

# AVITA Medical

August 7<sup>th</sup>, 2019



**avita** medical  
*transforming lives*

# Forward Looking Statements

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# AVITA Medical: Transforming Lives with Skin Regeneration

- RECELL® System: FDA approved for the treatment of acute thermal burns
  - Proprietary Spray-On Skin™ offers life changing benefits
  - Safe & effective; reduces hospital costs
- Ongoing platform expansion: \$2 billion total market opportunity
  - Pediatrics and outpatient settings in burns
  - Trauma and chronic wounds
  - Regenerative dermatology: Vitiligo
- Further potential for cell-based gene therapy and aesthetics
- Commercial launch success; BARDA support and funding
- Highly relevant and experienced team



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**Revolutionary treatment from  
a patient's own skin for life  
changing outcomes**

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# Experienced Leadership Team



**Dr. Michael S. Perry**  
CEO

>30 years  
experience

Affiliations:



BAY CITY CAPITAL

**Baxter**



GENETIC THERAPY, INC.

**Pharsight**



**Tim Rooney**  
CAO & Interim CFO

25 years  
experience

Affiliations:



**EcoStrip**



**Erin Liberto**  
CCO

17 years  
experience

Affiliations:

*Johnson & Johnson*



**Andrew Quick**  
CTO

25 years  
experience

Affiliations:

Boston  
Scientific



**SONOVA**



**Donna Shiroma**  
General Counsel

20 years  
experience

Affiliations:

ASCEND THERAPEUTICS



*Johnson & Johnson*

# Broad Pipeline with Strong Growth Potential

Indication	Discovery	Feasibility	Pivotal	Approval
<b>Regenerative Therapeutics - Wounds (Current Platform)</b>				
U.S. Acute Thermal Burns Adults				
U.S. Pediatric Donor Sites				
Japan Burns & Wounds				
U.S. Trauma/Soft Tissue Repair				
U.S. Pediatric Scalds				
<b>Regenerative Therapeutics - Dermatology (Current Platform)</b>				
U.S. Repigmentation: Vitiligo				
<b>Cell and Cell-Based Gene Therapy - Early Research Programs</b>				
Skin Diseases (e.g., Epidermolysis Bullosa)				
Rejuvenation				

# **RECELL® System: FDA Approved for the Treatment of Acute Thermal Burns**

# Addressing Critical Patient Need: Current Standard of Care Is Suboptimal and Expensive

## Split-Thickness Skin Grafts (STSG) are the Standard of Care (SoC)



*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 associated with donor site
- Extended hospitalization and costs
- Multiple complex, costly, surgical procedures
- Risk of infection

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**Current SoC for a 40% Total Body Surface Area (TBSA) burn:  
Average cost USD \$579,000 and 59.4 days in hospital<sup>1</sup>**

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# RECELL System: FDA-Approved Skin Regeneration Platform

## Regenerative Medicine Platform

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

## Designed by Burn Surgeons

- Elegantly delivers skin regeneration to patients *at point of care*

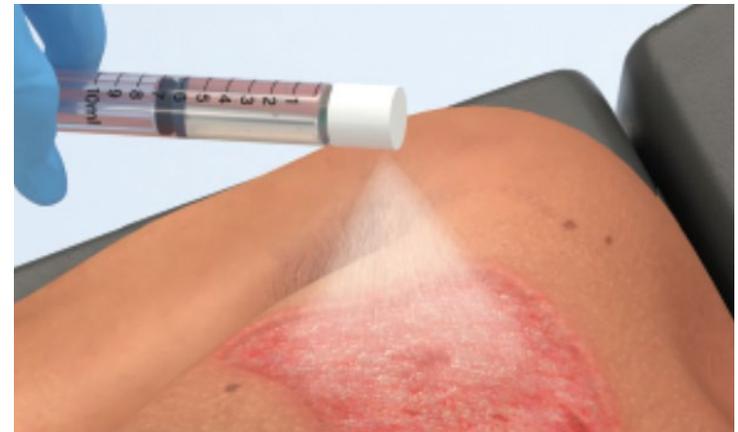
## Proven Safety and Effectiveness

- 8,000+ uses to date in multiple world markets with no observed safety signals
- Treatment area is 80X donor area (credit card size skin sample can treat an entire back)
- Compelling clinical results and robust health-economic data

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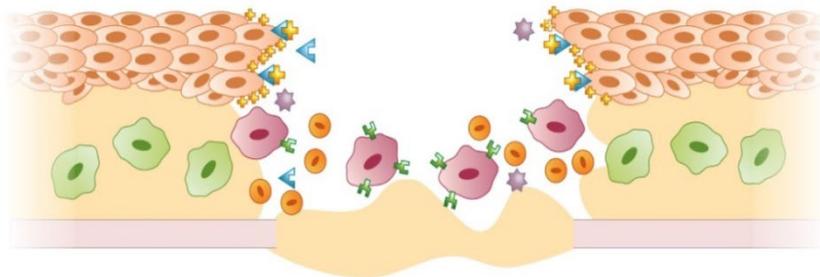
**>50 Peer-Reviewed Publications**

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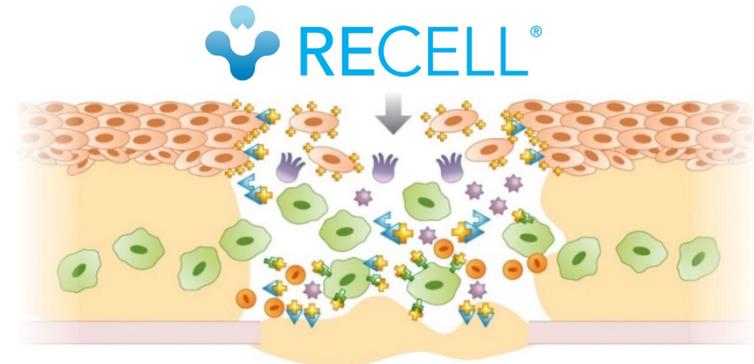


# MOA: Disaggregated Cells Facilitate Fast & Effective Skin Regeneration

## Healing Process without RECELL



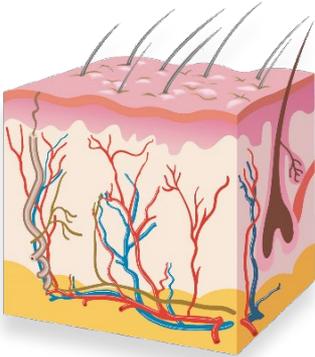
## Healing Process with RECELL



- 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
- 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

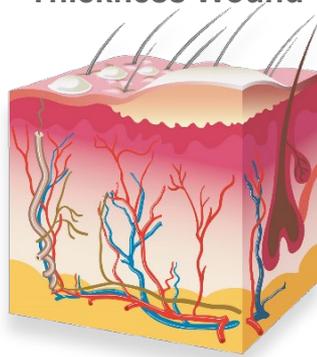
# Positive U.S. Clinical Trials in Burns

Superficial Wound



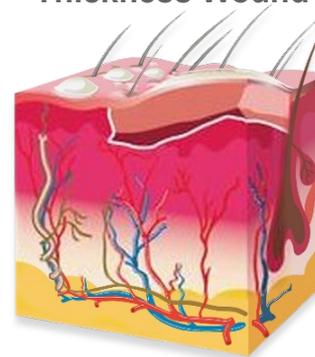
1<sup>st</sup> degree

Superficial Partial Thickness Wound



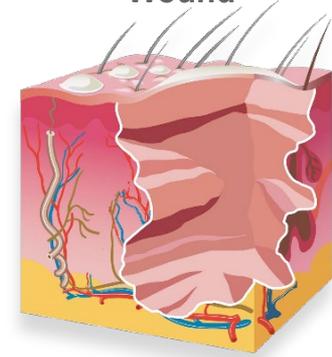
2<sup>nd</sup> degree

Deep Partial Thickness Wound



2<sup>nd</sup> degree

Full Thickness Wound



3<sup>rd</sup> degree

## Positive Trial Outcomes

- Two multicenter, randomized, controlled clinical trials consisting of 131 patients
- Additional 188 patients treated in Compassionate Use and Continued Access programs

Pivotal Trial #1  
RECELL versus SoC  
(STSG) in Second-  
Degree Burns

Pivotal Trial #2  
RECELL with widely expanded  
graft versus SoC (STSG) in  
Third-Degree Burns

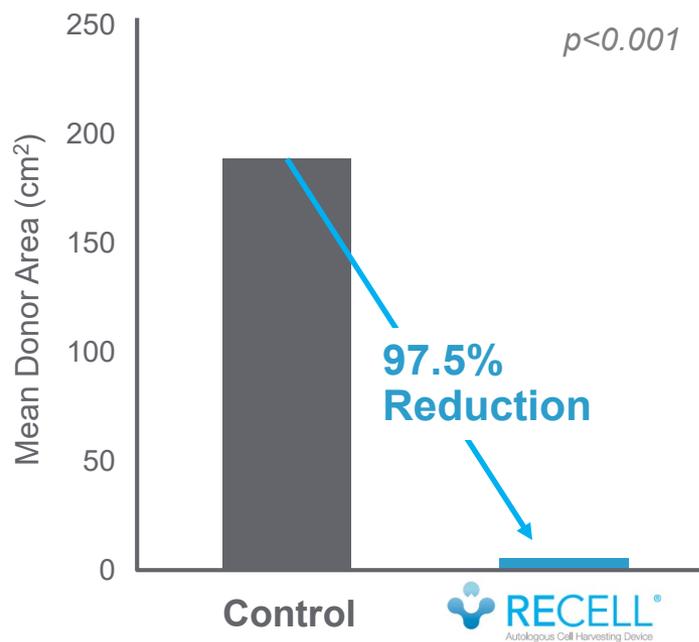
FDA Compassionate Use Investigational Device  
Exemption (IDE) Program (100 Patients)

FDA Continued Access Investigational Device  
Exemption (IDE) Program (88 Patients)

# Pivotal Trial 1: 97.5% Reduction in Donor Skin Requirement

## RECELL System *Alone* versus Standard of Care in Deep-Partial Thickness (Second-Degree) Burns

### Reduced Donor Skin Requirement



*Comparable healing and long-term outcomes for 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 ( $p < 0.001$ )

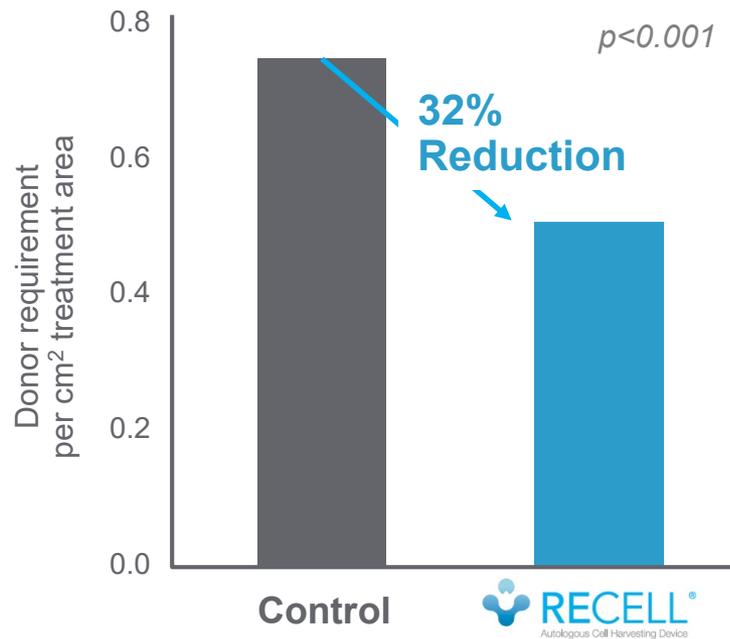
**Published in JBCR  
and Presented at ABA**



# Pivotal Trial 2: 32% Reduction in Donor Skin Requirement

## RECELL System Combined with Widely-Spaced Skin Grafts versus Standard of Care in 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%** of the burn sites treated with the RECELL System achieved complete healing versus **85%** for the sites treated with the Standard of Care

# Life Changing Outcomes & Economic Benefit



Treatment Day



Day 7



Day 21



3 Months



1 Year

## Case Series Presented at 50<sup>th</sup> Annual ABA Meeting

- Compassionate Use Example
- 12-year-old girl with 2nd-degree facial burn and widespread 3rd-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 deep partial-thickness facial burns**

# **RECELL U.S. Commercial Launch & Current Market Potential**

# In-Patient Burns: The Initial U.S. Target Market

**486,000**

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



**53,000**

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



**75%**

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



**~132**

Burn centers in the  
U.S.<sup>1</sup>



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**\$200MM Addressable Market**

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1. American Burn Association. National Burn Repository Report. 2016; Version 12.0 also <http://ameriburn.org/who-we-are/media/burn-incidence-fact-sheet/> Accessed 07/23/2018
2. Burn-Related Hospital Inpatient Stays and Emergency Department Visits, 2013 HCUP/AHRQ Statistical Brief 217, December 2016
3. ABA Burn Incidence Fact Sheet

# Well Positioned for Success

## Key Marketing Requirements

**Robust Clinical Data**

**Experienced Field Team**

**Health Economic Value Proposition**

**Physician Payment**

## AVITA Addresses the Market Need

**2 Randomized Controlled Clinical Studies Demonstrating Positive Safety & Efficacy** ✓

**21 Commercial Field Positions Averaging Over 15 Years of Industry Experience** ✓

**Attractive Pricing & Published Health Economic Model Demonstrating RECELL Can Reduce Overall Hospital Costs** ✓

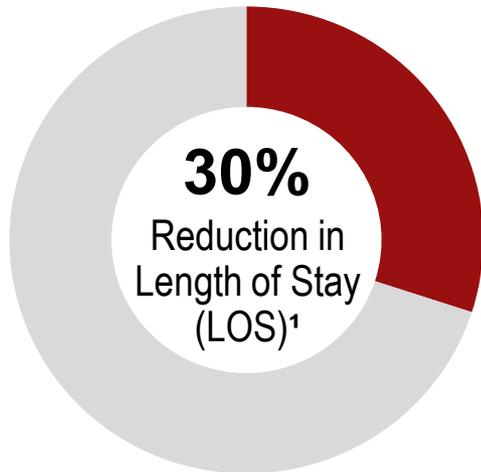
**Reimbursement / CPT Codes in Place** ✓

CPT Code	Code Description
15110	Epidermal autograph, trunk, arms, legs, first 100 sq cm or less, or 1% of body area of infants and children
+15111	each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof
15115	Epidermal autograph, 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
+15116	each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof

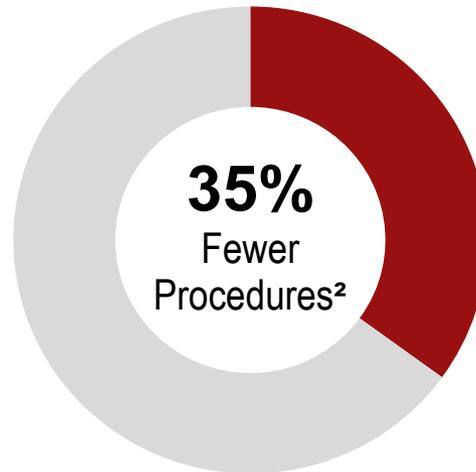
# Published Health Economic Model Demonstrates RECELL Can Reduce Overall Hospital Costs

## Transforming Care

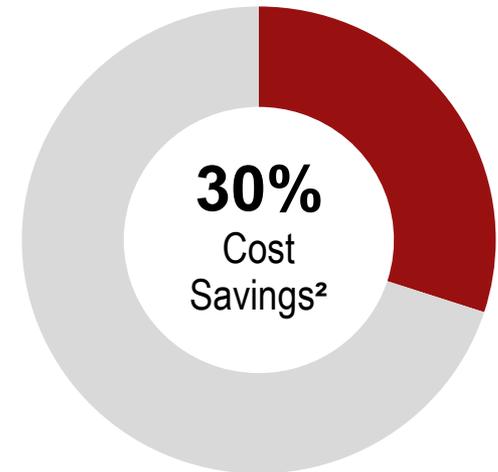
Reduces costs and accelerates recovery by decreasing the number of painful procedures and length of stay in hospital



Fewer procedures and faster healing times get patients home more quickly



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



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

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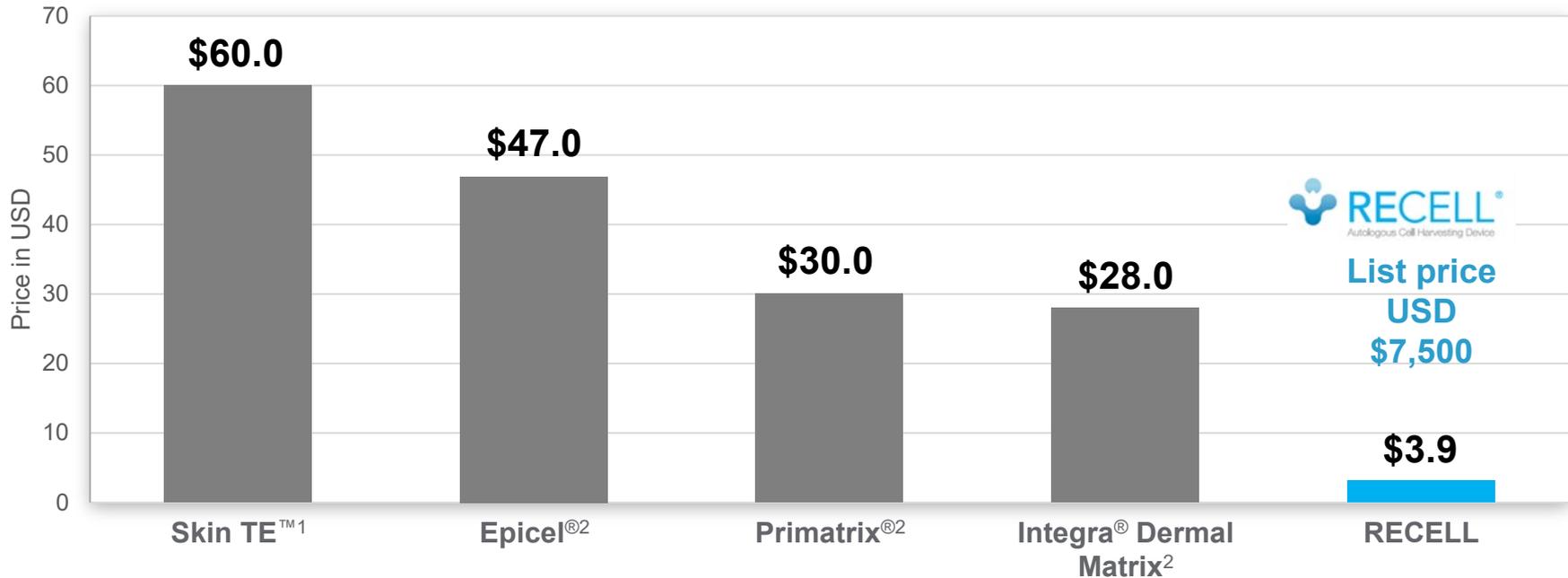
**RECELL Saves the Hospital Money in All In-Patient Scenarios Where the Burn is 10% Total Body Surface Area (TBSA) or Greater**

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# RECELL Priced Right

Pricing of Other Treatments Limits Them to Large Burns

Therapy Price/cm<sup>2</sup> (USD)



## Complementary Products\*

### 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® 1920 up to 10% TBSA. Complementary product presented for pricing comparison

## RECELL Is Priced for Broad Market Adoption

1. <https://seekingalpha.com/article/4193454-polarityte-paradigm-shift-expensive-skin-graft>

2. Sarah Schlatter, Biomedical Engineering, University of Rhode Island. Available at: [http://www.ele.uri.edu/Courses/bme281/F08/Sarah\\_1.pdf](http://www.ele.uri.edu/Courses/bme281/F08/Sarah_1.pdf)

\*Complementary Products are presented for pricing comparison only  
Epicel® is a registered trademark of Vericel Corporation, PriMatrix® is a registered trademark of Integra, SkinTE™ is a trademark of PolarityTE

# RECELL Launched Nationwide in January 2019

**NOW APPROVED: The RECELL® System**  Autologous Cell Harvesting Device

**LEARN MORE** ▶

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Inside their patients' skin cells are regenerative forces at the ready.

**GIVE THEM THE SIGNAL TO**

**RECELL**  
Autologous Cell Harvesting Device

FOR INTERNAL USE ONLY

**RECELL DRIVES POSITIVE OUTCOMES™**

RECELL DRIVES POSITIVE OUTCOMES™

LEADS TO QUICKER TREATMENT SITE RECOVERY

PATIENT EXPERIENCE RECOVERS

TREATMENT SITE RECOVERY

RECELL DRIVES POSITIVE OUTCOMES™

**HEALING AT A CELLULAR LEVEL®**

RECELL DRIVES POSITIVE OUTCOMES™

HEALING AT A CELLULAR LEVEL®

RECELL DRIVES POSITIVE OUTCOMES™

HEALING AT A CELLULAR LEVEL®



**RECELL**  
Autologous Cell Harvesting Device

**2018-2019 CODING & REIMBURSEMENT GUIDE for RECELL® System**



www.RECELLSystem.com

2018-2019 CODING & REIMBURSEMENT GUIDE for RECELL® System

Code	Description	Reimbursement
CPT 86300	Obtain autologous skin cells, including the following: 1) Harvesting autologous skin cells from the patient's body; 2) Processing the cells to create a suspension; 3) Applying the suspension to the wound site.	\$1,500
CPT 86301	Prepare autologous skin cells, including the following: 1) Harvesting autologous skin cells from the patient's body; 2) Processing the cells to create a suspension; 3) Applying the suspension to the wound site.	\$1,500
CPT 86302	Deliver autologous skin cells, including the following: 1) Harvesting autologous skin cells from the patient's body; 2) Processing the cells to create a suspension; 3) Applying the suspension to the wound site.	\$1,500

**RECELL CLINICAL STUDY: DEPT PARTIAL BURNS**

**RECELL**  
Autologous Cell Harvesting Device

**A Randomized Controlled Comparing the RECELL System to Meshed Autografting for Treatment of Deep Partial Thickness Burn Injuries**

This study supports RECELL as a safe and effective treatment for deep partial thickness burns.

RECELL CLINICAL STUDY: DEPT PARTIAL BURNS

**RECELL SYSTEM BIBLIOGRAPHY**

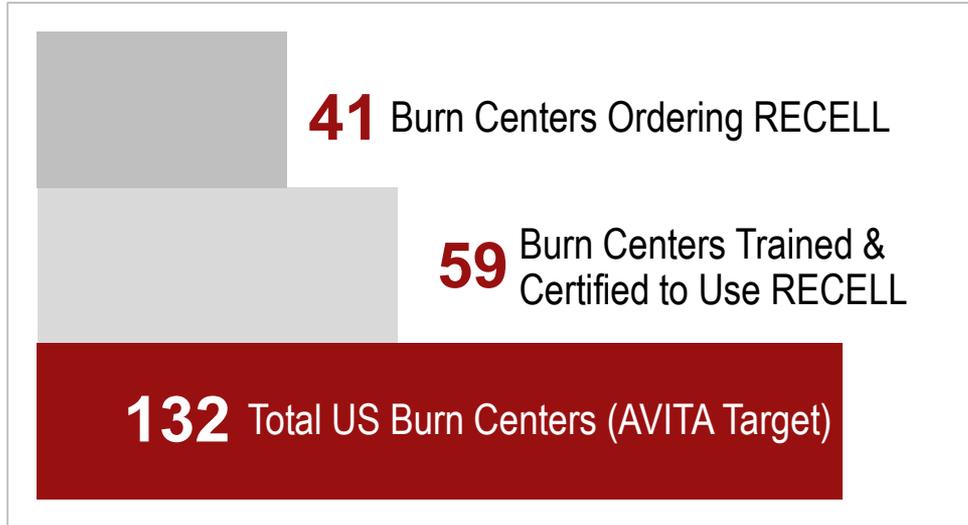
**BURN INJURIES**

RECELL SYSTEM BIBLIOGRAPHY

BURN INJURIES

# Impressive Market Penetration in Only 6 Months

## Account Performance



## HCP Performance



## 100% Success Rate Through Value and Analysis Committees (VAC) To Date

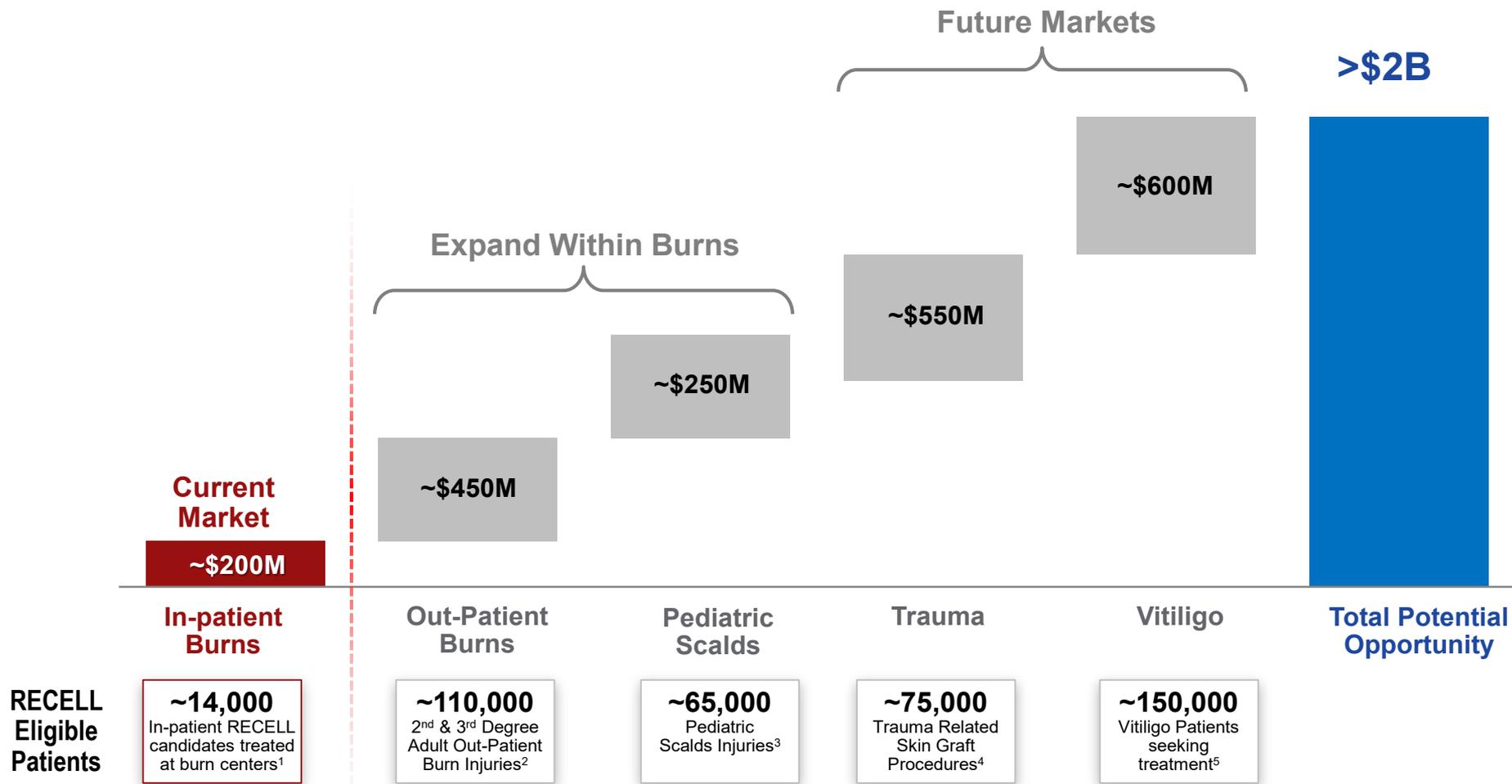
### FDA Approval – September 2018

- ✓ First commercial sale & shipment within 3 weeks of approval
- ✓ Entire U.S. field force in place within eight weeks of approval
- ✓ U.S. National Launch – January 2019

**A\$6.2 million in U.S. Product Sales since approval\***

# Development Pipeline & Growth Potential

# Current RECELL Platform Addresses Opportunities Exceeding \$2 Billion in the United States



1. Internal Research. 2. Calculations: 486,000 burns per year less 53,000 in-patient burns multiplied by adult factor of 70% multiplied by 37% factor to represent 2nd and 3rd degree burns (<http://ameriburn.org/who-we-are/media/burn-incidence-fact-sheet/>; Burn-Related Hospital Inpatient Stays and Emergency Department Visits, 2013 HCUP/AHRQ, American Burn Association. National Burn Repository Report. 2016; Version 12.0 and internal market research). 3. Calculations: 505,278 total skin graft procedures x internal estimates of proportion of pediatric procedures (2017 DRG Claims data). 4. Calculations: 486,000 burns per year x 30% pediatric factor x 45.2% scalds factor (American Burn Association. National Burn Repository Report. 2016); Version 12.0 also <http://ameriburn.org/who-we-are/media/burn-incidence-fact-sheet/>). 5. DRG 2017 Claims data. American Academy of Dermatology [www.aad.org/File%20Library/Top%20navigation/About/Burden%20of%20Skin%20Disease/Vitiligo.pdf](http://www.aad.org/File%20Library/Top%20navigation/About/Burden%20of%20Skin%20Disease/Vitiligo.pdf)

# Outpatient Burns Represent a Sizable Opportunity in the U.S. and an Important Strategic Step



- Approximately 430,000 burns are treated in the U.S. outpatient setting annually<sup>1</sup>
- An estimated 37% of those burns are 2<sup>nd</sup> and 3<sup>rd</sup> degree<sup>2</sup>
- Pursuing more favorable reimbursement in the outpatient setting establishes a general code that can be used for future indications

# Pediatric Patients Are a Unique Subset

- 30% of burns occur between ages 1-15 and ~45% of those injuries are estimated to be associated with scalds<sup>1</sup> (a total estimated population of 65,000)
- Scalds frequently present as “Indeterminate Depth” Burn, often not receiving optimal first line treatment
- Skin defects taking longer than 3 weeks to heal have a much higher rate of hypertrophic scarring<sup>3</sup>
- Conventional autografting is painful and the donor sites and autografted areas can be disfiguring as the child grows

## 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**

1. American Burn Association NBR Advisory Committee, National Burn Repository 2016 Report, [www.ameriburn.org/2016ABAFull.pdf](http://www.ameriburn.org/2016ABAFull.pdf)  
2. Chipp E, Charles L, Thomas C, Whiting K, Moiemien N, Wilson Y. A prospective study of time of healing to healing of hypertrophic scarring in paediatric burns: every day counts. Burns & Trauma 2017; 5:3. Published online 2017 Jan 19.

# Traumatic Wounds Indication Has a High Probability of Success

## Significant Unmet Need

Reduction of donor site morbidity and donor site requirements are top unmet needs<sup>1</sup>

## Strong Interest in RECELL

89% of respondents in surgeon research perceived the RECELL product profile as compelling<sup>2</sup>

## Synergistic with Current Commercial Efforts

70% of accounts currently purchasing RECELL also have trauma centers

## Same Treatment Protocol to Burns

Consistent treatment protocol across acute injuries



## High Probability of Success

RECELL used by multiple international surgeons in Traumatic Wounds with positive outcomes

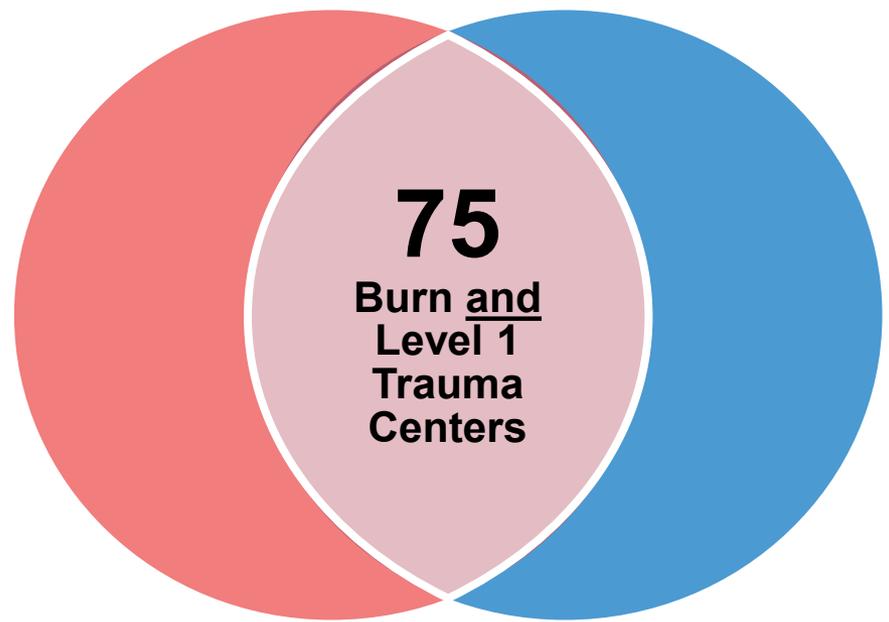
May 2019 AVITA Medical Market Research (N=77)

1. Relative Importance of Product Attributes when Evaluating a New Product Option vs. Conventional Autografting Methods for Soft Tissue Repair  
2. How compelling is Product S vs. conventional autografting methods on a scale of 1 to 9, where 1 is "not compelling at all" and 7 is "extremely compelling"?

# Trauma Would Expand Our Existing Opportunity While Still Maintaining a Narrow Customer Base

Target Expands to ~250 Total Centers

Current AVITA Burn Target: ~132 High Volume Burn Dedicated Centers<sup>2</sup>



Future AVITA Trauma Target: ~200 Level 1 Trauma Centers<sup>1</sup>

> 1/2 of All U.S. Burn Centers are also Level 1 Trauma Centers


 1. 2017 DRG coding reimbursement data – number of sites performing skin grafts for burn injuries.  
 2. American Burn Association  
 3. [https://en.wikipedia.org/wiki/Trauma\\_center](https://en.wikipedia.org/wiki/Trauma_center);  
 4. <https://www.amtrauma.org/page/FindTraumaCenter>; American College of Surgery ([www.facs.org](http://www.facs.org))

# Vitiligo Presents a Clear Opportunity to AVITA

6.5M Prevalence in the U.S.<sup>1</sup>

> 50% of Vitiligo Patients are considered “stable”<sup>2</sup>

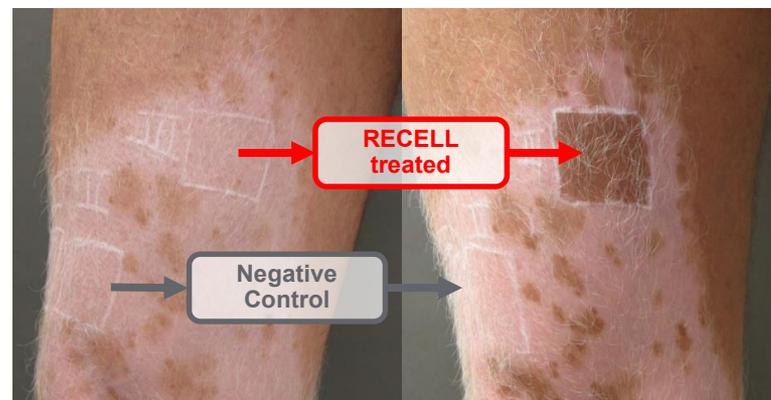
152k Vitiligo Patients Treated Annually in the U.S.<sup>3</sup>

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

Vitiligo Impacts Quality of Life  
Of the patients with vitiligo, 25% had a DLQI >10 which indicates severe QoL reductions, compared with 34% in psoriasis patients.<sup>5</sup>

## Strategic Fit

- ✓ Over 1,000 Vitiligo Patients treated internationally with RECELL
- ✓ 6 RECELL Vitiligo publications with positive outcomes
- ✓ RECELL is suitable for all types of stable vitiligo patients (both segmental and non-segmental)

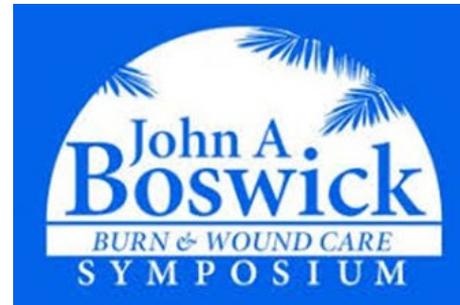


**At 6 Months, RECELL Treated Area Was 100% Repigmented<sup>6</sup>**

1. Advances in Vitiligo: An Update on Medical and Surgical Treatments. A. Dillon, et al. J Clin Aesth Derm. 2017  
 2. KOL input 3. AAD Vitiligo by the Numbers 2017 4. Internal market research 2018 5. Willingness-to-pay and quality of life in patients with vitiligo. Radtke, et al. BJD. 2009. Dermatology life Quality Index (DLQI) is a ten-question questionnaire used to measure the impact of skin disease on the quality of life of an affected person 6. Autologous cell suspension transplantation using a cell extraction device in segmental vitiligo and piebaldism patients: A randomized controlled pilot study. Koman, et al. JAAD 2015.

# Extensive Data & Presentations

- Pivotal studies in 2nd and 3rd degree burns
- Facial burns
- Health economic model demonstrating RECELL cost savings
- RECELL combined with dermal substitutes
- Reduction in hospital stay due to treatment with RECELL
- Necrotizing soft tissue infection reconstruction
- Extensive burn injuries

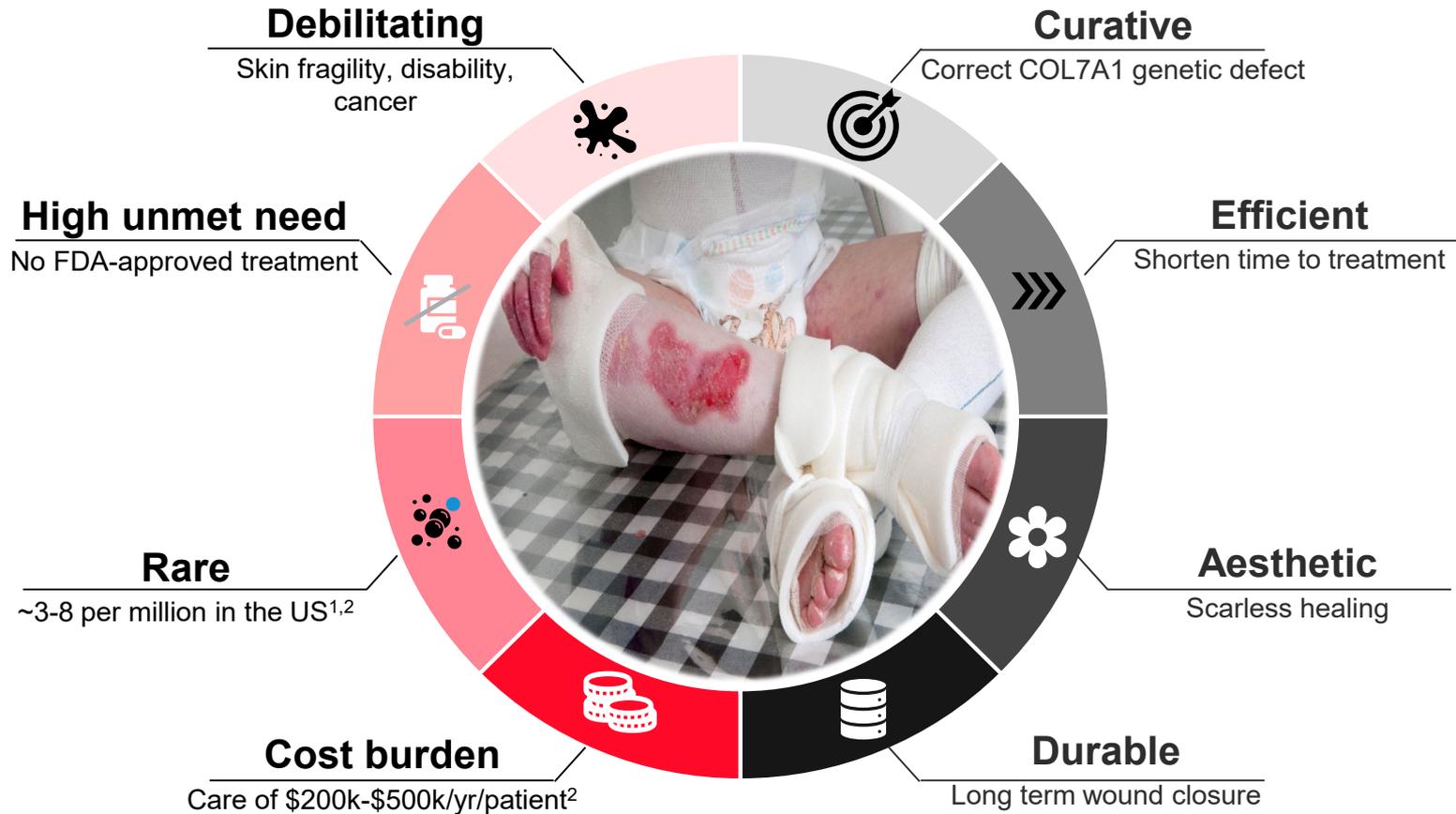


# **Cell-Based Gene Therapy & Aesthetics**

# Exploring Cell-Based Gene Therapy for Dystrophic Epidermolysis Bullosa - A Devastating Orphan Disorder

THE CHALLENGE

THE OPPORTUNITY



**Entering this market with high unmet need could also open doors to 400<sup>3</sup>+ genetically correctable disorders of the skin**

1. Prevalence estimate for DEB from 'Epidemiology of Inherited Epidermolysis Bullosa Based on Incidence and Prevalence Estimates From the National Epidermolysis Bullosa Registry'; Fine J, JAMA Dermatol. 2016;152(11):1231-1238.  
2. Estimates based on dressing & other costs for adults and 10 year olds - 'Management of chronic wounds in patients with dystrophic epidermolysis bullosa: challenges and solutions', Rashidghamat and Mellerio, Chronic Wound Care Mgmt and Res, 2017, Vol :4 Pages 45-54.  
3. Genodermatoses & Rare Skin Disorders Network.

# Early Research Programs Show Market Potential for Application in Rejuvenation

AMERICANS SPEND >\$16.5B IN AESTHETIC PROCEDURES ANNUALLY<sup>1</sup>



**10M**  
injectable cosmetic procedures per year

High patient satisfaction, but does not address skin quality



**Skin Rejuvenation**

>3M aesthetic procedures per year (US)<sup>2</sup> aimed to improve skin tightness, texture & evenness in skin tone

Consumers desire superior results over current offerings with a single treatment



**>500k**  
facial cosmetic surgical procedures per year

Lower volume of procedures due to fear of surgery/general anesthesia

**A 5% market capture of the skin rejuvenation market could represent > \$500MM opportunity**

# **Financial Overview & Milestones**

# Financial Overview

	12 Months Ended June 30, 2019	
(AUD in \$000s)	2019	2018
U.S. sales	6,215	-
Total revenue	17,026	11,372
Cash used in operations	(27,314)	(16,385)
Cash	29,155	14,825

Tickers: ASX:AVH and OTCQX:AVMXY



## BARDA Program

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



# Value-Creating Milestones

- **Received Pre-market Approval (PMA) in September 2018**
- **RECELL is Positioned for Successful Adoption in U.S. Burns**

## Key Accomplishments in 2019

- ✓ U.S. Nationwide Launch in January 2019
- ✓ Market & distribution collaboration in Japan and PMDA submission of RECELL
- ✓ Ten presentations of RECELL results at 2019 ABA meeting
- ✓ Publication of RECELL health economic model
- ✓ U.S. Product Sales of A\$6.2 million through June 30, 2019

## Key Milestones through 2020

- Listing of ADRs on NASDAQ
- RECELL U.S. revenue growth
- First patient enrolled in U.S. Pediatric Scalds Clinical Study
- First patient enrolled in U.S. Soft-Tissue Repair Clinical Study
- PMDA Approval of RECELL in Japan
- First patient enrolled in U.S. Vitiligo Clinical Study



# AVITA Medical: Transforming Lives with Skin Regeneration

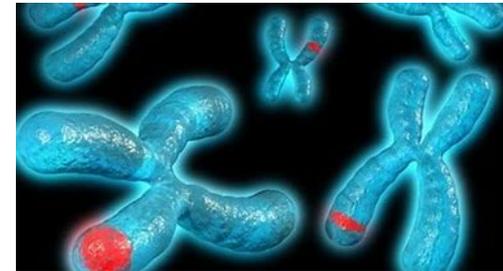
- Revolutionary treatment from a patient's own skin for life-changing outcomes
- FDA-approved RECELL® System for the treatment of acute thermal burns
- Commercial launch exceeding expectations
- Platform expansion into \$2 billion total market opportunity
- Further potential for cell-based gene therapy and aesthetics
- The right team to execute on upcoming milestones



**Life-Changing  
Outcomes**



**Platform Technology**



**Potential in Cell &  
Cell-Based Gene Therapy**

# Appendix

# 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.

# Important Safety Information

- **INDICATIONS FOR USE:** The RECELL<sup>®</sup> Autologous Cell Harvesting Device is indicated for the treatment of acute thermal burn wounds in patients 18 years of age and older. The RECELL<sup>®</sup> device is used by an appropriately-licensed healthcare professional at the patient's point of care to prepare autologous Regenerative Epidermal Suspension (RES<sup>™</sup>) for direct application to acute partial-thickness thermal burn wounds or application in combination with meshed autografting for acute full-thickness thermal burn wounds.
- **CONTRAINDICATIONS:** RECELL<sup>®</sup> is contraindicated for: the treatment of wounds clinically diagnosed as infected or with necrotic tissue, the treatment of patients with a known hypersensitivity to trypsin or compound sodium lactate (Hartmann's) solution, patients having a known hypersensitivity to anesthetics, adrenaline/epinephrine, povidone-iodine, or chlorhexidine solutions.
- **WARNINGS:** Autologous use only. Wound beds treated with a cytotoxic agent (e.g., silver sulfadiazine) should be rinsed prior to application of the cell suspension. RECELL<sup>®</sup> is provided sterile and is intended for single-use. Do not use if packaging is damaged or expired. Choose a donor site with no evidence of cellulitis or infection and process skin immediately. A skin sample should require between 15 and 30 minutes contact with Enzyme. Contact in excess of 60 minutes is not recommended. RECELL<sup>®</sup> Enzyme is animal derived and freedom from infectious agents cannot be guaranteed.
- **PRECAUTIONS:** RECELL<sup>®</sup> is not intended for use without meshed autograft for treatment of full-thickness burn wounds. The safety and effectiveness of RECELL<sup>®</sup> without meshed autograft have not been established for treatment of partial-thickness burn wounds: on the hands and articulating joints, >320 cm<sup>2</sup>, in patients with wounds totaling >20% total body surface area (TBSA). The safety and effectiveness of RECELL<sup>®</sup> with autografting have not been established for treatment of full-thickness burn wounds: on the hands and articulated joints, in patients with wounds totaling >50% TBSA.
- **SPECIAL PATIENT POPULATIONS:** The safety and effectiveness of RECELL<sup>®</sup> have not been established for treatment of acute thermal partial-thickness or full-thickness burn wounds in pediatric patients younger than 18 years of age. For complete Important Safety Information, refer to Instructions For Use at [www.RECELLSYSTEM.COM](http://www.RECELLSYSTEM.COM)

# AVITA Medical Board and Capital Structure

A\$0.425  
Share Price<sup>1</sup>

A\$795 Million  
Market  
Capitalization<sup>1</sup>

A\$29.1 Million  
Cash<sup>1</sup>

A\$0.0  
(Zero) Debt

## DIRECTORS



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



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



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



**Professor Suzanne Crowe**  
Professor Emeritus Burnet Institute



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



**Damien McDonald**  
Chief Executive Officer of LivaNova

## MAJOR SHAREHOLDERS

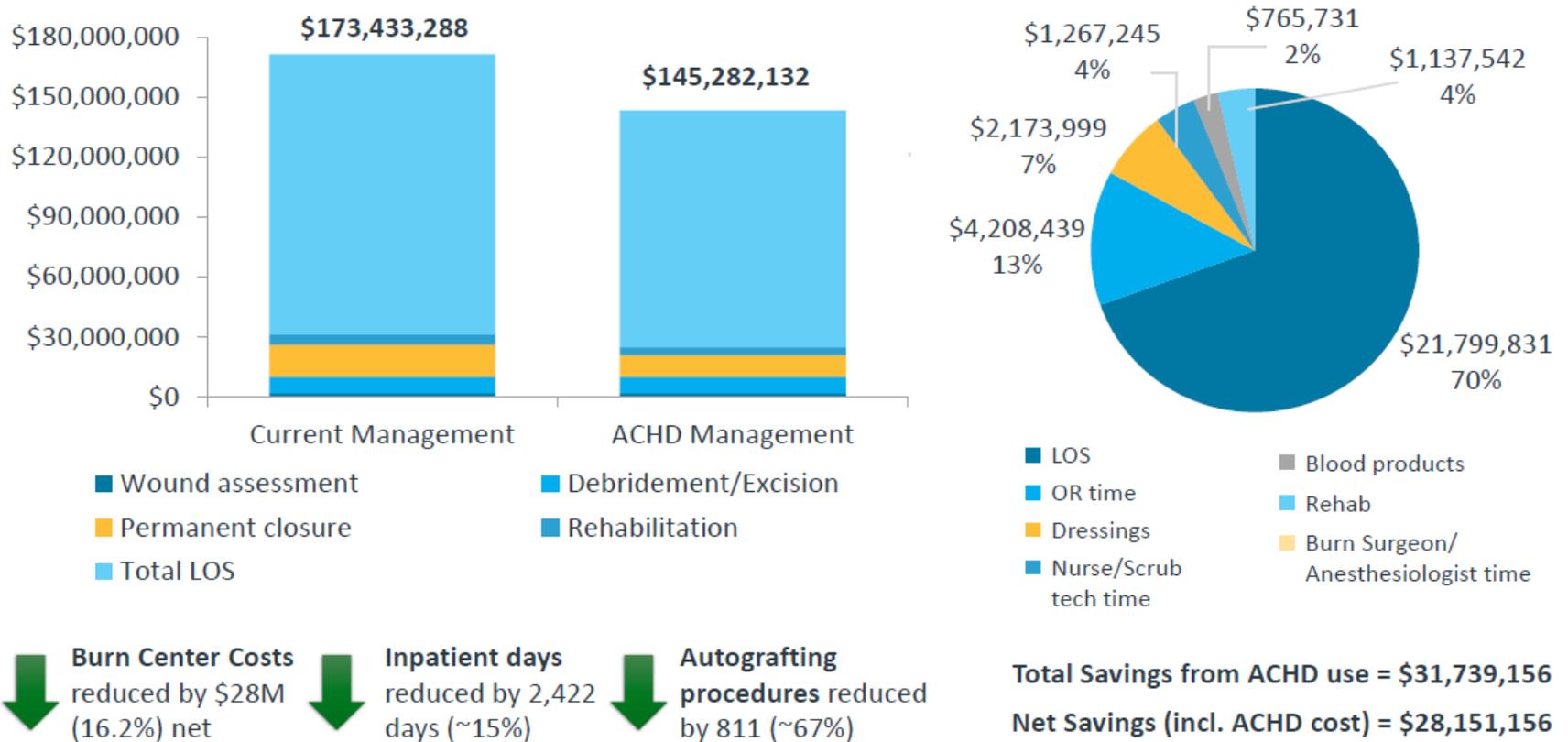
- Redmile Group
- Karst Peak Capital Limited
- BioScience Managers Pty Ltd
- The Capital Group Companies
- Montgomery Investment Management
- Pura Vida Investments
- Blackcrane Capital
- Oberweis Asset Management

## ANALYSTS

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

# Health Economic Model Demonstrates RECELL Cost Savings Presentation at 2019 ABA using data from Arizona Burn Center

**Figure 1: Total Annual Budget Impact (800 Burn Patients)**



**Estimated savings of \$28 million (16%) annually for single burn center**

# Japan Is an Attractive Opportunity for AVITA



- On March 3rd, 2019 AVITA announced a collaboration with COSMOTEC, an M3 Group company to market and distribute the RECELL System for the treatment of burns and other wounds in Japan
- An application for approval to market the RECELL System in Japan was submitted on February 25th, 2019.
- Large patient populations coupled with generally attractive reimbursement coverage makes Japan an attractive market for the RECELL System

## KEY PATIENT POPULATIONS IN JAPAN

### Chronic Wounds

**~183K**

DFU & VLU patients  
non-responsive to  
standard of care<sup>1,2,3</sup>

### Burn

**~6K**

Patients treated  
severe burns / yr<sup>5</sup>

### Vitiligo

**~2 million**

Patients Suffer  
from Vitiligo<sup>4</sup>

1. Pengzi Zhan et al. Global epidemiology of diabetic foot ulceration: a systematic review and meta-analysis†. Annals of medicine 2017
2. Guest 2017 Diabetic foot ulcer management in clinical practice in the UK: costs and outcomes (48% remained unhealed after 12 months. Excl those which were amputated - conservative.)
3. Guest 2017 Venous leg ulcer management in clinical practice in the UK: costs and outcome. (53% healed in 12 months)
4. Furue M, Yamazaki S, Jimbow K, Tsuchida T, Amagai M, Tanaka T et al. Prevalence of dermatological disorders in Japan: a nationwide, cross-sectional, seasonal, multi-center, hospital based study. J Dermatol. 2011 Apr; 38(4):310-20
5. Estimates based on data from 2016 JSBI National Burns Repository and DRG codes