PolarityTE<sup>™</sup>, Inc. 615 Arapeen Drive, Suite 102 Salt Lake City, UT 84108 www.PolarityTE.com ParadigmShift@PolarityTE.com (385) 237-2365

### NASDAQ: COOL

# PolarityTE

where self regenerates self

### Forward Looking Statements

#### FORWARD LOOKING STATEMENTS

This presentation contains forward-looking statements and projections. The company makes no express or implied representation or warrant as to the completeness of this information or, in the case of projections, as to their attainability or the accuracy and completeness of the assumptions from which they are derived, and it is expected that each prospective investor will pursue his, her, or its own independent investigation. It must be recognized that estimates of the company's performance are necessarily subject to a high degree of uncertainty and may vary materially from actual results. In particular, this presentation contains statements, including without limitation the projections, that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements appear in a number of places in this presentation and include, but are not limited to, statements regarding the company's plans, intentions, beliefs, expectations and assumptions, as well as other statements that are not necessarily historical facts. The company commonly uses words in this presentation such as "anticipates", "believes", "plans", "expects", "future", "intends" and similar expressions to identify forward-looking statements and projections. You are cautioned that these forward-looking statements and projections are not guarantees of future performance and involve risks and uncertainties. The company's actual results may differ materially from those in the forward-looking statements and projections due to various factors, including competition, market factors and general economic conditions. The information contained in this presentation describes several, but not necessarily all, important factors that could cause these differences.



## Company Overview

#### OPPORTUNITY

Clinical stage regenerative medicine company with a platform technology in development to create functional tissue, beginning with regenerated skin that grows all layers, glands, and hair

#### TECHNOLOGICAL ADVANTAGE

Autologous tissue with its stem cell niche and supporting elements aims to regenerate functional tissue, based in principles of both reconstructive surgery and cellular biology. No rejection or scarring.

#### STRATEGY

Rapid clinical development of launch product SkinTE<sup>TM</sup> to capture massive wound market, followed by development and future launches of diverse product portfolio created with platform technology

#### PIPELINE

SkinTE<sup>TM</sup> preparing for clinical application Q3 2017 and market entry by 1H 2018 OsteoTE<sup>TM</sup> (bone regeneration) following in parallel with anticipated market entry Q4 2018

#### TEAM

Experienced Plastic and Reconstructive Surgeons with extensive wound, burn, bone, and soft tissue reconstruction clinical knowledge and a network of national leaders across all surgical specialties

## The PolarityTEAM – Management



#### Denver Lough, MD, PhD

Chairman, President, CEO, Chief Scientific Officer

- Former Resident in Plastic and Reconstructive Surgery at Johns Hopkins
- Inventor of PolarityTE Technological Platform
- Resigned from Hopkins to Launch PolarityTE
- Stanford University, Georgetown University School of Medicine



#### Michael Neumeister, MD, FRCSC, FACS Chief Medical Officer

- Professor & Chairman of the Department of Surgery and The Elvin G. Zook Endowed Chair in Plastic Surgery at Southern Illinois University
- Past President of the American Society of Reconstructive Microsurgery, American Association for Hand Surgery, The Plastic Surgery Foundation (The Research Body of The American Society of Plastic Surgeons), Plastic Surgery Research Council, and the Midwest Association of **Plastic Surgeons**

GEORGETOWN UNIVERSITY

Shock Trauma Center

School of Medicine

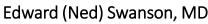
R Adams Cowley

NIVERSITY OF MARYLAND

UNIVERSITY OF

**TORONTO** 





Executive Vice President, COO, Director

- Former Resident in Plastic and Reconstructive Surgery at Johns Hopkins
- Resigned from Hopkins to Launch PolarityTE
- University of Pennsylvania Bioengineering
- Harvard Medical School

#### Stephen Milner, MD, DDS, DSc, FRCSE, FACS Chief Clinical Officer

- Former Director of the Johns Hopkins Burn Center and Professor of Plastic and Reconstructive Surgery, Pediatrics, and Public Health at Johns Hopkins
- Served as Lieutenant Colonel in the Royal Army Medical Corps with active duty in Operation Desert Storm
- Awarded the Humanitarian Award from the James R. Jordan Foundation in 2012 and the Sushruta-Guha Lectureship and medal in Plastic Surgery and Wound Healing from the Royal College of Surgeons of Edinburgh in 2013
- Resigned from Clinical Practice to Join PolarityTE Full-Time



MGH













Stanford University

**JOHNS HOPKINS** 

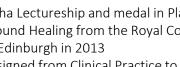
SCHOOL of MEDICINE



**SIU** MEDICINE

utmb Health

Blocker Burn Unit













John Stetson Executive Vice President, CFO, Director

Executive Vice President, CFO,

Director of Marathon Patent

VP of Product Development

Led Brand Turn-Around and

• Leader in Artificial Intelligence and

Cognitive Computing for Strategic

Product Development at JetBlue,

University of Pennsylvania

Burke Powers, MBA

**Business Analytics** 

IBM, & PayPal

Group, Inc. (MARA) (6/12-2/15)







## The PolarityTEAM – Board of Directors



#### Denver Lough, MD, PhD

Chairman, President, CEO, Chief Scientific Officer

• Former Resident in Plastic and Reconstructive Surgery at Johns Hopkins



Steve Gorlin

Regenerative Medicine and Biotech Pioneer:

Agilent), Theragenics Corporation, CytRx

Founder of Hycor Biomedical, Inc. (acquired by

Corporation, Medicis Pharmaceutical Corporation

(acquired by Valeant for \$2.6B), EntreMed, Inc.,

• Served on Business Advisory Council to The Johns

BioMedical Engineering Advisory Board, and

currently serves on the Board of the Andrews

Started The Touch Foundation, a nonprofit

organization for the blind and was a principal

Hopkins School of Medicine, The Johns Hopkins

Director

- Inventor of PolarityTE Technological Platform
- Resigned from Hopkins to Launch PolarityTE
- Stanford University, Georgetown University School of Medicine



#### Edward (Ned) Swanson, MD

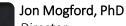
Executive Vice President, COO, Director

- Former Resident in Plastic and Reconstructive Surgery at Johns Hopkins
- Resigned from Hopkins to Launch PolarityTE
- University of Pennsylvania Bioengineering
- Harvard Medical School

#### John Stetson

Executive Vice President, CFO, Director

- Managing Member of HS Contrarian Investments LLC since 2010
- Executive Vice President, CFO, Director of Marathon Patent Group, Inc. (MARA) (6/12-2/15)
- University of Pennsylvania

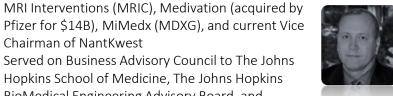




Director



- Vice Chancellor for Research, Texas A&M University System: 11 universities, 7 state agencies, 30K faculty, 135K students, \$945M annual budget
- Former Deputy Director of the Defense Advanced Research Projects Agency (DARPA), Defense Sciences Office (DSO)



#### Michael Beeghley, MPH, Macc



- Chairman and CEO Bioptix Inc. (NASDAQ: BIOP)
- President of Applied Economics LLC, a corporate finance and strategy consulting firm specializing in healthcare and biotech valuation: >\$1B in corporate transactions and >2,000 consulting engagements



#### Jeff Dyer, MBA, PhD

Director

- Horace Beesley Professor of Strategy at BYU as well as the Wharton School
- Internationally recognized strategy and innovation expert, author of business best-sellers The Innovator's DNA and The Innovator's Method, research frequently published in Forbes, Economist, Fortune, BusinessWeek, Wall Street journal, and Harvard Business Review (most published strategy scholar in HBR)







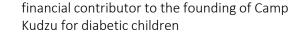


Nharton









Institute

Chairman of NantKwest









MARRIOTT SCHOOL OF MANAGEMENT

RYU









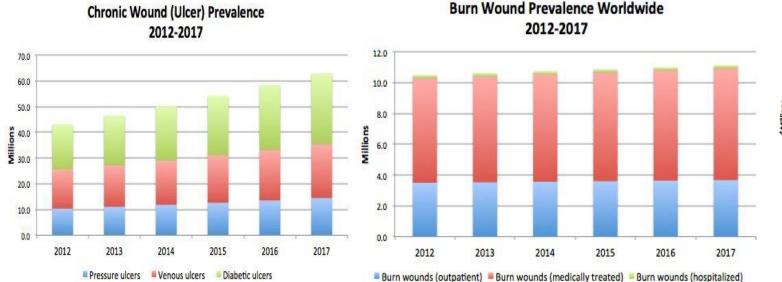


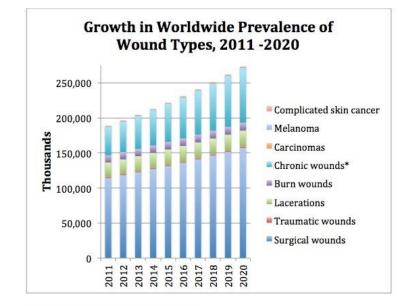


OHNS HOPKINS

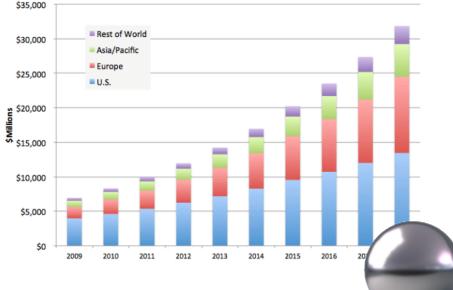
## Global Regenerative Medicine and Wound Care Markets

- Current markets remain untapped with redundant products and no autologous (patient's own tissue/cells) tissue engineering
- The global market for tissue engineering is expected to grow to \$56.9 billion by 2019, with a five-year CAGR of 22.3%
- Worldwide prevalence of wounds is exponentially rising in all categories, and expected to reach >250 million wounds by 2020





Global Tissue Engineering & Cell Therapy Market, by Region, 2009-2018



http://blog.mediligence.com/2014/04/17/applications-global-markets-in-tissue-engineering-and-cell-therapy/ <a href="http://www.bccresearch.com/market-research/healthcare/tissue-engineering-regeneration-report-hlc101b.html">http://mediligence.com/ret/ret-search/healthcare/tissue-engineering-regeneration-report-hlc101b.html</a> <a href="http://mediligence.com/ret/ret-search/healthcare/tissue-engineering-regeneration-report-hlc101b.html">http://mediligence.com/ret/ret-search/healthcare/tissue-engineering-regeneration-report-hlc101b.html</a> <a href="http://mediligence.com/ret/ret-search/healthcare/tissue-engineering-regeneration-report-hlc101b.html">http://mediligence.com/ret/ret-search/healthcare/tissue-engineering-regeneration-report-hlc101b.html</a> <a href="http://mediligence.com/ret/ret-search/healthcare/tissue-engineering-regeneration-report-hlc101b.html">http://mediligence.com/ret/ret-search/healthcare/tissue-engineering-regeneration-report-hlc101b.html</a> <a href="http://mediligence.com/ret/ret-search/healthcare/tissue-engineering-regeneration-report-hlc101b.html">http://mediligence.com/ret/ret-search/healthcare/tissue-engineering-regeneration-report-hlc101b.html</a> <a href="http://mediligence.com/ret/ret-search/healthcare/tissue-engineering-regeneration-report-hlc101b.html">http://mediligence.com/ret/ret-search/healthcare/tissue-engineering-regeneration-report-hlc101b.html</a> <a href="http://mediligence.com/ret/ret-search/healthcare/tissue-engineering-regeneration-report-hlc101b.html">http://mediligence.com/ret/ret-search/healthcare/tissue-engineering-regeneration-report-hlc101b.html</a> <a href="http://mediligence.com/ret/ret-search/healthcare/tissue-engineering-regeneration-report-hlc101b.html">http://mediligence.com/ret-search/healthcare/tissue-engineering-regeneration-report-hlc101b.html</a> <a href="http://mediligence.com/ret-search/healthcare/tissue-engineering-regeneration-report-hlc101b.html">http://mediligence.com/ret-search/healthcare/tissue-engineering-regeneration-report-hlc101b.html</a> <a

## Competitive Landscape

SkinTE

A Massive Market Saturated with Stagnant Products Lacking Fundamental Principles and Building Blocks for True Functional Skin Regeneration

Product	Company	Cellular	Cell Source	Stem Cells	Cellular Architecture and Interfaces	Full Thickness Functional Skin Regeneration with Appendages (Hair, Glands)
SkinTE <sup>TM</sup> (In Development)	PolarityTE <sup>™</sup>	Yes	Autologous Full Thickness Skin	Yes	Yes	Yes
Integra Bilayer Wound Matrix	Integra LifeSciences	No	None	No	No	No
GRAFTJACKET	Wright Medical Group	No	None (Acellular Allogeneic Dermis)	No	No	No
Epifix	MiMedx	Dead	Allogeneic Human Amnion	No	No	No
Grafix	Osiris	Yes	Allogeneic Human Placenta	No	No	No
Apligraf	Organogenesis	Yes	Allogeneic Neonatal Foreskin	No	No	No
Allograft Skin	Allosource, MTF, Others	Yes	Allogeneic Human Skin	No	No	No
Epicel	Vericel	Yes	Autologous Split Skin plus <b>Mouse</b>	No	No	No



## Current Therapies: Limitations

#### No Cells:

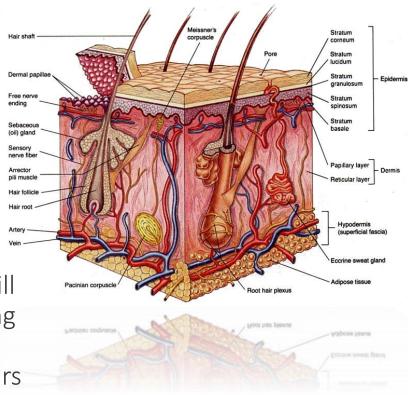
Acellular scaffolds lack the innate ability to regenerate tissue and rely on surrounding tissue in-growth and ultimately secondary skin grafts for definitive coverage

#### Allogeneic/Xenogeneic Cells:

Another person's cells or animal cells will always reject and result in scarring, leaving a wound reliant on native healing or secondary surgery to attain coverage

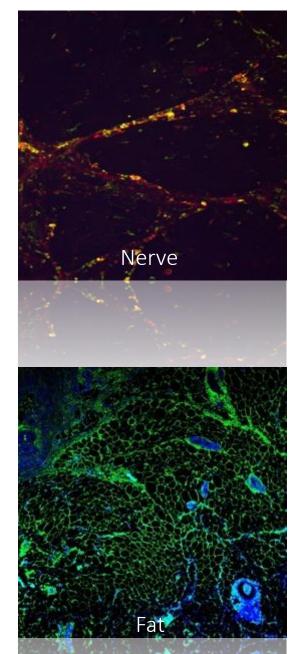
#### The Wrong Cells:

The "gold standard" - split-thickness autograft skin (3,000 year old surgery), and the only approved autologous product (Epicel which still requires MOUSE fibroblasts) only capture the top layer of skin, leaving behind the stem cell niche and multilayer/appendage regenerative capacity. Best case scenario is a healed barrier that contracts and scars with no function.

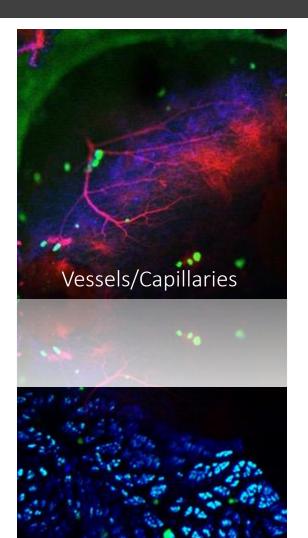


Ultimately, skin is so much more than a single layer to provide a barrier – it's the largest organ in the human body with numerous functions that require regeneration of all components (hair, sweat glands, sebaceous glands, capillary beds, etc.) and all layers (epidermis, rete ridges, dermis, hypodermis, subdermal fat, etc.)

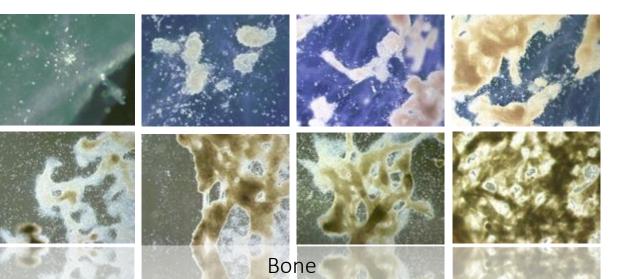
## The PolarityTE<sup>TM</sup> Platform Technology



Discovered through careful observation of tissue regeneration in real-time, the PolarityTE<sup>™</sup> Platform Technology has proved its regenerative capacity in preclinical models in **SKIN**, bone, muscle, fat, cartilage, nerve, blood vessels, and more

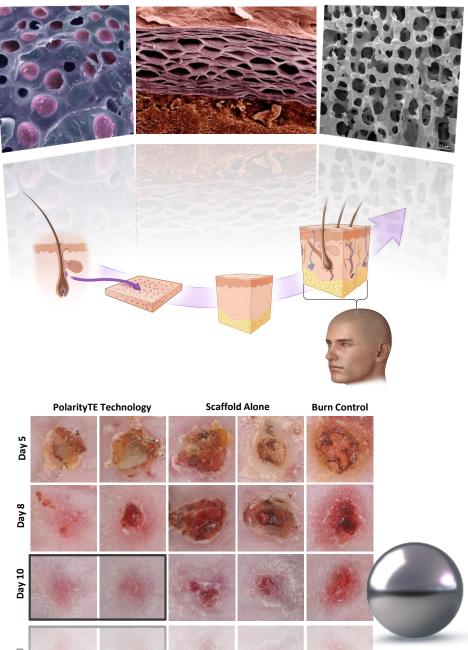


Muscle



## The PolarityTE Advantage

- Autologous: The immune system is highly complex and evolved to recognize anything that isn't "self". Our foundation is built on using autologous tissue, avoiding allogeneic tissue rejection and foreign body reactions. Autologous tissue immediately removes 99% of the competition.
- Stem Cell Niche: In order to regenerate functional tissue, the stem cell niche must be captured. Without the appropriate stem cell, even an autologous approach will fail. The inclusion of the stem cell niche within autologous tissue eliminates the remaining competition there is no other company or product with these two simple features.
- The Recognition of Polarity: Polarity is the directionality within cells and tissues (up, down, left, right, front, back, outside and inside). Polarity drives development and ultimate function. Our platform maintains polarity to harness the regenerative capacity of the autologous stem cell niche.
- A Paradigm Shift: It's not a single cell. It's not a single growth factor. It's not a single scaffold. It takes a village of cells to regenerate functional tissue, both progenitors and differentiated, with natural interfaces and interactions. The proprietary PolarityTE platform works across all tissue, while stem cell suspension seeded on artificial scaffolds with growth factors struggles to perform in any tissue.
- Top-Down: Why deconstruct tissue down to a minimal component (single stem cell) and attempt to synthetically rebuild from the ground up? We cannot outsmart nature. We start our process with the end goal autologous full thickness tissue with all of its components. Starting with this top-down approach, the tissue is taken down to its base unit capable of regenerating functionally polarized tissue, and allowed to rebuild itself.
- The Human Bioreactor: The PolarityTE approach acknowledges the complexity of living tissue substrates. The human body evolved to provide the ideal nutrients and extracellular environment for controlled wound healing. We cannot engineer a better system in a petri dish or incubator. Our process delivers the autologous-homologous polarized functional units back to the patient immediately. The human bioreactor drives the regeneration forward.



## The PolarityTE Launch Product in Development – SkinTE<sup>™</sup>

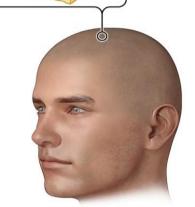
## SkinTE

Using our platform technology, we aim to regenerate full-thickness, fully functional skin. The process we are developing should allow a patient's own skin to be fully expanded from a small biopsy, and then regenerate ALL LAYERS (epidermis & dermis), hair and appendages - which has never been done before.

Patient Biopsy: Acquire patient's skin

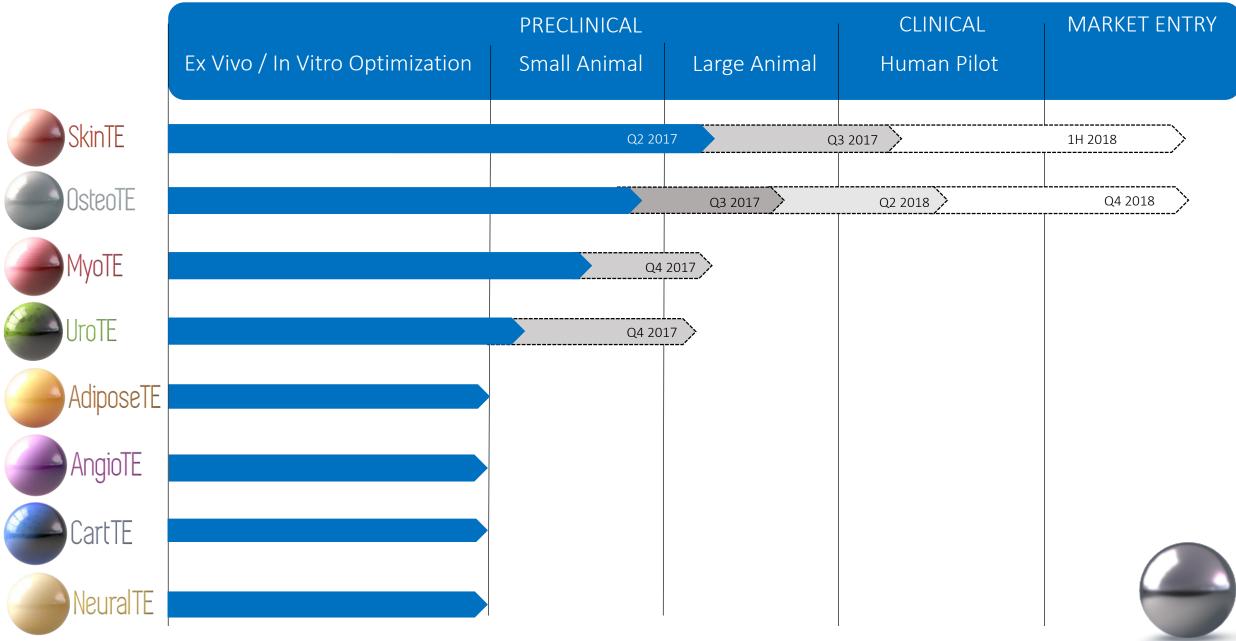
> **Polarization:** Natural skin layer formation, including hair and appendages

Imprint cells in laboratory in 3D system using our platform technology Apply regenerated construct back to the best known bioreactor – the patient

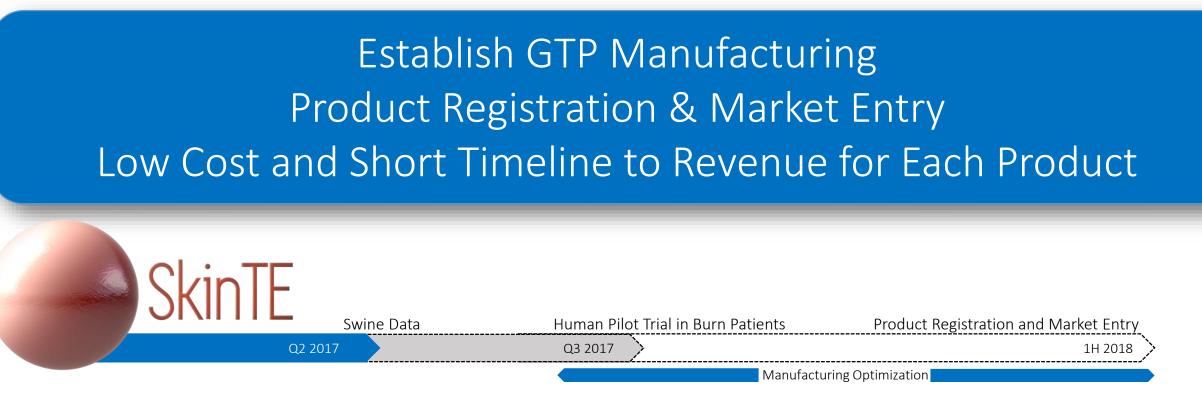


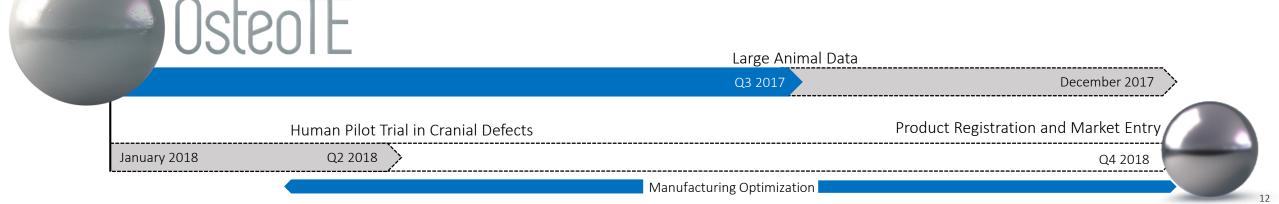


## Development Pipeline



## Strategy, Pathway, and Timelines





## Burn Market Commercialization Strategy

#### Mational Landscape:

126 burn centers nationwide, creating a straightforward scale-up plan

#### Key Decision Makers:

Burn Center treatments dictated by Burn Center Directors

#### Leaders in the Field on PolarityTE Team:

Chief Clinical Officer Dr. Stephen Milner, Former Director of Johns Hopkins Burn Center

Chief Medical Officer Dr. Michael Neumeister, Chairman of Surgery and Plastic Surgery at Southern Illinois University World Class Clinical Board of Advisors

#### Limited Market Release:

First year in market composed of a controlled limited market release to select burn centers prior to complete market rollout in second year





	Converted Common Stock	Options	Polarity1
Preferred Stock			-
Series A	792,933		NASDAQ:
Series B	801,820		www.Polarity
Series C	410,247		
Series D	157,776		
Series E	7,050,000		
Common Stock	4,976,768		
Stock Options		700,000*	
Total**	14,189,544	700,000	

## Summary

# PolarityTE<sup>™</sup>, Inc. (NASDAQ: COOL) provides a unique investment opportunity with a high potential for large returns within a short timeline - repeatedly

- A regenerative medicine company with a revolutionary proprietary platform technology developing products to regenerate fully functional tissue across a wide spectrum of tissues – skin, bone, muscle, cartilage, nerve, liver, and more
- The proprietary platform technology provides a springboard for repeated product development targeting independent multibillion dollar markets wounds, bone (trauma, spinal fusion, craniofacial, dental), osteoarthritis, etc.
- A paradigm shift in tissue engineering concepts, utilizing autologous tissue with its stem cell niche and supportive cellular elements for immediate redeployment to the patient, taking advantage of the human bioreactor an approach never taken before despite sound and simple principles with true regeneration of functional tissue as the goal
- Mear-term major milestones include SkinTE<sup>™</sup> clinical application Q3 2017 and market entry 1H 2018, Osteo<sup>™</sup> clinical application Q2 2018 and market entry Q4 2018, and numerous products following in parallel
- Tissue regeneration is a prime focus for the government, specifically military and disaster applications, providing numerous prospects for large grants and contracts
- The leaders of the company have extensive clinical and surgical experience, with a strong backing of leading physicians across numerous specialties, allowing for targeted product development and streamlined clinical roll-out
- Most importantly, PolarityTE<sup>TM</sup> truly provides a platform for continuous growth, with every corner of the \$57B regenerative medicine market available for disruption

# PolarityTE

## Welcome to the Shift<sup>TM</sup>



## Thank You

PolarityTE<sup>™</sup>, Inc. NASDAQ: COOL 615 Arapeen Drive Salt Lake City, UT 84108 (385) 237-2365 www.PolarityTE.com ParadigmShift@PolarityTE.com

