

# AVITA MEDICAL

## Extraordinary General Meeting



**14 January 2019**

## Disclaimer – Forward Looking Statements

This presentation may include forward-looking statements. You can identify these statements by the fact that they use words such as “anticipate”, “estimate”, “expect”, “project”, “intend”, “plan”, “believe”, “target”, “may”, “assume” or similar expressions.

These forward looking statements speak only as at the date of this presentation and are based on management’s expectations and beliefs concerning future events. Forward-looking statements are necessarily subject to risks, uncertainties and other factors, many of which are outside the control of Avita Medical that could cause actual results to differ materially from such statements.

Avita Medical makes no undertaking to subsequently update or revise the forward-looking statements made in this release to reflect events or circumstances after the date of this release.

This presentation is intended to provide background information only and does not constitute or form part of an offer of securities or a solicitation or invitation to buy or apply for securities, nor may it or any part of it form the basis of, or be relied on in any connection with any contract or commitment whatsoever.

# Overview of Avita Medical

# AVITA Medical – Regenerative Medicine Company

## About AVITA

- Regenerative medicine company with platform technology providing innovative treatments *derived from the regenerative properties of a patient's own skin*
- Experienced leadership team
- Headquartered in California
- Traded on ASX, with ADRs in U.S.
- Substantial U.S. Government support under BARDA program

## Lead Product Approved

FDA approved the RECELL System® PMA on 20 September 2018 as Class III device for treatment of acute thermal burns

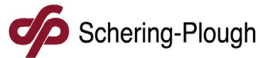


# Leadership Team with the Right Expertise



**Dr. Michael S. Perry**  
**CEO**  
*>30 years experience*

**Affiliations:**



**Dale Sander**  
**CFO**  
*>30 years experience*

**Affiliations:**



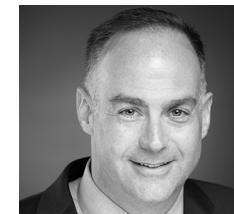
**Erin Liberto**  
**CCO**  
*16 years experience*

**Affiliations:**



**Tim Rooney**  
**CAO**  
*25 years experience*

**Affiliations:**



**Andrew Quick**  
**Sr VP, Clinical Dev.**  
*22 years experience*

**Affiliations:**



**Donna Shiroma**  
**General Counsel**  
*20 years experience*

**Affiliations:**



# AVITA Medical Board and Capital Structure

A\$0.011  
Share  
Price<sup>1</sup>

1.652  
Billion  
Shares  
Outstanding

A\$181.7  
Million  
Market  
Capitalization<sup>1</sup>

A\$36.5  
Million  
Cash<sup>2</sup>

A\$0.0  
(Zero)  
Debt

## DIRECTORS



**Dr. Michael Perry**  
CEO, AVITA Medical



**Professor Suzanne Crowe**  
Multiple positions including  
Associate Director of the  
Burnet Institute



**Lou Panaccio, Chairman**  
Non-Executive Director  
Sonic Healthcare Limited



**Louis Drapeau**  
Nektar Therapeutics, BioMarin  
Pharmaceutical, Inc., and  
Arthur Andersen LLP.



**Jeremy Curnock Cook**  
Managing Director of  
Bioscience Managers Pty  
Ltd



**Damien McDonald**  
Chief Executive Officer of  
LivaNova

## MAJOR SHAREHOLDERS

Karst Peak Capital Limited	17.3%
Redmile Group	9.4%
BioScience Managers Pty Ltd	5.0%

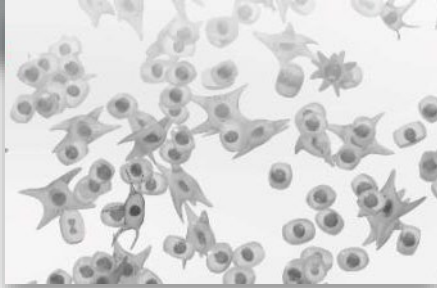
## ANALYSTS

John Hester, Bell Potter (AUS)  
Brooks O'Neil, Lake Street (US)

1. As of 11 January 2019

2. As of 30 September 2018, pro forma to include A\$22.4 million in net proceeds from equity placement received in December 2018. Excludes \$13.7 million in net proceeds scheduled to be received from 2<sup>nd</sup> Tranche of equity placement in January 2019.

# Strategic Path: Transforming Lives with Skin Regeneration



**Leading the way in skin  
regenerative wound therapy**  
*Acute thermal burns, trauma, &  
chronic wounds*

**Expanding our footprint within  
regenerative dermatology**  
*Hypopigmentation: Vitiligo*

**Advancing into Cell and  
Cell-Based Gene Therapy**  
*Aesthetics, Cell & Gene  
Therapy e.g., Dystrophic EB*



# RECELL Overview

Healthcare professionals should read the INSTRUCTIONS FOR USE - RECELL® Autologous Cell Harvesting Device for a full description of important safety information including contraindications, warnings and precautions.



# RECELL System Skin Regeneration Platform

## Regenerative Medicine Platform

- An *Autologous Cell Harvesting Device* that uses proprietary enzyme and buffer formulations to generate *Spray-on Skin™ Cells within 30 minutes*

## Designed by Surgeons

- An elegant means to deliver skin regeneration to patients *at point of care*

## Proven Safety and Effectiveness

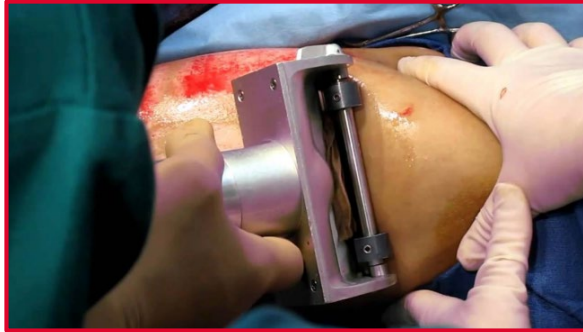
- 7,000+ uses to date in multiple world markets with no observed safety signals
- Treatment area is 80X donor area (skin sample the size of credit card can be used to treat a patient's entire back)
- Compelling clinical results (RCTs) and robust health-economic data

>50 Peer-Reviewed Publications



# Current Standard of Care Is Suboptimal and Expensive

Autografts - Split-Thickness Skin Grafts (STSG) - Used in 75% of Cases



*Harvesting skin from donor site for STSG*



*Donor site wound created while harvesting skin for autograft*



*Typical SOC donor site scar 52 weeks post procedure*

## KEY SHORTCOMINGS OF SOC

- Large donor area required
- Pain during and post procedure
- Extended hospitalization and costs
- Multiple complex, costly, surgical procedures
- Risk of infection

*Healing burn injuries  
induces trauma of its own*

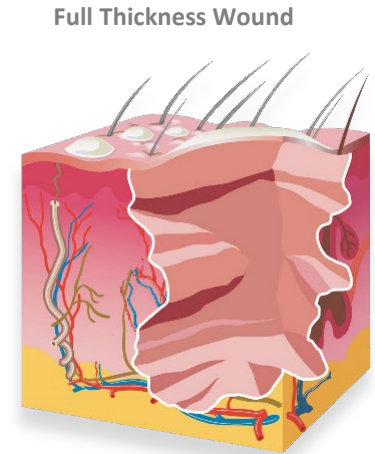
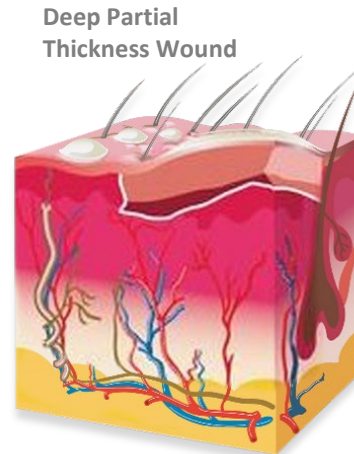
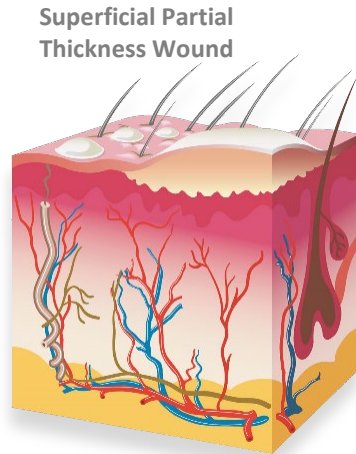
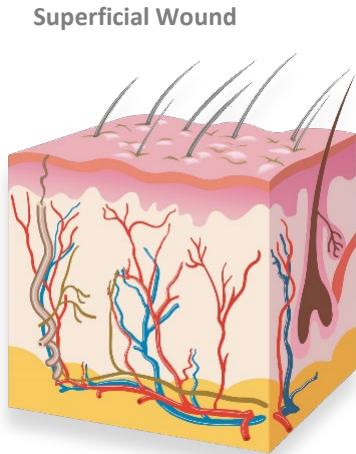
---

**Under Current Standard of Care**

**Average USD \$792,000 cost and 59.4 days in hospital for 40% TBSA burns<sup>1</sup>**

---

# U.S. Clinical Trials Supporting RECELL Use in Burns



## Clinical Support for RECELL System

- Two multicenter, randomized, controlled clinical trials consisting of 131 patients
- Additional 155+ patients treated in Compassionate Use and Continued Access programs
- Real-world experience in more than 7,000 patients globally

Pivotal Trial #1  
RECELL Versus SOC  
(STSG) in Second-  
Degree Burns

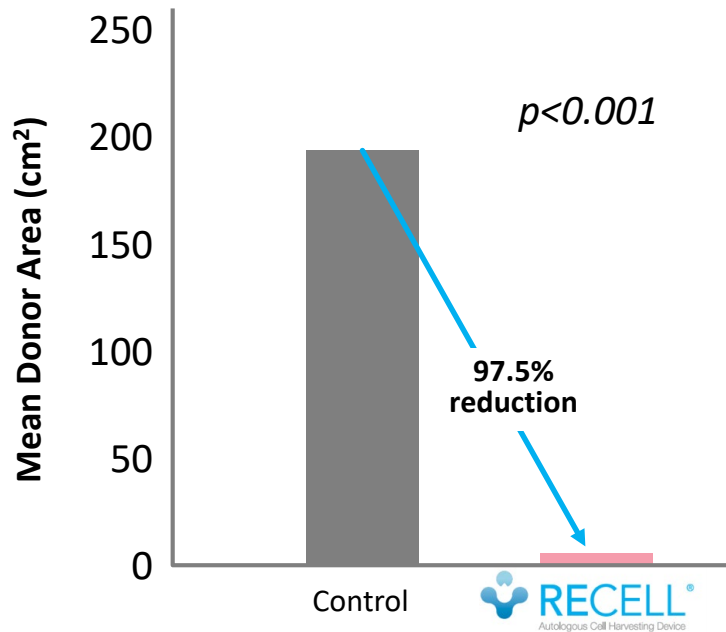
Pivotal Trial #2  
RECELL with widely  
spaced SG Versus  
SOC (STSG) in Third-  
Degree Burns

FDA Compassionate Use Investigational Device  
Exemption (IDE) Program (90+ Patients)

FDA Continued Access Investigational Device  
Exemption (IDE) Program (65+ Patients)

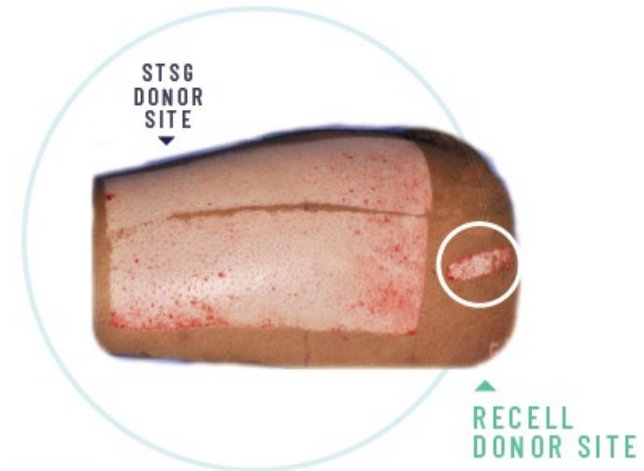
# Pivotal Trial 1: RECELL System *Alone* Versus SoC (STSG) Deep-Partial Thickness (Second-Degree) Burns

## Reduced Donor Skin Requirement



*Equivalent healing of burn sites  
with significantly less donor skin  
required*

## Reduced Pain and Scarring



- Significantly less donor-site pain ( $p \leq 0.0025$ )
- Significantly better donor-site appearance ( $p \leq 0.0025$ )
- Significantly reduced donor-site scarring ( $p \leq 0.0025$ )
- Significantly greater incidence of donor-site healing at two weeks ( $p < 0.001$ )

**Published in JBCR and  
Presented at ABA**

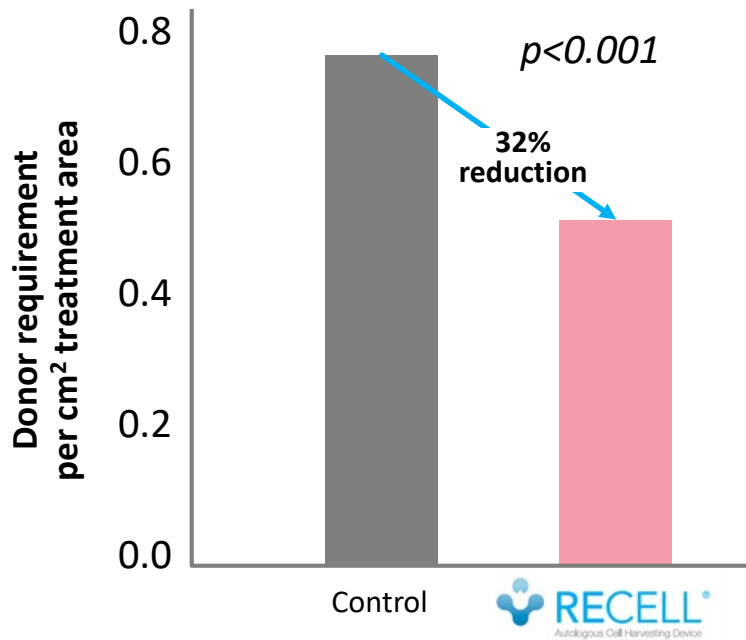


REFERENCE: Holmes JH, Molnar JA, Carter JE, et al. A comparative study of the ReCell® device and autologous split-thickness meshed skin graft in the treatment of acute burn injuries. J Burn Care Res. September/October 2018 issue (Volume 39, Issue 5).

# Pivotal Trial 2: RECELL System Combined With Widely-Spaced Skin Grafts Versus SoC (STSG)

## Full-Thickness (Third-Degree) Burns

### Reduced Donor Skin Requirement



Published in Burns and  
Presented at ABA



### Positive Treatment Outcome

- RECELL System achieved definitive closure comparable to standard of care with significantly less donor skin
- At eight weeks post treatment,
  - **92 percent** of the burn sites treated with the RECELL System achieved complete healing versus
  - **85 percent** for the sites treated with the standard of care



# Compassionate Use Provides Additional Case Studies



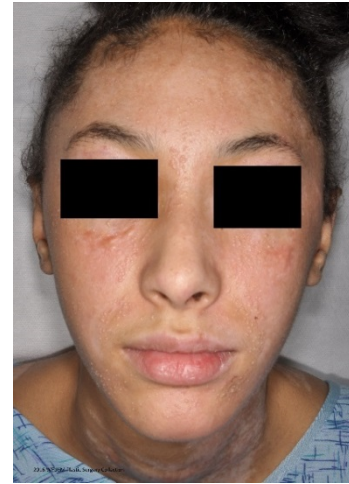
Treatment Day



Day 7



Day 21



3 months



1 year

## A CASE FROM A FACIAL BURN PATIENT

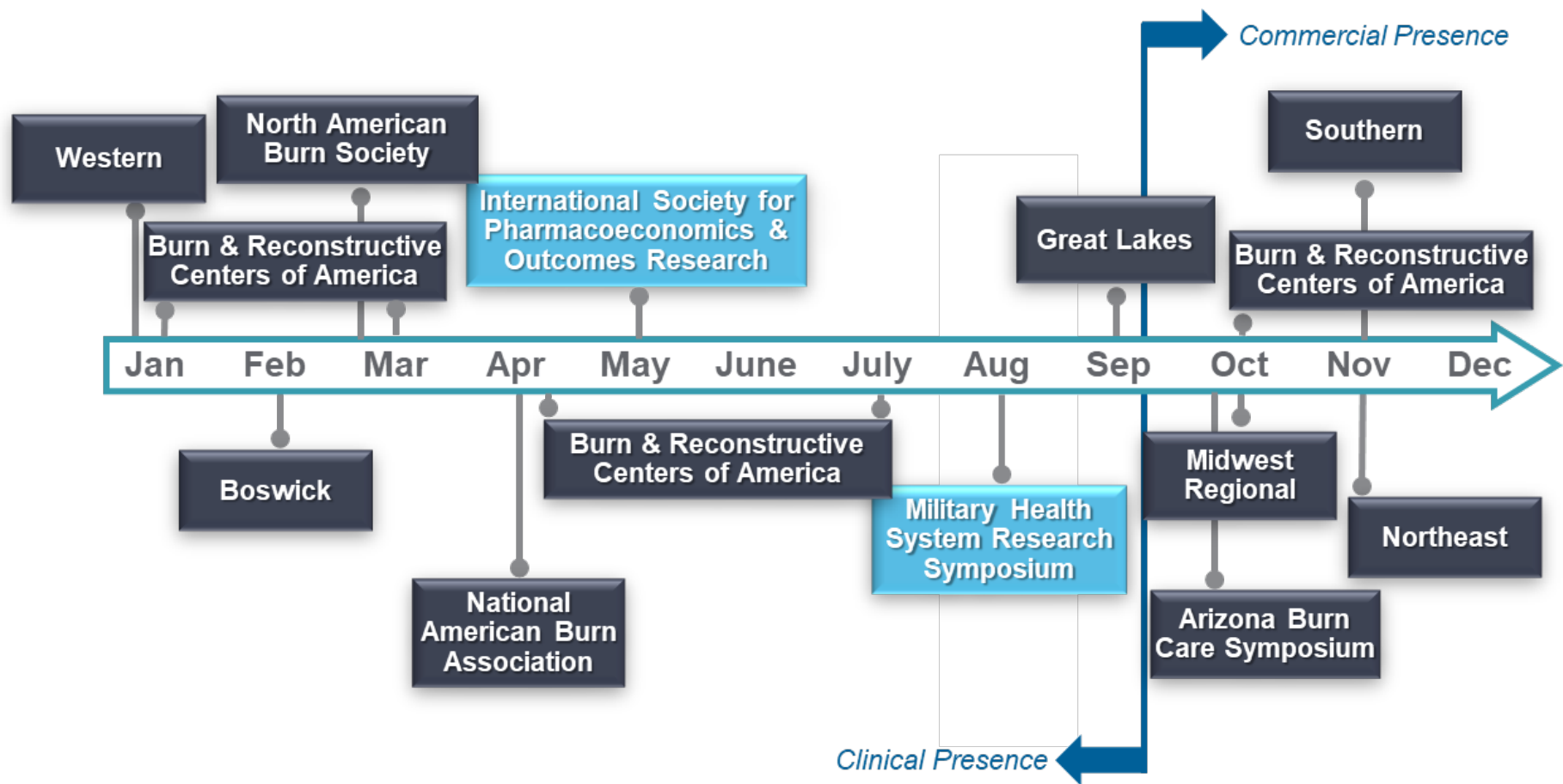
### Case Series Presented at ABA Meeting - APRIL 2018

- 12-year-old girl with 2<sup>nd</sup>-degree facial burn and widespread 3<sup>rd</sup>-degree burns
- 62% Total Body Surface Area (TBSA) burn injury
- Insufficient donor skin available for SoC (STSG)
- Reintroduction of melanocytes resulted in an excellent cosmetic outcome
- No facial contracture release surgery required
- Discharged in 24 days



**RECELL is ideal for treatment of facial burns**

# RECELL Results Highlighted Throughout 2018 at U.S. Conferences





# Additional RECELL Clinical Results to be Featured at 2019 Burn Meetings (18 Abstracts Already Accepted)



**American Burn Association Annual Meeting**  
**2-5 April 2019**  
9 abstracts accepted for presentation

## **Presentations include:**

- Pediatric patients
- Large burn injuries, TBSA 52% to 91%
- Donor sites
- Burn injuries of the hands
- Budget impact of RECELL use versus SOC (Arizona Burn Center)



**John A Boswick Burn & Wound Symposium**  
**2-7 February 2019**  
8 abstracts accepted for presentation

## **Presentations include:**

- Pivotal trials in 2<sup>nd</sup> and 3<sup>rd</sup> degree burns
- Health economic model
- Necrotizing soft tissue infection
- Large TBSA burn injuries
- RECELL combined with dermal substitutes

**LA-ACS/SAL ANNUAL MEETING**  
**JANUARY 18-20, 2019**

LA-ACS/SAL Annual Meeting

avita<sup>medical</sup>  
transforming lives

**LA-ACS/SAL Annual Meeting**  
**18-20 January 2019**  
One abstract accepted for presentation

## **Presentation:**

Reduction in hospital stay due to treatment with RECELL

# Burn Market & RECELL Commercial Strategy

# Commercial Plan was Well Prepared. FDA Approval Triggered a Cascade of Activities



FDA Approval: September 20, 2018



Customer Service Line Active Within 2 Business Days



American Burn Association (ABA) Issued Reimbursement Coding Guidelines Within 1 Week of Approval



Commercial Product Availability Within 2 Weeks of Approval



First Commercial Sale Within 2 Days of Product Availability



Entire US Field Force in Place Within 8 Weeks of Approval



National Sales Launch Commenced January 2019

# Initial U.S. Target Market: In-Patient Burns of 10%+ TBSA that Require Autografting

**486,000**

Burn Patients  
Treated Annually  
in the US<sup>1</sup>



**42,402**

In-patient  
Burn Treatments<sup>2</sup>



**75%**

In-patient  
Burns are Treated  
in Burn Centers<sup>3</sup>

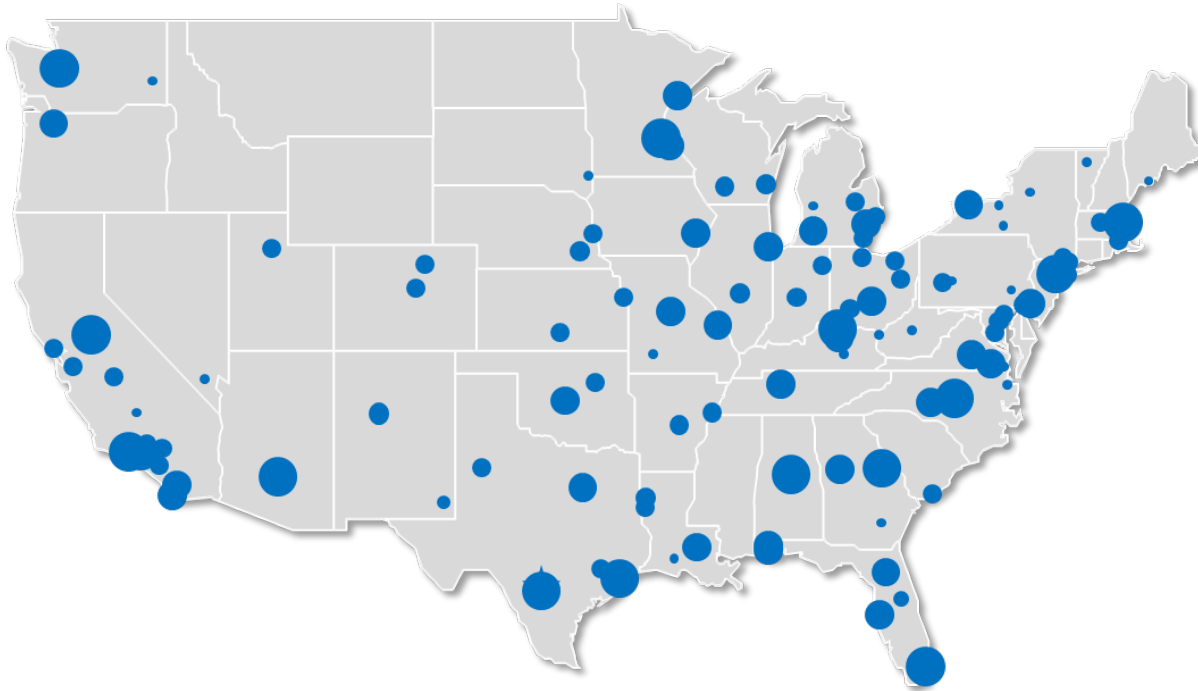


**14,146**

10%+ TBSA  
In-Patients at  
Burn Centers are  
Target Candidates  
for RECELL<sup>4</sup>



# U.S. Burn Market is Highly Concentrated Making It Easily Accessible



- 134 burn centers in the U.S.<sup>1</sup>
- 300 burns surgeons in the U.S.<sup>2</sup>
- Burn centers see 65 times more burn hospitalizations than in general hospital setting<sup>3</sup>
- The ABA mandates that severe burns, meeting certain criteria, must be transferred to an ABA burn center

---

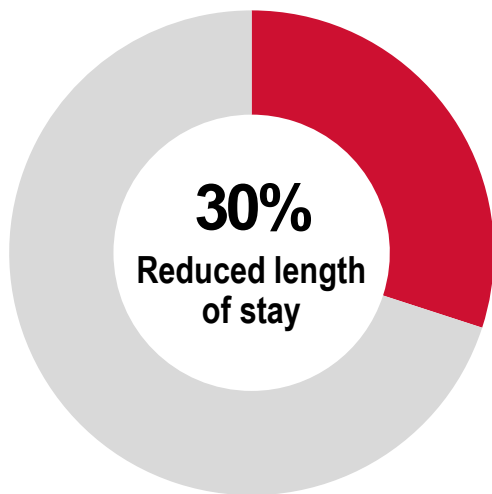
24 Burn Centers Already Have Experience with RECELL System<sup>4</sup>  
Represent 30% of Patients Treated, Includes #1 and #2 Centers in U.S.

---

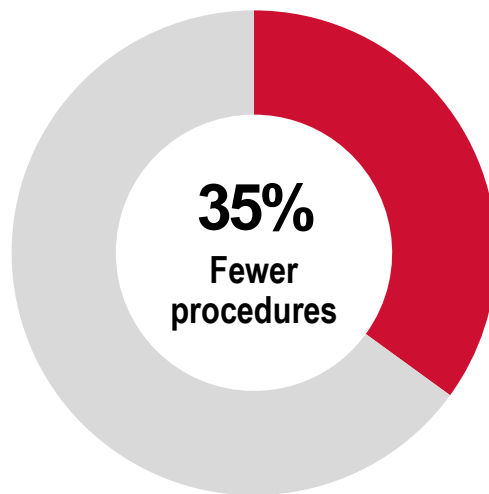
# Health Economic Model Demonstrates that RECELL Can Reduce Overall Hospital Costs

## Transforming Care

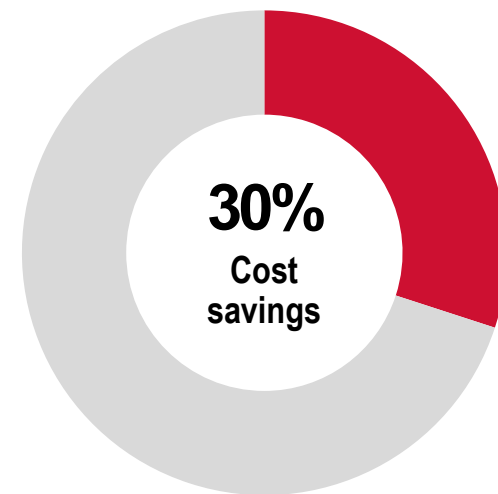
Reduces costs and accelerates recovery by decreasing the number of painful procedures and hospital length of stay



Fewer procedures and faster healing time gets patients home quicker



Reduced donor site size and greater meshing ratio enables permanent closure with fewer invasive autograft procedures



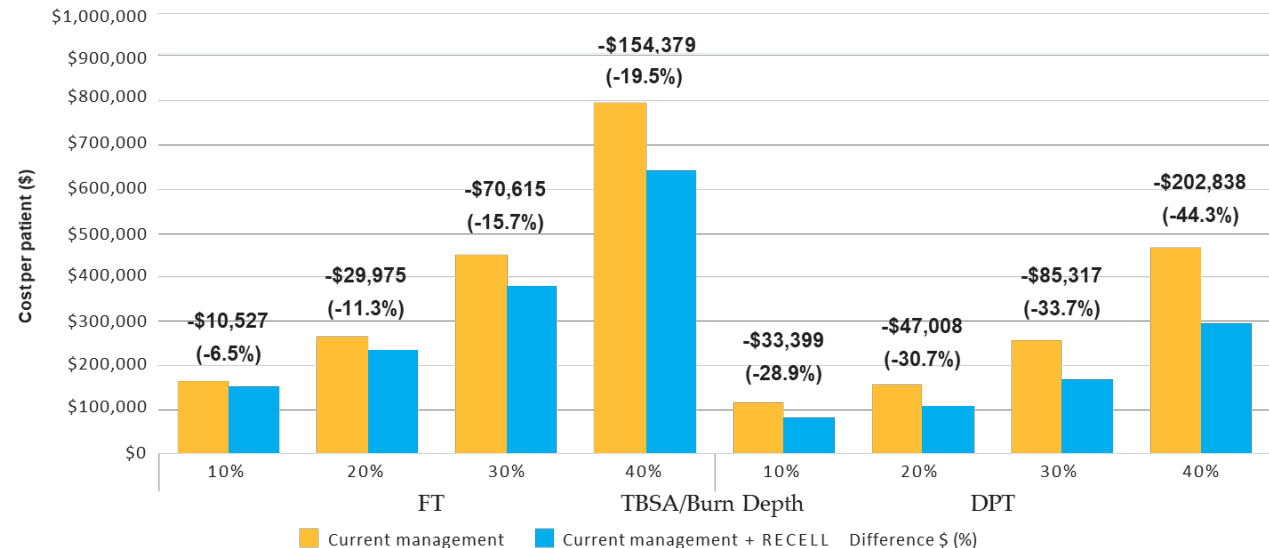
Shorter and fewer procedures, reduced length of stay, and reduced resource use translates into burn center savings

**RECELL Saves the Hospital Money in All In-Patient Scenarios  
Where the Burn is 10% Total Body Surface Area (TBSA) or Larger**

# Health Economic Model Demonstrates RECELL Cost Savings Per-Patient Savings

- IQVIA (IMS) developed a Burn Care Pathway Health Economic model demonstrating RECELL savings
- Validated model provides VAC (Value & Analysis Committees) strong economic justification for adopting RECELL

**Figure 1: Relative cost per patient of current management versus RECELL by TBSA and depth**



**Conclusion:** Use of RECELL is expected to reduce costs across TBSA ranges for FT and DPT patients, with relative savings increasing as TBSA increases.

Use of the RECELL System could reduce the cost of treatment by 44% or greater in patients with large burns

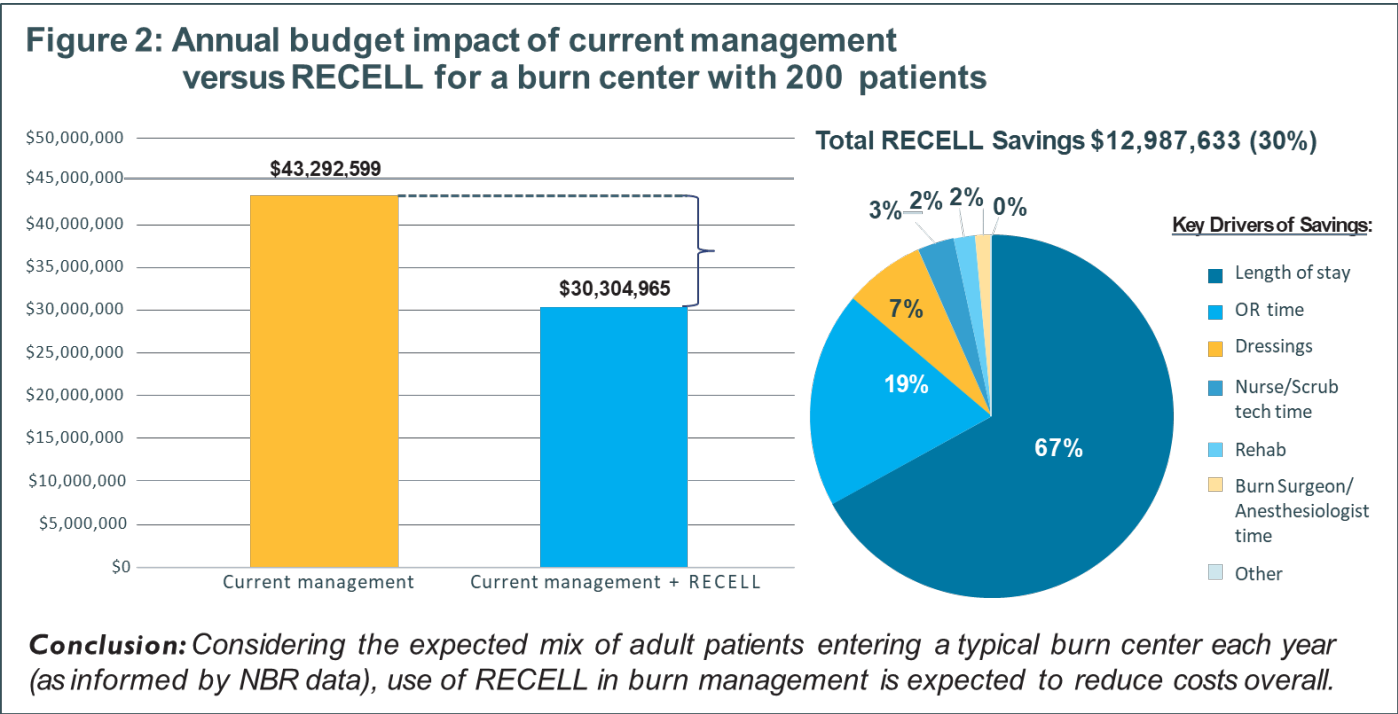
Sets a New Standard of Validating Cost Effectiveness for Any New Product in Burns



# Health Economic Model Demonstrates RECELL Cost Savings

## Annual Burn Center Savings

- Model can be tailored to patient populations relevant to individual hospitals, healthcare systems, etc.
- Robust publication and podium schedule

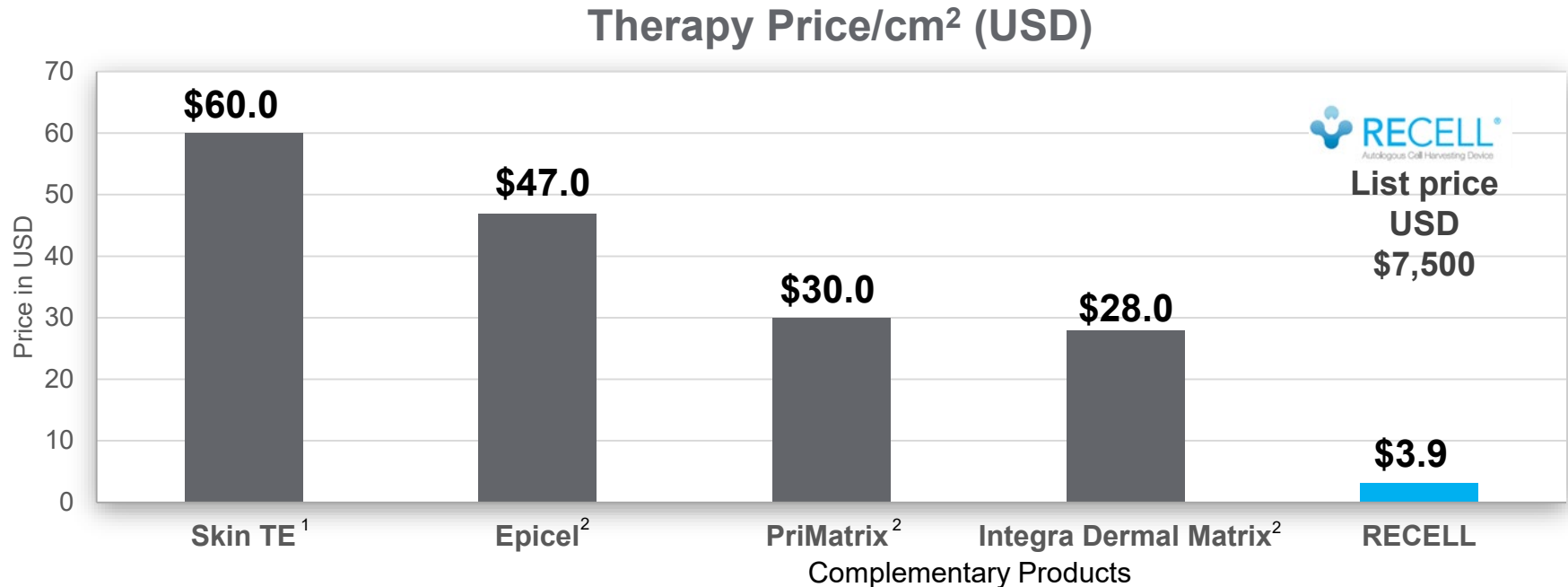


For a burn center with 200 patients, the use of RECELL would reduce annual total treatment costs from \$43.3 million to \$30.3 million, saving 30% or \$13.0 million

Customized Projections Can be Created for Each Burn Center Showing Annual Savings

# RECELL System is Priced Right for All Burn Sizes

## Pricing of Other Treatments Limit Them to Large Burns



#### Assumptions

- Skin TE \$60/cm<sup>2</sup>
- Epicel ~\$50/cm<sup>2</sup>; 1%TBSA treatment with Epicel costs at \$6-10,000; Epicel Skin Grafts
- Integra \$28/cm<sup>2</sup>. Complementary product presented for pricing comparison
- RECELL<sup>®</sup> 1920 up to 10% TBSA. Complementary product presented for pricing comparison

**RECELL is Priced for Broad Market Adoption**

# Creation of Best in Class Market Access Program Will Address Market Needs

## Key Launch Need

Physician payment

Ensure Hospital Payment

Reimbursement Guidelines

Customers need quick, knowledgeable responses for reimbursement inquiries

## Addressing the Need

CPT Codes

CPT Code	Code Description
16110	Epidermal autograft, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children
+16111	each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof
16116	Epidermal autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children
+16116	each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof

ICD-10 Code for procedural coding



Reimbursement and Coding Guides

Reimbursement Customer Service Line  
Director of Market Access

**ABA Provided Recommended CPT Codes Within One Week of Approval**

CPT = Current Procedural Terminology  
ICD = Internal Classification of Disease

# US Commercial Field Team is in Place

**25**

**Average** Years of  
Industry Experience  
(Sales Leadership)

**15.8**

**Average** Years of  
Burn Care  
Experience  
(Entire Field)

**100%**

Have Burn Care  
Experience

**12**

**Average** Years of  
Surgical Selling &  
Case Support  
Experience

**100%**

Have Successful  
Launched a New  
Product

**20 Field Positions Will Provide Deep Coverage to All 134 US Burn Centers**

# All Preliminary Indicators Point to Success

Tremendous excitement and interest from potential customers



Approximately half of the U.S. burn centers are in discussion with our sales team



36 burn centers have begun the purchase authorization process with their hospital administration



27 burn centers have already been trained and certified



14 accounts have already placed orders

**We are excited to see the response now that our full sales team of 20 has been deployed**

# All Requirements for Successful U.S. Launch in Place

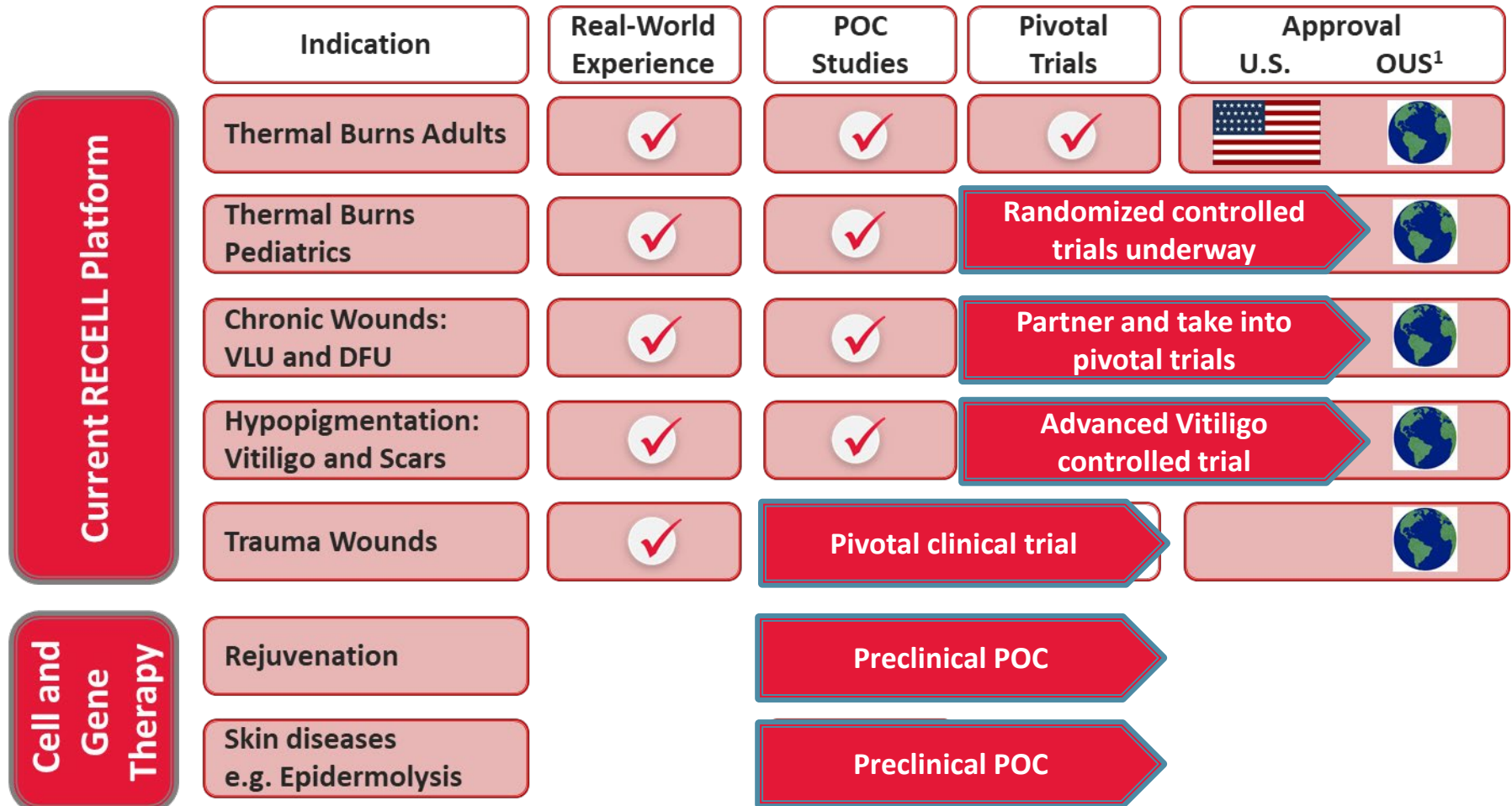
- ✓ Highly concentrated market
- ✓ Strong clinical data package
- ✓ Significant improvement in patient care
- ✓ Compelling health economics (cost savings)
- ✓ Priced to maximize revenue
- ✓ Reimbursement in place and well supported
- ✓ Experienced field force in place
- ✓ Credible and active communication plan
- ✓ Robust field deployment model
- ✓ Customer service center

# Pipeline and Milestones



# AVITA Medical Pipeline

## Development Programs



1 OUS APPROVED INDICATIONS

Europe: Burns, chronic wounds, scars and vitiligo

China: Burns, acute wounds, scars and vitiligo

Australia: Burns, acute wounds, scars and vitiligo

# Financial Overview

(AUD in 000s)	Year Ended	
	2018	2017
	June 30,	
Revenue	\$11,372	\$8,132
Operating Costs	28,571	20,186
Net Loss	(16,484)	(11,511)
Cash	14,826 <sup>1</sup>	3,790

Tickers: ASX:AVH and OTCQX:AVMX



<sup>1</sup>Excludes additional A\$3.0 million in net proceeds received in July 2018, A\$22.4 million in net proceeds received in December 2018, and \$13.7 million in net proceeds scheduled to be received in January 2019 from equity financings.

## BARDA Program

- U.S. Biomedical Advanced Research and Development Authority
  - Mandate: disaster preparedness & response
- Providing sizable non-dilutive funding
- Total estimated contract value US\$80.1M
- Major programs supported:
  - PMA
  - Health Economic Model
  - Pediatric clinical trials
  - Disaster preparedness stockpile



# 2018/2019 Value-Creating Milestones

- **2018 has been a Transformative Year for AVITA**
  - ✓ PMA approval by US Food & Drug Administration
  - ✓ Accelerated launch preparation activities
  - ✓ Robust manufacturing capabilities
  - ✓ High impact of RECELL clinical data
  - ✓ Continuing to advance pipeline
- **RECELL is Positioned for Successful Adoption in US Burns during 2019**
- **Key milestones for 2019**
  - RECELL U.S. market launch / revenue growth
  - Publication of 3rd degree burn pivotal trial results
  - Publication of RECELL health economic model
  - Presentations of RECELL compassionate use data at 2019 ABA meeting
  - Commencement of traumatic wounds pivotal clinical trial
  - Commencement of vitiligo clinical trial(s)
  - BARDA procurement
  - Listing of ADRs on NASDAQ

# Risk Factors

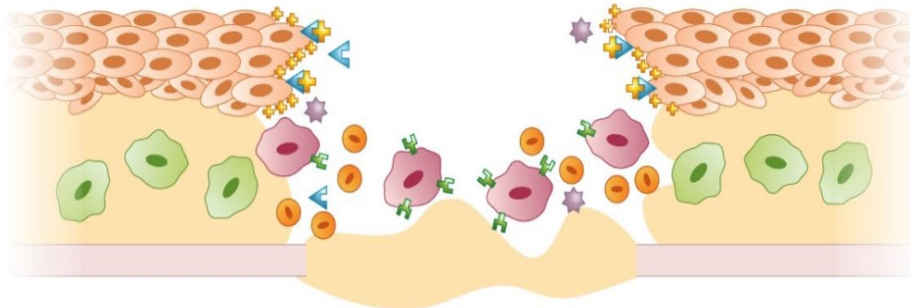
There are numerous risk factors involved with the Company's business. Some of these risks can be mitigated by the use of safeguards and appropriate systems and controls, but some are outside the control of the Company and cannot be mitigated. Accordingly, an investment in the Company carries no guarantee with respect to the payment of dividends, return of capital or price at which securities will trade. The following is a summary of the more material matters to be considered. However, this summary is not exhaustive. Potential investor should consult their professional advisors before deciding whether to invest.

- **Technological Change:** Technological change presents the Company with significant opportunities for growth. However, the risk remains that any competitor may introduce new technology enabling it to gain a significant competitive advantage over the Company.
- **Reliance on key personnel:** The Company's success depends to a significant extent upon its key management personnel, as well as other management and technical personnel including sub-contractors. The loss of the services of any such personnel could have an adverse effect on the Company.
- **Competition:** The Company competes with other companies, including nationally in Australia and internationally. Some of these companies have greater financial and other resources than the Company and, as a result, may be in a better position to compete for future business opportunities. There can be no assurance that the Company can compete effectively with these companies.
- **Patent Protection:** The patent protection that the Company may obtain varies from product to product and country to country and may not be sufficient, including to maintain product exclusivity. Patent rights are also limited in time and do not always provide effective protection for products and services: competitors may successfully avoid patents through design innovation, the Company may not hold sufficient evidence of infringement to bring suit, or the infringement claim may not result in a decision that the rights are valid, enforceable or infringed. Legislation or regulatory actions subsequent to the filing date of a patent application may affect what an applicant is entitled to claim in a pending application and may also affect whether a granted patent can be enforced in certain circumstances. Laws relating to biotechnology remain the subject of ongoing political controversy in some countries. The risk of changed laws affecting patent rights is generally considered greater for the biotechnology field than in other longer established fields.
- **Change in government policy and legislation:** Any material adverse changes in relevant government policies or legislation of Australia / United States may affect the viability and profitability of the Company, and consequent returns to investors. The activities of the Company are subject to various federal, state and local laws governing prospecting, development, production, taxes, labor standards and occupational health and safety, and other matters."

# **Appendix Mechanism and Additional Burn Case Studies**

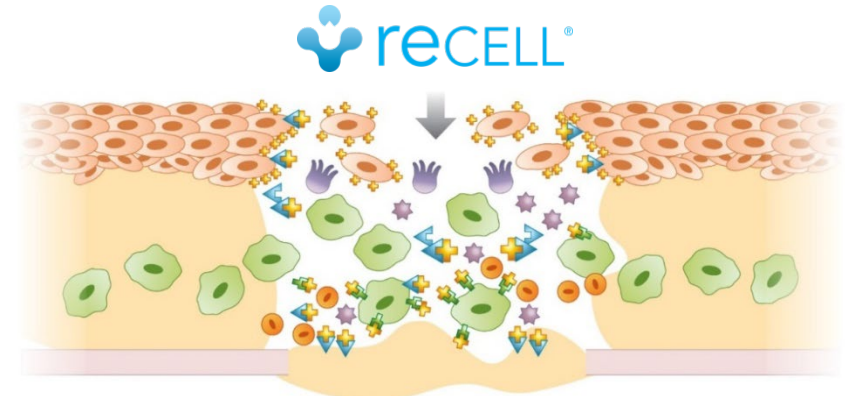
# MOA: Disaggregated cells facilitate fast & effective skin regeneration

## Healing Process Without RECELL



- ReCell processes small samples of patients' own skin to create a cell suspension of disaggregated cells
- Disaggregated skin cells in suspension form new tissue across the entire area rather than waiting for cellular resources from the wound edge

## Healing Process With RECELL



- Cell suspension includes pigment-producing cells (melanocytes)
- Cell suspension facilitates re-epithelialization of areas of viable dermis (partial-thickness burns), and areas within the spaces of split-thickness autografts for full-thickness burns

## Disaggregated Autologous Cells from RECELL Support Re-epithelialization



# RECELL Achieved Healing and Pigmentation When Standard of Care Failed

## Case Report: RECELL Treatment Outcome for Deep Partial-Thickness Burn

- 48-year-old victim of a gas boiler explosion
- Standard of care failed to heal the 2nd degree facial burn wounds
- Use of RECELL achieved wound healing
- Reintroduction of melanocytes resulted in an excellent cosmetic outcome
- RECELL 's unique advantages make it the ideal solution for facial burns and other visible burn sites

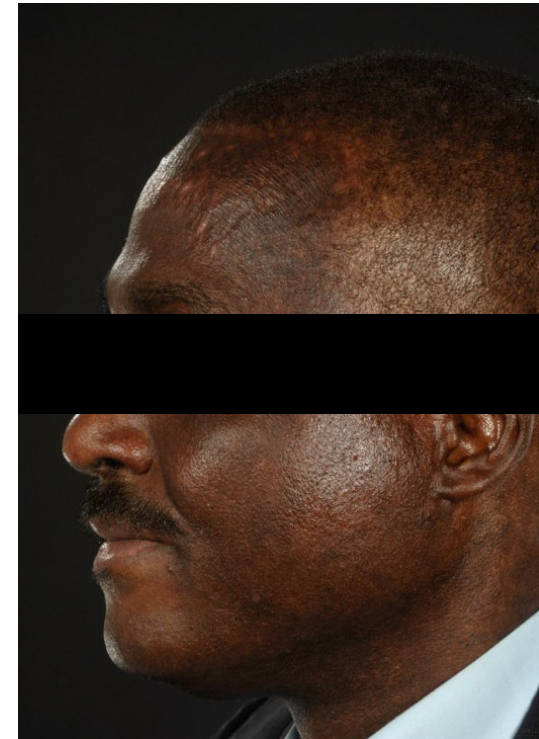
### Treatment

Excision and ReCell®



### Post-Operation

14 weeks



Restoration of Normal Pigment Critical For Patients



# Pediatric Opportunity

## High Percentage of Burns are in Pediatric Patients

- 32% of burns occur between ages 5 and 15.9
- Majority suffer from scald burns (65%)

## Avita has Initiated studies with RECELL in Pediatrics

- Q3 2018 - Commencement of US Paediatric Burns Clinical Trial
- Q3 2018 - Commencement of Australian Paediatric Scald Study

## Scalds Allows Expansion into another Site-of-Service – Outpatient Setting

### Case Study: 2-year old with Scald treated with RECELL



Before treatment



3 weeks  
post RECELL treatment



10 weeks  
post RECELL treatment



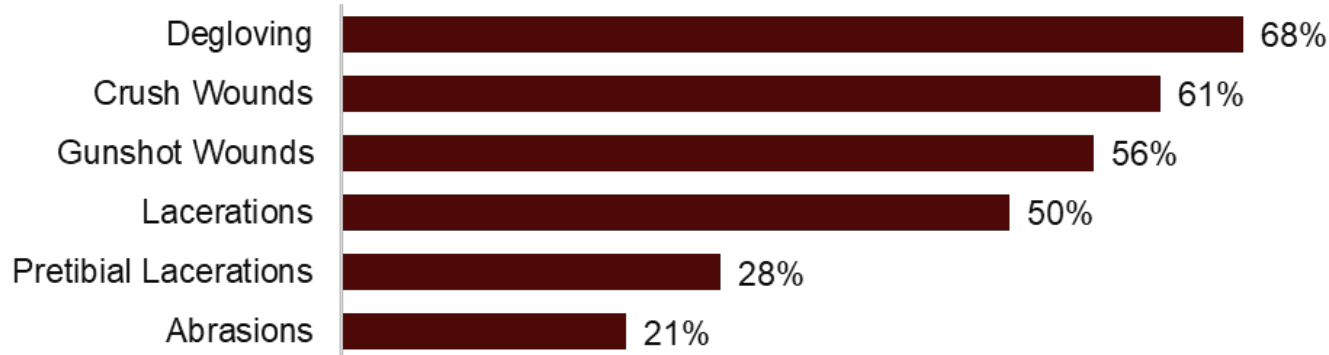
10 months  
post RECELL treatment

# **Appendix**

## **Follow-On Indications Beyond Burns**

# RECELL Presents a Strategic Opportunity in Traumatic Wounds

## Percentage of Wounds Requiring Skin Grafts



- ~1/3 of all skin grafts are trauma related
- ~50% of Burn Surgeons also work in trauma centers
  - Synergistic with current commercial efforts in burns
- RECELL used by multiple international surgeons in Traumatic Wounds with positive outcomes

# Regenerative Dermatology Opportunity in Vitiligo

High Market Value • Large Population • Focused to a Specialty • Clinical Data



## Vitiligo

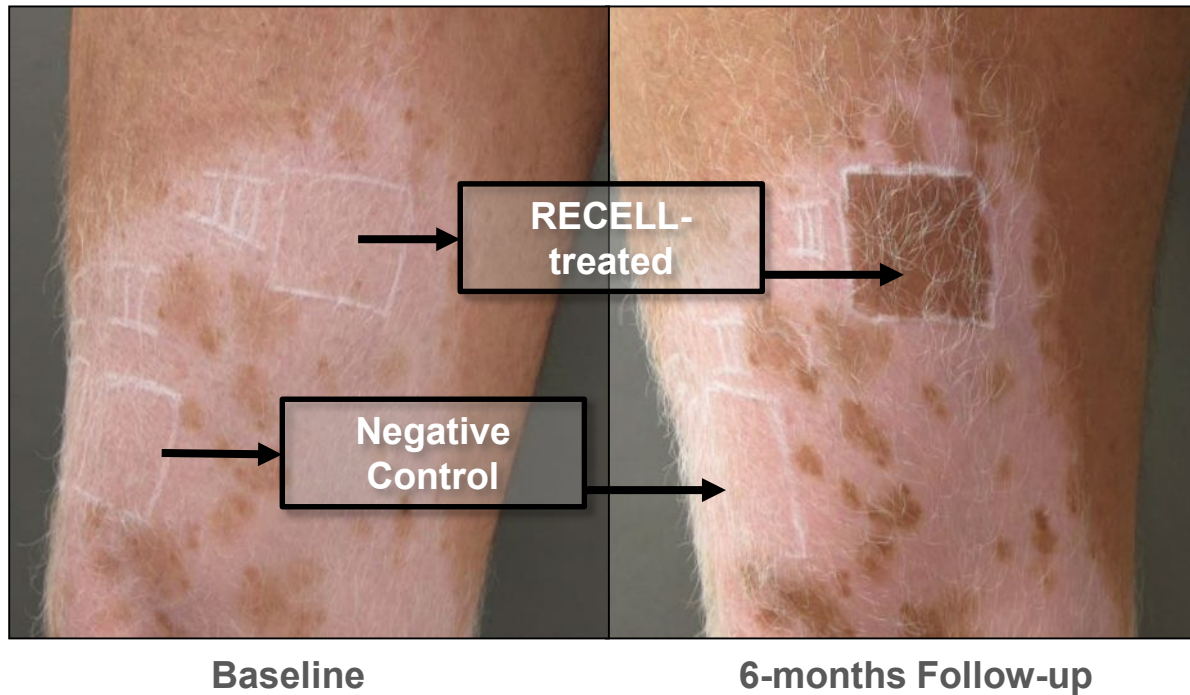
\$2B Global Market<sup>1</sup>

>10M (US & China)<sup>2,3</sup>

Extremely low patient & doctor satisfaction with existing products<sup>4</sup>

5 RECELL & Vitiligo publications with positive outcomes

# RECELL Was Able to Repigment 100% at 6-months (Vitiligo)



- After 6-months, the RECELL-treated area is 100% re-pigmented, with mild hyperpigmentation (UVA daily)
- Control area is 0% re-pigmented

# Early Research Programs to Advance RECELL Platform

High Market Value • Focused to a Specialty • Expansion into other Disease States



## Cell-based Skin Gene Therapy e.g., Epidermolysis Bullosa (EB)

**EB:** An incurable, group of genetic disorders characterized by skin fragility and blistering

25-50K/yr (US)<sup>1</sup>



## Skin Aesthetics

\$22B Global Market<sup>2</sup>

>1MM aesthetic procedures/yr (US)<sup>2</sup>

Evolution of current RECELL platform required to incorporate cellular manipulation and/or genetically modified cells

Successful development of engineered (autologous) cell therapies will create a pathway to other applications