UNITED STATES DISTRICT COURT
DISTRICT OF UTAH

_____, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. POLARITYTE, INC., DAVID B. SEABURG, JACOB ALEXANDER PATTERSON, and RICHARD HAGUE, Defendants.	**CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED** Civil No. _____ Judge _____

Plaintiff _____ ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding PolarityTE, Inc. ("PolarityTE" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired PolarityTE securities between April 30, 2020 and August 23, 2021, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. PolarityTE, a biotechnology company, develops and commercializes a range of regenerative tissue products and biomaterials for the fields of medicine, biomedical engineering, and material sciences in the United States. The Company operates through two segments, Regenerative Medicine Products and Contract Services. It offers SkinTE, a tissue product used to repair, reconstruction, replacement, and supplementation of skin in patients for the treatment of

acute or chronic wounds, burns, surgical reconstruction events, scar revision, or removal of dysfunctional skin grafts, as well as contract research services.

3. On April 30, 2020, PolarityTE issued a press release announcing that the Company had decided to pursue a plan to submit an Investigational New Drug Application ("IND") and thereafter a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for SkinTE.

4. On July 23, 2021, PolarityTE submitted an IND to the FDA seeking authorization to commence a clinical trial to evaluate SkinTE for the proposed indication of treatment of chronic cutaneous ulcers (the "SkinTE IND").

5. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the SkinTE IND was deficient with respect to certain Chemistry, Manufacturing, and Control items; (ii) as a result, it was unlikely that the FDA would approve the SkinTE IND in its current form; (iii) accordingly, the Company had materially overstated the likelihood that the SkinTE IND would obtain FDA approval; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

6. On August 24, 2021, PolarityTE issued a press release "provid[ing] an update regarding correspondence from the U.S. Food and Drug Administration (FDA) related to its Investigational New Drug Application (IND) for SkinTE® with a proposed indication for chronic cutaneous ulcers, which was filed on July 23, 2021. The FDA provided feedback that certain Chemistry, Manufacturing, and Control (CMC) items need to be addressed prior to proceeding with a pivotal study. As a result, the study proposed in the IND has been placed on clinical hold. In

accordance with standard practice and regulations, the FDA has advised that it will issue a clinical hold letter providing details on the basis for the hold to the Company by September 21, 2021."

7. On this news, PolarityTE's stock price fell $0.08 per share, or 9.52%, to close at $0.76 per share on August 24, 2021.

8. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

9. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

11. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). PolarityTE is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' activities took place within this Judicial District.

12. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

13. Plaintiff, as set forth in the attached Certification, acquired PolarityTE securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

14. Defendant PolarityTE is a Delaware corporation with principal executive offices located at 1960 S. 4250 West, Salt Lake City, UT 84104. PolarityTE's securities trade in an efficient market on the Nasdaq Capital Market ("NASDAQ") under the ticker symbol "PTE."

15. Defendant David B. Seaburg ("Seaburg") served as PolarityTE's Chief Executive Officer ("CEO") for the entirety of the Class Period and currently serves as a Director.

16. Defendant Jacob Alexander Patterson ("Patterson") served as PolarityTE's Interim Chief Financial Officer for the entirety of the Class Period and currently serves as PolarityTE's Chief Financial Officer.

17. Defendant Richard Hague ("Hague") served as PolarityTe's President and Chief Operating Officer throughout the entirety of the Class Period and currently serves as PolarityTE's President and CEO.

18. Defendants Seaburg, Patterson, and Hague are sometimes referred to herein collectively as the "Individual Defendants."

19. The Individual Defendants possessed the power and authority to control the contents of PolarityTE's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of PolarityTE's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with PolarityTE, and their access to material information available to them but not to the public,

the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

20. PolarityTE, a biotechnology company, develops and commercializes a range of regenerative tissue products and biomaterials for the fields of medicine, biomedical engineering, and material sciences in the United States. The Company operates through two segments, Regenerative Medicine Products and Contract Services. It offers SkinTE, a tissue product used to repair, reconstruction, replacement, and supplementation of skin in patients for the treatment of acute or chronic wounds, burns, surgical reconstruction events, scar revision, or removal of dysfunctional skin grafts, as well as contract research services.

21. On April 30, 2020, PolarityTE issued a press release announcing that the Company had decided to pursue a plan to submit an IND and thereafter a BLA to the FDA for SkinTE.

22. On July 23, 2021, PolarityTE submitted the SkinTE IND to the FDA seeking authorization to commence a clinical trial to evaluate SkinTE for the proposed indication of treatment of chronic cutaneous ulcers.

Materially False and Misleading Statements Issued During the Class Period

23. The Class Period begins on April 30, 2020, when PolarityTE issued a press release "Provid[ing] [an] Update on Corporate Strategy and Regulatory Pathway for SkinTE." The press release stated, in relevant part:

> PolarityTE has decided to pursue a plan to submit an investigational new drug application (IND) and thereafter a biologics license application (BLA) for SkinTE.

Following informal, voluntary discussions between the U.S. Food and Drug Administration (FDA) and the Company, and preliminary views expressed by FDA received on April 21, 2020, the Company believes that it is prudent to pursue a BLA for SkinTE, and that a BLA will create a more valuable asset with a greater likelihood of achieving widespread commercial adoption.

PolarityTE will request a meeting with FDA as soon as possible to determine the most appropriate development plan for a BLA submission. Since 2018 the Company has been actively engaged in a clinical development program which includes a completed SkinTE study in burn wounds, ongoing randomized controlled trials (RCTs) in repairing diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs), and outcomes data from many of the approximately 700 SkinTE clinical cases. The Company intends to submit these data to FDA, and believes that the RCTs in DFUs and VLUs could be potential candidates for inclusion in a clinical data package to support a BLA.

To focus on pursuit of the BLA, the Company plans to substantially reduce commercial operations and other functions to conserve capital and significantly decrease cash burn. FDA has not asked the Company to stop marketing SkinTE as a human cell, tissue, or cellular and tissue-based product regulated solely under Section 361 of the Public Health Service Act (i.e., a 361 HCT/P). SkinTE will remain available under a limited sales and marketing program, subject to the Company's future discussions with FDA. The decision to focus on a BLA for SkinTE and limit commercial operations proactively addresses FDA feedback on the regulatory pathway for SkinTE, the high costs associated with maintaining a commercial footprint, and the headwinds associated with the COVID-19 pandemic.

"Our decision to quickly implement this new strategy will allow us to pursue a focused plan to obtain the necessary clinical data to support our BLA submission. We believe this pathway will align more clearly with our goal of delivering to healthcare providers additional data to establish SkinTE as the standard of care for chronic and traumatic wounds," said David Seaburg, Chief Executive Officer.

24. On May 11, 2020, PolarityTE filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended March 31, 2021 (the "Q1 2020 10-Q"). The Q1 2020 10-Q stated, in relevant part:

FDA Developments

Following informal, voluntary discussions between us and the United States Food and Drug Administration (FDA), and preliminary views expressed by FDA received on April 21, 2020 regarding the regulatory pathway for SkinTE, the Company believes that it is prudent to submit an investigational new drug application (IND) and thereafter a biologics license application (BLA) for SkinTE.

> We are in the process of arranging meetings with FDA to determine the most appropriate development plan for a BLA submission. Since 2018 we have been actively engaged in a clinical development program, which includes a completed SkinTE study in burn wounds, ongoing randomized controlled trials (RCTs) in repairing diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs), and outcomes data from many of the approximately 700 SkinTE clinical cases. We intend to submit these data to FDA as potential candidates for inclusion in a clinical data package to support a BLA.
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> Moving Forward
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> Given the Company's recent decision to change the regulatory pathway for SkinTE with the FDA, and the headwinds associated with the COVID-19 pandemic, management has determined the best use of the Company's capital resources going forward is to focus on the preparation and prosecution of an IND and then a BLA with the FDA. We believe a BLA will enhance the value of SkinTE as a product and increase the likelihood of achieving widespread commercial adoption. We believe this pathway will align more clearly with our goal of delivering to healthcare providers additional data to establish SkinTE as the standard of care for chronic and traumatic wounds. In connection with pursuing this strategy, over the next several months we will substantially decrease commercial operations and other functions to reduce historical monthly cash burn and redirect our capital resources to advancing our IND and BLA submissions.

25. Appended to the Q1 2020 10-Q as an exhibit was a signed certification pursuant to Rule 13a-14(b) and Section 1350, Chapter 63 of Title 18, United States Code by Defendants Seaburg and Patterson, attesting that the "information contained in the [Q1 2020 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

26. That same day, PolarityTE hosted an earnings call with investors and analysts to discuss the Company's Q1 2020 results (the "Q1 2020 Earnings Call"). During the scripted portion of the Q1 2020 Earnings Call, Defendant Seaburg stated, in relevant part:

> Now I'd like to address a few important points regarding our recent decision to pursue a BLA for SkinTE. First, why we made this decision? We received preliminary feedback from the FDA which indicated that a BLA pathway for SkinTE would be most appropriate. The catalyst for this decision was not a formal designation or final determination from the FDA. Rather, we made this decision because we believe that it's the BLA pathway for SkinTE will create a more

valuable asset as a result of the clinical data that will support our submission and the benefits from regulatory exclusivity that can be gained through a BLA. We also think that we're more likely to be successful by taking a collaborative approach with the FDA and that a pivot to making PolarityTE primarily a clinically-staged development company is in the best interest of shareholders.

Second, we're hopeful that we will be able to leverage our existing data to demonstrate the safety and effectiveness of SkinTE. Over the past two years, we have been actively engaged in a clinical development program which includes a completed SkinTE study in burn wounds, our ongoing randomized control trials in diabetic foot ulcers and venous leg ulcers and outcomes data from many of the approximate 700 SkinTE clinical cases completed to-date. Importantly there have been zero reported adverse reactions to SkinTE since the launch of this product.

We intend to submit these data set -- this data to the FDA and are hopeful they will be considered in a clinical package to support a BLA.

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The most important thing, I hope investors take away from today's call is our commitment to execute on the following three specific objectives. One, working closely with the FDA to determine the most efficient development pathway to obtain a BLA for SkinTE; two, generating the necessary clinical data to support a BLA submission and approval for SkinTE; and three, significantly reducing and managing cash burn.

Also during the scripted portion of the Q1 2020 Earnings Call, Defendant Hague stated, in relevant part:

Having been previously involved with two autologous products that were ultimately approved as a BLA halfway, I'm confident that pursuing a BLA for SkinTE is the right decision for the company. As a successful outcome should address two critical areas, that have eliminated SkinTE adoption in the past.

First is regulatory clarity. Given the nature of the 361 pathway, products in this class are inherently susceptible to significant scrutiny by FDA, healthcare providers in their hospital systems, and payers. The BLA approval provides validation and self-confidence that a product is clearly safe and effective, and is manufactured and released according to strict standards.

Second is that the development and delivery of the comprehensive clinical data required to receive BLA approval. Early adopters have seen positive outcomes to SkinTE and based on this real world experience, we believe that through the BLA pathway, SkinTE can deliver results to demonstrate its value to a wide range of wound care physicians and patients.

27. On November 2, 2020, PolarityTE issued a press release "Announc[ing] Successful Completion of Initial Pre-IND Interaction with U.S. Food and Drug Administration for SkinTE." The press release stated, in relevant part:

> PolarityTE [. . .] announced that it recently received written responses from FDA following a Type B Pre-IND meeting request that the Company submitted in August 2020 regarding an indication for SkinTE to treat diabetic foot ulcers (DFUs). FDA's responses included, among other things, feedback and recommendations on SkinTE manufacturing, preclinical studies, clinical data submitted in the Company's briefing package, and additional clinical studies to support our IND submission. The Company expects to discuss additional indications in pressure injuries and traumatic wounds with FDA in the coming months. Based on the FDA input gathered in these interactions, the Company plans to prepare and submit an IND to enable clinical studies for one or more indications in the second half of 2021.
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> The Company believes that the guidance and recommendations received from FDA provide a well-defined regulatory pathway, and plans to proceed with IND-enabling activities over the coming months. In addition, the Company is developing a strategy to pursue multiple indications based on its continuing dialog with the FDA regarding the DFU indication, and additional planned meetings regarding other indications.

28. On November 9, 2020, PolarityTE filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended September 30, 2020 (the "Q3 2020 10-Q"). The Q3 2020 10-Q stated, in relevant part:

> In August 2020 we submitted a Type B Pre-IND meeting request to FDA regarding an indication for SkinTE to treat diabetic foot ulcers (DFUs), and we received written responses to our meeting request and questions in October 2020. FDA's responses included, among other things, feedback and recommendations on SkinTE manufacturing, preclinical studies, and clinical data submitted in the Company's briefing package, and guidance on additional information for the Company to include in its IND submission. Consistent with published FDA guidance documents, including "Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products," the Agency stated that for a condition like DFUs, it would generally expect at least two adequate and well-controlled studies to provide substantial evidence of effectiveness and evidence of safety to support a future marketing application. The Agency noted that our ongoing randomized controlled trial (RCT) in DFUs has elements of an adequate and well-controlled study, but stated that it would not accept our ongoing

post-marketing RCT in DFUs as one of the two adequate and well-controlled studies to support a future marketing application.

With this FDA feedback we are re-evaluating our development plan for SkinTE. We believe much of the chemistry, manufacturing and controls (CMC) work, as well as non-clinical work, we will do for the DFU indication can be leveraged for multiple indications. Based on our experience with the deployment of SkinTE, we believe SkinTE can be successful in closing complex wounds such as DFU Wagner grade 2 through 4, grade 3 & 4 pressure injuries, and acute wounds. Our present intention is to focus our efforts on these wound types, where we believe there are significant unmet needs, and pursue these indications in our IND submission for approval either in parallel or a tight sequential process.

In the coming months we will pursue the preparation of an IND filing with FDA, which we believe we will be able to file in the second half of 2021. This effort will include, among other things, the completion of CMC and pre-clinical work to satisfy FDA requirements, interaction with FDA on additional indications, trials design, preparation and submission of the IND, and planning for clinical trial enrollment to begin as soon as we have an open IND.

29. Appended to the Q3 2020 10-Q as an exhibit was a substantively similar certification as referenced, *supra*, in ¶ 25, signed by Defendants Seaburg and Patterson.

30. That same day, PolarityTE hosted an earnings call with investors and analysts to discuss the Company's Q3 2020 results (the "Q3 2020 Earnings Call"). During the scripted portion of the Q3 2020 Earnings Call, Defendant Seaburg stated, in relevant part:

I'd like to highlight three notable accomplishments. First, since announcing the decision to transition our regulatory pathway for SkinTE back in April, our team has made significant progress preparing for BLA. We completed necessary data and patient outcomes that enabled us to submit a pre-IND briefing material to the FDA in August. And we received feedback from the FDA in October, and are actively developing a plan to submit an IND with multiple indications including DFUs, pressure ulcers, and acute wounds, which represents a multi-billion dollar market opportunity.

Also during the scripted portion of the Q3 2020 Earnings Call, Defendant Hague stated, in relevant part:

I would like to start by saying that, overall, we were encouraged by the feedback we received from FDA as part of our recent pre-IND interactions.

> As expected, we have considerable work to do. But we now have a level of clarity that is allowing us to define an exciting development plan for SkinTE under a 351 BLA pathway that I will describe momentarily.
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> With regard to our interaction with the agency, there were three main areas of focus that we sought clarity on, which were clinical, non-clinical, and chemistry, manufacturing and controls, or CMC.
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> With regards to the non-clinical and CMC subject matters, the agency's responses were consistent with industry guidance and confirmed our current strategy. We will continue our work to fully characterize the final SkinTE product in a way that allows us to identify, quantify and implement the key release assays required by FDA. In parallel, we will complete any additional pre-clinical work as needed.

31. On March 30, 2021, PolarityTE issued a press release announcing the Company's Q4 and fiscal year 2020 results. The press release stated, in relevant part:

> David Seaburg, Chief Executive Officer, commented, "2020 was a transformational year for PolarityTE as we made the decision to pursue an IND and BLA for SkinTE. If we successfully obtain a BLA for SkinTE, we believe it will create a more valuable asset with a greater likelihood of achieving widespread commercial adoption bolstered by robust clinical data, which should have a positive effect on stockholder value. As a result of this change in direction, we reduced our commercial operations in May 2020 and have realized a substantial reduction in our operating expenses. This cost savings coupled with our recent capital raises means we have the resources to pursue the FDA regulatory process and fund our operations well into 2022. Our team weathered COVID-19's headwinds to our SkinTE business and leveraged our internal resources to build out our testing business, allowing us to defray expenses and support the public health effort to combat the pandemic. We have also made great progress towards our planned IND submission, which we remain on track to file in the second half of 2021. I am proud of what we have accomplished over the past year, and look forward to what the future holds for PolarityTE and all of our stakeholders."

32. That same day, PolarityTE filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2020 (the "2020 10-K"). In providing an overview of the Company, the 2020 10-K stated, in relevant part:

> Following informal, voluntary discussions between us and the FDA we were advised by the FDA in April 2020 that its preliminary assessment is that SkinTE does not meet the requirements to be regulated solely as a 361 HCT/P. Rather, the FDA's preliminary assessment was that SkinTE is a biological product that should be regulated under Section 351 of the Public Health Service Act. We re-evaluated our regulatory approach and determined it is prudent to submit an investigational new drug application ("IND") for SkinTE and an eventual biologics license application ("BLA") because we believe it will create a more valuable asset with a greater likelihood of achieving widespread commercial adoption, and to avoid the possibility of a protracted dispute with the FDA. As a result of the change in the regulatory approach for SkinTE, we decided to adjust our SkinTE commercial operations accordingly.
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> We plan to focus our SkinTE activity on the preparation and submission of an IND in the second half of 2021, and the commencement of clinical trials under that IND once it is open. We believe that the network of physicians and other healthcare providers who have treated more than 1,100 patients to date with SkinTE will provide valuable support for our clinical development program as we work towards a BLA for SkinTE.

Further, in discussing the Company's "Plan for Advancing SkinTE," the 2020 10-K stated, in relevant part:

> In August 2020 we submitted a Type B Pre-IND meeting request to FDA regarding an indication for SkinTE to treat DFUs, and we received written responses to our meeting request and questions in October 2020. FDA's responses included, among other things, feedback, and recommendations on SkinTE manufacturing, preclinical studies, and clinical data submitted in the Company's briefing package, and guidance on additional information for the Company to include in its IND submission. Consistent with published FDA guidance documents, including "Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products," the Agency stated that for a condition like DFUs, it would generally expect at least two adequate and well-controlled studies to provide substantial evidence of effectiveness and evidence of safety to support a future marketing application. The Agency noted that our ongoing DFU RCT has elements of an adequate and well-controlled study but stated that it would not accept our ongoing post-marketing DFU RCT as one of the two adequate and well-controlled studies to support a future marketing application.
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> Based on FDA's feedback and our real-world experience with SkinTE, we plan to pursue multiple indications addressing complex wounds, including wounds with exposed critical structures. The initial indications we plan to pursue are DFUs penetrating to tendon, capsule, and bone classified Wagner Grades 2 through 4

> (corresponding to University of Texas Grades 2 and 3), Stage 3 and 4 pressure injuries, and acute wounds. These wound types occur in patients with different demographics and have different etiologies, but they have common characteristics including significant wound depth, significant wound volume, frequent presence of tunnelling and undermining, and exposure of critical structures. We believe much of the chemistry, manufacturing, and controls (CMC) work, as well as preclinical work, that we would do for our initial IND in the DFU indication can be leveraged for multiple subsequent indications. Our present intention is to focus our efforts on an initial IND submission for the above-referenced DFU indication and make further IND submissions to develop the indications for pressure injuries and acute wounds either in parallel or a tight sequential process.

33. Appended to the 2020 10-K as an exhibit was a substantively similar certification as referenced, *supra*, in ¶ 25, signed by Defendants Seaburg and Patterson.

34. Also that same day, PolarityTE hosted an earnings call with investors and analysts to discuss the Company's Q4 and full year 2020 results (the "Q4 2020 Earnings Call"). During the scripted portion of the Q4 2020 Earnings Call, Defendant Seaburg stated, in relevant part, "[n]ow I'd like to highlight some of these notable achievements. First, last April we announced plans to pursue BLA for SkinTE. Since we submitted the [Inaudible] received feedback from the FDA in October. With that feedback from the IND, we believe it will provide a framework for achieving the successes with BLA." Also during the scripted portion of the Q4 2020 Earnings Call, Defendant Hague stated, in relevant part:

> I am pleased to share the progress we've made towards our goal of submitting an IND for SkinTE in the second half of this year. As I described in our last earnings call, we received our initial pre-IND feedback from FDA in Q4. Since then, we have had other interactions with the agency that have given us additional clarity and confidence around our ongoing IND enabling activities.
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> These activities remain specifically focused on three areas; CMC or Chemistry Manufacturing and Controls, pre-clinical and clinical. With regard to CMC, our team is making excellent progress towards characterizing SkinTE, which over the next few months should allow us to validate and implement a matrix of product release assays to meet FDA requirements. In parallel, we are making similarly strong progress on our transition to current good manufacturing practices or CGMP.

35. On May 13, 2021, PolarityTE issued a press release reporting the Company's Q1 2021 results and providing a business update. The press release stated, in relevant part:

> **SkinTE Biologic License Application (BLA) Update**
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> PolarityTE continues to make strong progress with its pursuit of a BLA for SkinTE and is reiterating its guidance on the submission of an IND to the FDA in the second half of 2021. In connection with this transition to the BLA pathway and based on the FDA's recent announcement that enforcement discretion related to 361 HCT/P products will not be extended beyond May 31, 2021, the Company will cease commercial sales of SkinTE and wind down commercial operations. The Company is planning to make substantial reductions in the costs associated with its commercial operations, which will mitigate the effect on cash flow resulting from the loss of SkinTE revenues.
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> David Seaburg, Chief Executive Officer, commented, "The decision to wind down our commercial effort is based on the end of FDA's stated period of enforcement discretion, and given our pending IND submission, to complete our transition to a clinical stage biotech company. I am incredibly grateful to the commercial team for what they have achieved through their dedication to SkinTE, and to the many providers who have successfully treated patients suffering from debilitating wounds of various types. With a limited team of just eight sales representatives, we reported record SkinTE sales of $1.73 million in the first quarter of 2021. This is not only a testament to the true potential of SkinTE, but to the amazing talent of all those involved with the product." Mr. Seaburg continued, "Because many HCPs have already witnessed the benefits SkinTE can offer patients with challenging, hard to heal wounds, we are committed to exploring opportunities for physicians to continue to treat patients in need through compassionate use programs, such as FDA's Expanded Access IND program."
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> Richard Hague, President & COO, commented, "Our team firmly believes that a successful BLA for SkinTE will create a highly valuable asset based on the clinical data that will support our eventual BLA submission, which should drive widespread adoption, enable favorable payer coverage and clear marketing claims, and provide regulatory exclusivity if SkinTE is deemed a reference product. With over 1,200 clinical uses of SkinTE to date and many positive outcomes, we look forward to submitting an IND and commencing the clinical trials that will support our BLA, so that many more patients can benefit from treatment with SkinTE."

36. That same day, PolarityTE hosted an earnings call with investors and analysts to discuss the Company's Q1 2021 results (the "Q1 2021 Earnings Call"). During the scripted portion of the Q1 2021 Earnings Call, Defendant Hague stated, in relevant part:

> Transitioning to regulatory, I am pleased to share that our team is continuing to make good progress, as we are now in the final phase of our IND-enabling activities. We remain on track to submit our IND in the second-half of this year, and are working diligently to accelerate that timeline as much as possible. We're very much looking forward to engaging FDA as a part of the upcoming IND process, as we believe these interactions will inform and crystallize our future development plans for SkinTE.
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> The FDA's acceptance of our IND and subsequent enrollment of patients in our first pivotal trial are the critical near-term catalysts for the company. As we complete our transition and become a true clinical stage company, we recognize the need and look forward to being able to articulate future milestones and timelines that will significantly enhance shareholder value. Following the acceptance of our IND, we plan to formalize our milestones and timelines, so that the roadmap to a BLA for SkinTE is clear to our stakeholders.
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> In turn, we are confident that a successful SkinTE BLA, supported by robust clinical evidence will drive widespread adoption, enable favorable payer coverage and clear marketing claims, and provide regulatory exclusivity as SkinTE is deemed a reference product.

37. On July 26, 2021, PolarityTE issued a press release announcing the Company's submission of the SkinTE IND to the FDA. The press release stated, in relevant part:

> PolarityTE expects to receive feedback related to this IND submission from the FDA within approximately 30 days. This could result in an accepted IND or, if FDA raises questions regarding certain aspects of the Company's IND, correspondence from FDA (i.e., information requests and potentially a clinical hold if information requests or other issues are unresolved) after which PolarityTE would work with FDA in an effort to resolve any outstanding issues. The Company plans to take all necessary steps as it works towards achieving an accepted IND and expects to commence its first clinical trial under the IND soon after acceptance by FDA.
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> Responses and feedback from the FDA can vary widely, and PolarityTE notes that other companies transitioning 361 HCT/Ps to the biologics regulatory pathway have experienced a variety of outcomes ranging from INDs accepted as submitted to responses and clinical holds from FDA requiring an interactive process with the Agency to obtain an accepted IND.
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> The Company deems this submission as a significant milestone in the pursuit of a Biologic License Application (BLA) and a key development in PolarityTE's transition to a clinical-stage development company. David Seaburg, Chief

> Executive Officer, commented, "Chronic cutaneous ulcers are a major burden on the US healthcare system, and impact millions of patients while costing the healthcare system billions of dollars each year." Mr. Seaburg continued, "Based on our prior experience, we believe that SkinTE represents a promising potential treatment for patients suffering from these types of wounds, and we are deeply committed to working expeditiously towards the initiation of clinical trials under this IND to support a BLA."

38. On August 12, 2021, PolarityTE issued a press release announcing the Company's Q2 2021 financial results and providing a business update. The press release stated, in relevant part:

> **Recent Business Updates**
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> - Submitted an Investigational New Drug application (IND) for SkinTE® on July 23, 2021, for the proposed indication of treatment of chronic cutaneous ulcers
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> 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.
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> 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."

39. That same day. PolarityTE hosted an earnings call with investors and analysts to discuss the Company's Q2 2021 results (the "Q2 2021 Earnings Call"). During the scripted portion of the Q2 2021 Earnings Call, Defendant Seaburg stated, in relevant part:

> I want to congratulate our entire team because it was their hard work and dedication and commitment that allowed us to submit our IND to the FDA in July. Now that our IND has been submitted, our top two priorities going forward as a clinically staged company are as follows: first, securing acceptance of our IND and commencing our first pivotal study as we advance SkinTE through the regulatory process towards an eventual BLA submission; and second, continued focus on capital efficiency.
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> The progress we've made during the past several months to execute on our development plan for SkinTE reinforces my confidence that we have a team in place with the talent, dedication and experience required to achieve a successful BLA approval. Our recent IND submission was a critical first step to advance SkinTE through the regulatory process, which along with our commitment and focus on capital efficiency remains our highest priorities.

Also during the scripted portion of the Q2 2021 Earnings Call, Defendant Hague stated, in relevant part:

> As [Defendant Seaburg] described, we were very pleased to have submitted our SkinTE IND with a proposed indication for chronic cutaneous ulcers on July 23. In response to our submission, we recently received requests from FDA's clinical and CMC reviewers for additional information, and we have provided responses to those requests earlier this week. I would categorize the feedback and questions we received as very helpful and generally in line with what we had anticipated.
>
> We feel that our responses and our revised clinical plan align well with FDA's feedback and further support our position on key elements of our IND.

40. The statements referenced in ¶¶ 23-39 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the SkinTE IND was deficient with respect to certain Chemistry, Manufacturing, and Control items; (ii) as a result, it was unlikely that the FDA would approve the SkinTE IND in its current form; (iii) accordingly, the Company had materially overstated the likelihood that the SkinTE IND would

obtain FDA approval; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Emerges

41. On August 24, 2021, PolarityTE issued a press release "provid[ing] an update regarding correspondence from the U.S. Food and Drug Administration (FDA) related to its Investigational New Drug Application (IND) for SkinTE® with a proposed indication for chronic cutaneous ulcers, which was filed on July 23, 2021." Specifically, the press release stated:

> The FDA provided feedback that certain Chemistry, Manufacturing, and Control (CMC) items need to be addressed prior to proceeding with a pivotal study. As a result, the study proposed in the IND has been placed on clinical hold. In accordance with standard practice and regulations, the FDA has advised that it will issue a clinical hold letter providing details on the basis for the hold to the Company by September 21, 2021.
>
> PolarityTE previously disclosed that there was the potential for a wide range of outcomes with respect to its SkinTE IND submission, including but not limited to a clinical hold, and the Company is already formulating a plan to address the issues identified by the FDA. Based on FDA feedback the Company is confident that the modifications made to its proposed clinical trial protocol in Wagner Grade 2 diabetic foot ulcers will enable this pivotal study to begin enrolling once the CMC issues are resolved.
>
> David Seaburg, Chief Executive Officer, commented, "In our July 26, 2021, press release regarding the IND submission we described the FDA's well-established procedures for IND submissions and we believe that the CMC issues FDA has identified are not necessarily unusual for companies working diligently to transition their products from 361 HCT/Ps to 351 HCT/Ps. We are actively working to address the issues identified by the FDA and our team plans to respond to the Agency's feedback as expeditiously as possible, and we are hopeful that we will be able to resolve any open items. Chronic cutaneous ulcers represent a substantial unmet medical need with significant economic burden, and we are grateful for FDA's engagement and eager to advance SkinTE through clinical studies and the regulatory process towards an eventual BLA submission."

42. On this news, PolarityTE's stock price fell $0.08 per share, or 9.52%, to close at $0.76 per share on August 24, 2021.

43. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

44. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired PolarityTE securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

45. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, PolarityTE securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by PolarityTE or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

46. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

47. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

48. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of PolarityTE;
- whether the Individual Defendants caused PolarityTE to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of PolarityTE securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

49. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

50. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- PolarityTE securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold PolarityTE securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

51. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

52. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

53. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

54. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

55. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of PolarityTE securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire PolarityTE securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

56. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for PolarityTE securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about PolarityTE's finances and business prospects.

57. By virtue of their positions at PolarityTE, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants

acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

58. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of PolarityTE, the Individual Defendants had knowledge of the details of PolarityTE's internal affairs.

59. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of PolarityTE. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to PolarityTE's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of PolarityTE securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning PolarityTE's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired PolarityTE securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

60. During the Class Period, PolarityTE securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of PolarityTE securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of PolarityTE securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of PolarityTE securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

61. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

62. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

63. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

64. During the Class Period, the Individual Defendants participated in the operation and management of PolarityTE, and conducted and participated, directly and indirectly, in the conduct of PolarityTE's business affairs. Because of their senior positions, they knew the adverse non-public information about PolarityTE's misstatement of income and expenses and false financial statements.

65. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to PolarityTE's financial condition and results of operations, and to correct promptly any public statements issued by PolarityTE which had become materially false or misleading.

66. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which PolarityTE disseminated in the marketplace during the Class Period concerning PolarityTE's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause PolarityTE to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of PolarityTE within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of PolarityTE securities.

67. Each of the Individual Defendants, therefore, acted as a controlling person of PolarityTE. By reason of their senior management positions and/or being directors of PolarityTE, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, PolarityTE to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of PolarityTE and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

68. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by PolarityTE.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.