquisitions, Inc., et al.*, Case No. 05-10429 (MFW) (Bankr. D. Del. Feb. 15, 2005) [Docket No. 33].

Accordingly, the Debtors submit that the use of estate funds to honor the prepetition obligations to Alira is in the best interests of the Debtors, the estates, and their creditors. Therefore, the Court should grant the Motion.

VI. NOTICE

No trustee or examiner has been appointed in the Chapter 11 Cases. The Debtors have or will provide notice of this Motion to (a) the Office of the United States Trustee for the District of Utah; (b) the parties listed on the combined List of Creditors Holding the 20 Largest Unsecured Claims for the Debtors; (c) all ECF notice parties; (d) the United States Internal Revenue Service; (e) the Utah Tax Commission; and (f) the United States Securities and Exchange Commission.. In

light of the nature of the relief requested in this Motion, the Debtors respectfully submit that no further notice is necessary.

No prior application for the relief sought in this Motion has been made to this Court or any other court in connection with the Chapter 11 Cases.

VII. CONCLUSION

WHEREFORE, for the reasons set forth above, the Debtors respectfully request that the Court enter the Order authorizing the Debtor to pay the prepetition claims of Alira.

DATED July 6, 2023.

PARSONS BEHLE & LATIMER

/s/ Brian M. Rothschild
J. Thomas Beckett
Brian M. Rothschild
Darren Neilson

Attorneys for the Debtors.

Exhibit A
Proposed Order

Order prepared and submitted by:
J. Thomas Beckett, USB #5587
Brian M. Rothschild, USB #15316
Darren Neilson, USB #15005
PARSONS BEHLE & LATIMER
201 South Main Street, Suite 1800
Salt Lake City, Utah 84111
Telephone: 801.532.1234
Facsimile: 801.536.6111
TBeckett@parsonsbehle.com
BRothschild@parsonsbehle.com
DNeilson@parsonsbehle.com
ecf@parsonsbehle.com

Attorneys for the Joint Debtors

IN THE UNITED STATES BANKRUPTCY COURT
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In re: PolarityTE, Inc., a Nevada corporation Debtor	**THIS FILING RELATES TO ALL DEBTORS**[2]

[2] 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.

ORDER AUTHORIZING, BUT NOT REQUIRING, THE DEBTORS TO PAY CERTAIN PREPETITION CLAIMS OF ALIRA HEALTH

Upon the motion (the "**Motion**") filed by the above-captioned debtors and debtors in possession (the "**Debtors**") seeking entry of an order authorizing the Debtors to pay pre-petition claims of Alira Health; and the Court, having reviewed the Motion and having heard the statements of counsel in support of the relief requested in the Motion at the hearing (the "**Hearing**"), and for cause shown, finds that the Court has jurisdiction over this matter under 28 U.S.C. §§ 157 and 1334, that this is a core matter under 28 U.S.C. § 157(b)(2), that notice of the Motion and the Hearing were sufficient under the circumstances and that no further notice need be given; and the legal and factual bases set forth in the Motion and at the Hearing establish just cause for the relief granted herein and that such relief is necessary to avoid immediate and irreparable harm to the Debtors' estates,

THEREFORE IT IS HEREBY ORDERED AS FOLLOWS:

1. The Motion is GRANTED as provided herein.

2. The Debtors are authorized, but not required, to honor its existing contractual relationship with Alira Health and pay all pre-petition expenses related thereto up to $358,835.53.

3. The Debtors are authorized to continue utilizing the services of Alira Health and honor such payments as shall come due under the ongoing service agreement with Alira Health.

4. To the extent that the Alira contract or related agreements may be deemed executory contracts within the meaning of section 365 of the Bankruptcy Code, the Debtors do not at this time seek authority to assume such contracts, no relief is granted in respect thereof, and no determination is made as to whether any such contracts are executory.

5. Notwithstanding Bankruptcy Rules 6004, 7062, or 9014, the terms and conditions of this Order shall be immediately effective upon its entry.

6. The Court retains jurisdiction with respect to all matters arising from or related to the implementation of this Order.

[END OF DOCUMENT]

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