Docket #0200 Date Filed: 3/27/2025

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

In re:

PolarityTE, Inc., a Delaware corporation

Debtor

In re:

PolarityTE, MD Inc., a Nevada corporation

Debtor

Case No. 23-bk-22358-KRA

Case No. 23-bk-22360-KRA

Case No. 23-bk-22361-KRA

FILED* US Bankruptcy Court-UT MAR 27 2025 PM1:40

Chapter 11

Judge Kevin R. Anderson



Edward W. Swanson, MD 25 Hawkins Place Duxbury, MA 02332 (508) 868-1328 nedwswanson@gmail.com

March 24, 2025

The Honorable Kevin R. Anderson United States Bankruptcy Court District of Utah Frank E. Moss, U.S. Courthouse 350 S Main Street, Salt Lake City, Utah 84101

Re: Fee Application (Case 23-22358)

Dear Judge Anderson,

I am writing today to submit a fee application for \$17,000 for the medical monitoring services that I provided to PolarityTE MD, Inc. (Case 23-22358) for their Phase 3 FDA Clinical Trial in July 2023 during the post-petition period.

During that time period, I had two active contracts with the company - an hourly rate agreement signed in May 2022 (the "Hourly Rate May 2022 Contract") and a \$10,000 per month fixed rate agreement signed in May 2023 (the "Fixed Rate May 2023 Contract").

For my services performed in July 2023, PolarityTE MD, Inc. paid my \$10,000 fixed rate invoice tied to the Fixed Rate May 2023 Contract. However, PolarityTE MD, Inc. did not pay my invoice for \$17,000 for my hourly services performed in July 2023 during the post-petition period because they stated it was above the pre-specified maximum allowed monthly payment to me that they filed. They calculated the maximum of \$10,125 based on my average monthly invoice for the preceding 12 months.

However, my services as Medical Monitor were critical to maintaining the ongoing Phase 3 Clinical Trial, which was a critical operation of their business required to be maintained in good standing in the executed Asset Purchase Agreement ("APA") with the stalking horse bid.

Furthermore, they did not take into account the new Fixed Rate May 2023 Contract that they signed with me in their maximum calculation. They also failed to recognize that my Medical Monitor services had steadily and progressively increased throughout the trial, which is to be expected based on increasing numbers of patients being enrolled, followed, and requiring review of safety events.

In addition, the company never notified me that either contract was terminated, nor did they notify me to cap my medical monitoring services in July 2023. Therefore, I continued to perform all services necessary to maintain the clinical trial by reviewing all of the safety events during July 2023.

Finally, within the APA, it was agreed to reinstate me, Ned Swanson, in Section 6.12:

"PTE has, or will as of or before the Effective Date, fully reinstate each of Nick Betts, MaryTheresa, and Ned Swanson to the positions respectively held by them as of their last date of active employment or engagement by the applicable Seller (or to such other positions as reasonably approved by Purchaser). Without limiting Sellers' obligations under Sections .1 (b), Sellers shall maintain each of these individuals in their respective positions through the Closing Date."

Therefore, not only was the Fixed Rate May 2023 Contract not factored into the filed spending limits in the bankruptcy filing, nor was the increasing workload of medical monitoring factored into the calculated maximum payment allowed, nor was I notified to cap my services, but according to the APA, the Seller was obligated to continue my engagements until the Closing Date to satisfy Section 6.12. Therefore, I believe my services should be paid in full because they were essential to the success of the clinical trial, which could not have continued without a medical monitor and necessitated the work I performed and invoiced.

Contained in this filing is the unpaid July 2023 invoice, the executed contracts with the company that were active at the time the services were rendered, and emails from the company stating the invoice was approved to be paid.

I am requesting that you approve this fee application so that I can be paid for the services that I provided in July 2023.

Thank you for your consideration.

Sincerely,

Edward W. Swanson, MD

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Edward Swanson 211 Plymouth Rd Blue Bell PA 19422 Desc Main
Invoice

Ashlee Fishleigh, Exec Dir Clin Res PolarityTE MD, Inc. 1960 South 4250 West Salt Lake City UT 84104

Edward Swanson (508) 868-1328 nedwswanson@gmail.com

Invoice#:

INV016

Invoice Total:

Issued:

7/27/2023

Due:

7/27/2023

\$17,000.00

to describe a supplier of the			
Item Description	Price	Quantity	Total
Medical Monitoring	* 500.00	0.50	# 250.00
7/3/23 - Call with sponsor PTE to review trial enrollment	\$500.00	0.50	\$250.00
Medical Monitoring			
7/5/23 - Pre-review of materials and preparation for call with PolartyTE and Alira Health, plus attendance/participation on weekly PTE/CRO COVER DFU update call	\$500.00	1.00	\$500.00
Medical Monitoring			
7/6/23 - SAE report and ICSR v2 001-116 - review of all SAE updated materials, drafting of queries, and correspondence with safety team	\$500.00	3.00	\$1,500.00
Medical Monitoring			
7/7/23 - Safety medical monitoring call - weekly review all subjects in screening and actively enrolled in COVER DFU trial including image review for eligibility for randomization or re-application, review and discussion of any AE/SAEs	\$500.00	1.00	\$500.00
Medical Monitoring			
7/7/23 - Call with management of sponsor PTE and Alira Health to review trial status and major issues/obstacles and potential solutions	\$500.00	1.00	\$500.00
Medical Monitoring			
7/10/23 - Call with sponsor PTE to review enrollment	\$500.00	0.50	\$250.00
Medical Monitoring			
7/11/23 – AE Report for Quarterly DSMB – Review and research, call with sponsor to review and discuss, and separate call with sponsor and biostatistician to review and discuss report	\$500.00	4.00	\$2,000.00

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Document Dago E of 1)3/2//23 14 2		Desc Main
Document Page 5 of 13	Price	Quantit	y Total
Medical Monitoring			
7/12/23 - Pre-review of materials and preparation for call with PolartyTE and Alira Health, plus attendance/participation on weekly PTE/CRO COVER DFU update call	\$500.00	1.00	\$500.00
Medical Monitoring			4500.00
7/12/23 - Data Quality Review Call with sponsor and CRO	\$500.00	1.00	\$500.00
Medical Monitoring			
7/13/23 - Safety medical monitoring call - weekly review all subjects in screening and actively enrolled in COVER DFU trial including image review for eligibility for randomization or re-application, review and discussion of any AE/SAEs	\$500.00	1.00	\$500.00
Medical Monitoring			
7/13/23 - Trial related contracts - cell with sponsor to review and discuss existing contracts and plan for future	\$500.00	2.00	\$1,000.00
Medical Monitoring			
7/14/23 - Call with management of sponsor PTE and Alira Health to review trial status and major issues/obstacles and potential solutions	\$500.00	1.00	\$500.00
Medical Monitoring			4050.00
7/17/23 - Call with sponsor PTE to review enrollment	\$500.00	0.50	\$250.00
Medical Monitoring			
7/19/23 - Pre-review of materials and preparation for call with PolartyTE and Alira Health, plus attendance/participation on weekly PTE/CRO COVER DFU update call	\$500.00	1.00	\$500.00
Medical Monitoring			
7/19/23 - SAE report and ICSR v3 001-116 - review of all SAE updated materials, drafting of queries, and correspondence with safety team	\$500.00	3.00	\$1,500.00
Medical Monitoring			
7/19/23 - Review of AEs - call with sponsor and CRO to review and discuss AEs	\$500.00	1.00	\$500.00
Medical Monitoring			
7/19/23 - Budget Review from CRO - call with sponsor to review budget received from CRO $$	\$500.00	1.00	\$500.00
Medical Monitoring			
7/20/23 - Safety medical monitoring call - weekly review all subjects in screening and actively enrolled in COVER DFU trial including image review for eligibility for randomization or re-application, review and discussion of any AE/SAEs	\$500.00	1.00	\$500.00

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Item Description	Document	Page 6 of 13	Price	Quantity	Total
Medical Monitoring 7/21/23 - Medical Coding Questions for site closed	out - review of a	ularias from			
CRO, calls with sponsor and CRO to discuss, review understand outputs based on decisions			\$500.00	3.00	\$1,500.00
Medical Monitoring 7/24/23 - Call with sponsor PTE to review enrollme	nt.		\$500.00	0.50	\$250.00
7/24/23 - Call with sponsor PTE to review enrolline	erit.				
Medical Monitoring 7/25/23 & 7/26/23 - Numerous calls and emails an	nd meetings to d	iscuss potential	\$500.00	5.00	\$2,500.00
upcoming harvests to navigate logistical issues					
Medical Monitoring					
7/26/23 - Pre-review of materials and preparation for call with PolartyTE and Alira Health, plus attendance/participation on weekly PTE/CRO COVER DFU update call		\$500.00	1.00	\$500.00	
		Subtotal			\$17,000.00
		Total			\$17,000.00
		Balance Du	ıe		\$17,000.00

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Ned Swanson < nedwswanson@gmail.com >

July Invoices Through 7/26/23

outy invoices Through 7/20/20
Ashlee Fishleigh <ashleefishleigh@polarityte.com> Thu, Jul 27, 2023 at 10:49 A To: Ned Swanson <nedwswanson@gmail.com>, Accounts Payable <ap@polarityte.com>, Nikolai Sopko <niksopko@polarityte.com>, Jacob Patterson <jacobpatterson@polarityte.com></jacobpatterson@polarityte.com></niksopko@polarityte.com></ap@polarityte.com></nedwswanson@gmail.com></ashleefishleigh@polarityte.com>
Hello AP,
The attached invoices are approved on my end. Please upload to SAGE asap for formal approval.
Best,
Ashlee Fishleigh
Executive Director of Clinical Research
PolarityTE, Inc (NASDAQ:PTE)
M: 385.272.1449 www.PolarityTE.com
ashleefishleigh@polarityte.com
From: Ned Swanson <nedwswanson@gmail.com> Sent: Thursday, July 27, 2023 7:44 AM To: Accounts Payable <ap@polarityte.com>; Ashlee Fishleigh <ashleefishleigh@polarityte.com>; Nikolai Sopko <niksopko@polarityte.com>; Jacob Patterson <jacobpatterson@polarityte.com> Subject: July Invoices Through 7/26/23</jacobpatterson@polarityte.com></niksopko@polarityte.com></ashleefishleigh@polarityte.com></ap@polarityte.com></nedwswanson@gmail.com>
Please see attached two invoices for July 2023 for my hourly work as a Medical Monitor on the COVER DFUS trial INV016A, and consulting services at a fixed monthly rate outside my medical monitor role under a separate agreement executed on May 3, 2023 INV016B
Please let me know if there are any questions and if anything is needed based on the change in procedures with payments today to facilitate these.
Thanks.
Ned

Ned Swanson, MD

nedwswanson@gmail.com

3/24/25, 5:59 PM Case 23-22358 Doc 200 Filed 03/27/25 July Entered 03/27/25 14:17:05 Desc Main mobile: (508) 868-1328 Document Page 8 of 13

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INDEPENDENT CONTRACTOR AGREEMENT

This Independent Contractor Agreement (this "Agreement") is made as of the 17th day of May 2022, (the "Effective Date") by and between PolarityTE MD, Inc. (the "Company") and Edward Swanson ("Independent Contractor"). The Company and Independent Contractor may each be referred to in this Agreement as a "Party" and collectively as the "Parties."

- 1. Services. Independent Contractor shall provide to the Company the services set forth in Schedule A attached hereto and incorporated herein (the "Services").
- **2. Compensation.** In consideration for Independent Contractor's performance of the Services, the Company shall pay Independent Contractor as set forth in Schedule A.
- 3. Expenses. All costs and expenses incurred by Independent Contractor in connection with the performance of the Services and for which Independent Contractor will seek reimbursement from the Company shall be approved by the Company in advance of being incurred.
- 4. Term and Termination. Independent Contractor's engagement with the Company under this Agreement shall commence on the Effective Date. This Agreement may be terminated by the Company or Independent Contractor upon 10 days' prior written notice. Independent Contractor's obligations with respect to the Company's Confidential Information exchanged under this Agreement survive termination of this Agreement for so long as the information remains the Company's Confidential Information as defined herein.
- 5. Independent Contractor. The Parties agree and acknowledge that Independent Contractor is an independent contractor and is not, for any purpose, an employee of the Company. Independent Contractor does not have any authority to enter agreements or contracts on behalf of the Company and shall not represent that it possesses any such authority. Independent Contractor shall not be entitled to any of the Company's employment benefits, including, but not limited to, coverage under medical, dental, retirement or other plans (if any). The Company shall not be obligated to pay worker's compensation insurance, unemployment compensation, social security tax, withholding tax, or other taxes or withholdings for or on behalf of Independent Contractor in connection with the performance of the Services under this Agreement. Nothing contained in this Agreement shall be deemed or construed by the Parties to create the relationship of a partnership, a joint venture, or any other fiduciary relationship.
- 6. Indemnification. Independent Contractor shall indemnify and hold harmless the Company from any damages, claims, liabilities, loss, and expenses, including reasonable attorney's fees, arising out of any act or omission of Independent Contractor in performing the Services or the breach of any provision of this Agreement by Independent Contractor.
- 7. Confidential Information; Inventions; Restrictive Covenants. The Proprietary Information, Invention Assignment, and Restrictive Covenant Agreement dated May 17, 2021, between the Company and Independent Contractor (the "NDA") shall remain in full force and effect and apply to the Independent Contractor in the performance of the Services hereunder, and the NDA is incorporated herein by this reference.

- 8. Mutual Representations and Warranties. Both the Company and Independent Contractor represent and warrant that each Party has full power, authority and right to execute and deliver this Agreement, has full power and authority to perform its obligations under this Agreement, and has taken all necessary action to authorize the execution and delivery of this Agreement. No other consents are necessary to enter into or perform this Agreement.
- 9. Notice Regarding Insider Trading. Independent Contractor hereby acknowledges that it is aware that the United States and other applicable securities laws globally prohibit any person who has material, non-public information about a company from purchasing or selling securities of such company or from communicating such information to any other person under circumstances in which it is reasonably foreseeable that such person is likely to purchase or sell such securities.
- 10. Independent Contractor Representation and Warranties. Independent Contractor represents and warrants that Independent Contractor (a) has all the necessary licenses, permits and registrations, if any, required to perform the Services under this Agreement in accordance with applicable federal, state and local laws, rules and regulations (b) has the required skill, experience and qualifications to perform the Services; (c) shall perform the Services in a professional and workmanlike manner in accordance with generally recognized industry standards for similar services; and (d) shall devote sufficient resources to ensure that the Services are performed in a timely and reliable manner.
- 11. Governing Law. The terms of this Agreement and the rights of the Parties hereto shall be governed exclusively by the laws of the State of Utah, without regarding its conflicts of law provisions.
- 12. **Disputes.** Any dispute arising from this Agreement shall be resolved in state or federal court in the State of Utah.
- 13. Notices. Any notice required or permitted to be given pursuant to this Agreement shall be in writing (unless otherwise specified herein) and shall be deemed effectively given upon personal delivery or upon receipt by the addressee by courier or by email addressed to each of the other Parties thereunto entitled at the respective address listed below, with a copy by email, or at such other addresses as a party may designate by ten (10) days prior written notice:

If to PolarityTE:
PolarityTE MD, Inc.
Attn: Legal Department
1960 S 4250 W
Salt Lake City, UT 84104
E: Contracts@polarityte.com

If to Independent Contractor: Edward Swanson 211 Plymouth Rd Gwynedd Valley, PA 19437 E: nedswanson@gmail.com

- 14. Binding Effect. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.
- 15. Assignment. The interests of Independent Contractor are personal to Independent Contractor and cannot be assigned, transferred, or sold without the prior written consent of the Company.
- 16. Entire Agreement. This Agreement, together with the NDA, constitute the entire agreement between the Parties hereto with respect the subject matter hereof, and supersedes all prior negotiations, understandings, and agreements of the Parties.
- 17. Amendments. No supplement, modification or amendment of this Agreement will be binding unless executed in writing by both Parties.
- 18. Severability. If any provision of this Agreement is held to be invalid, illegal, or unenforceable in whole or in part, the remaining provisions shall not be affected and shall continue to be valid, legal, and enforceable as though the invalid, illegal or unenforceable parts had not been included in this Agreement.

19. Counterparts; Electronic Signatures.

- **a.** <u>Counterparts.</u> The Parties may execute this Agreement in any number of counterparts, each of which is an original but all of which constitute one and the same instrument.
- **b.** <u>Electronic Signatures</u>. This Agreement, agreements ancillary to this Agreement, and related documents entered into in connection with this Agreement are signed when a Party's signature is delivered by facsimile, email, scan, PDF, or other electronic medium. A facsimile, scanned, or other signature delivered via electronic medium shall be deemed in all respects as having the same force and effect as an original signature.

IN WITNESS WHEREOF, this Agreement has been executed and delivered as of the date first written above.

PolarityTE MD, Inc.

Title: Chief Executive Officer

INDEPENDENT CONTRACTOR

Edward Swanson

SCHEDULE A

(Services)

<u>Time Commitment.</u> Independent Contractor shall perform Services at the Company's request, but in no event shall the Company request nor the Independent Contractor provide more than 12 hours of service each month without the prior written consent of the Company.

Scope of Services. Independent Contractor will provide consultation on medical monitoring for the Company's randomized controlled trial entitled, "Closure Obtained with Vascularized Epithelial Regeneration for DFUs with SkinTE," or "COVER DFUs." Such services may include the review and completion of any required documentation related to suspected adverse events, interfacing with the Company's leadership regarding the conduct of the COVER DFUs study, and interacting with the data safety monitoring board ("DSMB") for the COVER DFUs study on an as-needed basis.

<u>Compliance with Company Policies and Applicable Laws</u>. All Services shall be performed by Consultant in accordance with the following:

- All current and future policies and procedures, training, program requirements and/or guidelines of Company that are applicable to the Services and communicated by Company to Consultant ("Company Policies");
- All federal and state laws, rules, and regulations applicable to the Services and relationship between the parties including HIPAA and patient privacy laws;
- Any other guidances or requirements (e.g., AMA Code of Medical Professional Ethics, AdvaMed or PhRMA Codes of Interactions with Healthcare Professionals, Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers, FDA Guidances and others) applicable to the Services and the relationship between the parties;
- Consultant understands and agrees that making a promotional presentation for or on behalf of PolarityTE requires Consultant to adhere to all legal and regulatory requirements related to medical product promotion in general, and Company Policies, including but not limited to product promotion policies and procedures with respect to compliance with all applicable laws; and
- In the event that Consultant is unable to comply with any new or existing Company Policies, Consultant shall notify PolarityTE of inability to comply within ten (10) business days of receipt of such policies and the parties shall work in good faith to resolve the issue.

<u>Compensation</u>. In consideration for Independent Contractor's performance of the Services set forth in this Schedule A, the Company shall pay Independent Contractor \$500 per hour. At the end of each calendar month Independent Contractor shall deliver to the Company a written invoice

showing the number of hours of service performed on each day during said month that services were provided. The Company shall make payment of the invoice within 15 days following receipt.

Reimbursement of Expenses: The Company shall reimburse Independent Contractor for all reasonable and necessary business and travel expenses actually incurred by Independent Contractor in performing the Services and approved in advance by the Company, subject to receipt of a written request for reimbursement accompanied by appropriate supporting documentation. The Company shall reimburse Independent Contractor for expenses not less frequently than monthly.