

# AVITA Therapeutics, Inc.

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AVITA’s products are Rx only. Please reference the Instructions for Use ([www.avitamedical.com](http://www.avitamedical.com)) for more information on indications, contraindications, warnings, precautions and adverse events.

In the United States, RECELL is approved for use in patients 18 years and older suffering acute thermal burns. Use of RECELL in other patient populations is either prohibited by United States law or may be made available pursuant to a relevant investigational device exemption granted by the FDA (and likewise limited by United States law to investigational use only).

# AVITA Therapeutics: Spray-On Skin™

## Spray-On Skin Enables Skin Regeneration

### RECELL harnesses the skin's own regeneration capabilities

- Standard of care enabling technology
  - **Donor skin-sparing + activated mechanism + point-of-care**
- Deep scientific and clinical pedigree
  - **2 randomized controlled trials + and 1<sup>st</sup> PMA in burns in > 20yrs**
  - 10,000+ patients, 180+ publications and presentations
  - U.S. FDA approved for acute burns\*
- **Published health economic model demonstrating hospital cost savings**
- **Multi-billion serviceable market opportunity**
  - Platform technology with numerous adjacent applications
- **PMA label expansion underway with three (3) pivotal studies**

## SKIN INJURY

- **Burns\***
- Scalds
- Pediatric
- Soft Tissue
- Traumatic Wounds



## SKIN FLAWS / DEFECTS

### Cell / Gene Therapy



• Vitiligo

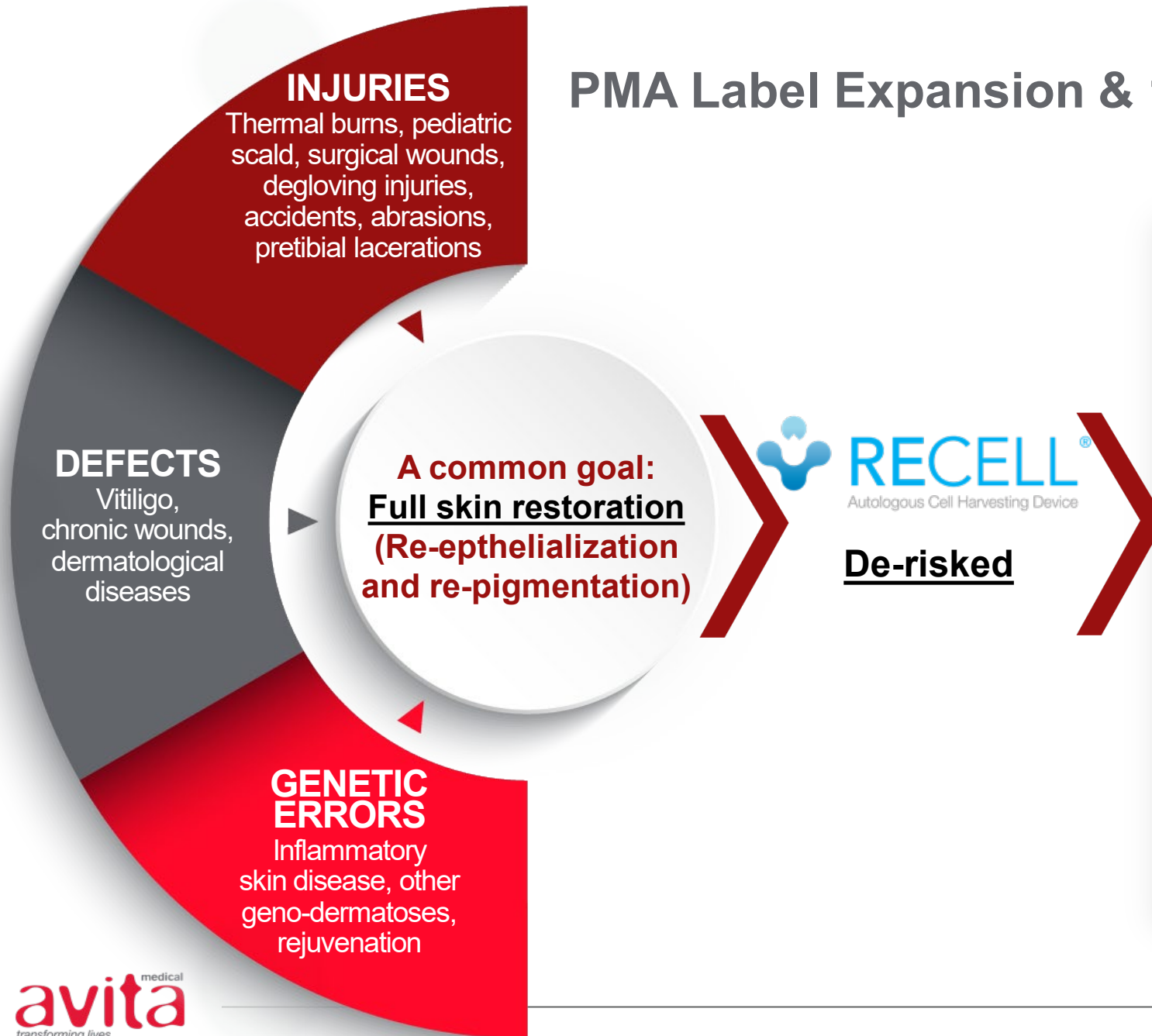


• EB



• Rejuvenation

# PMA Label Expansion & 10,000 Patients Treated Globally



Patients (In studies)		Publications & Presentations
1,281	Burns	121
<u>1st PMA approved burn product in &gt;20 years*</u>		
163	Non-Healing Wounds (DFU, VLU)	10
481	Defects / Vitiligo	39
108	Acute Wounds	15

**>10,000 Patients Treated Globally**

# Challenges with Split-Thickness Skin Graft Outcomes

**Scarring, functional impairment, pigmentation, infection ...**

***Donor Site Scarring / Failure to Heal***



***Pigmentation and Discoloration***



***Donor Site Infection Risk***



***Scarring, Atrophy, Contracture***





# RECELL Spray-On Skin™ Treats 80cm<sup>2</sup> of Skin from a 1cm<sup>2</sup> Biopsy



**AUTOLOGOUS**

Cell Harvesting Device that delivers Spray-On Skin™ Cells within 30 minutes at the point of care

**ACTIVATED**

Fresh (non-cultured cells) with the "free edge healing cascade"

**DONOR SPARING**

Treatment area = 80x donor area  
(credit card size skin sample can treat an entire adult back)

**COMPLETE**

Full range of skin cell types with re-pigmentation

**SAFE & EFFECTIVE**

2x PMA randomized controlled trials  
1st PMA burn product approval ~ 20 yrs  
10K+ clinical uses & 150+ reviews

**PUBLISHED HEALTH ECONOMIC DATA**

# RECELL Delivers Life-Changing Outcomes

## Case Series Presented at 50th Annual ABA Meeting (2018)



Treatment Day



Day 7



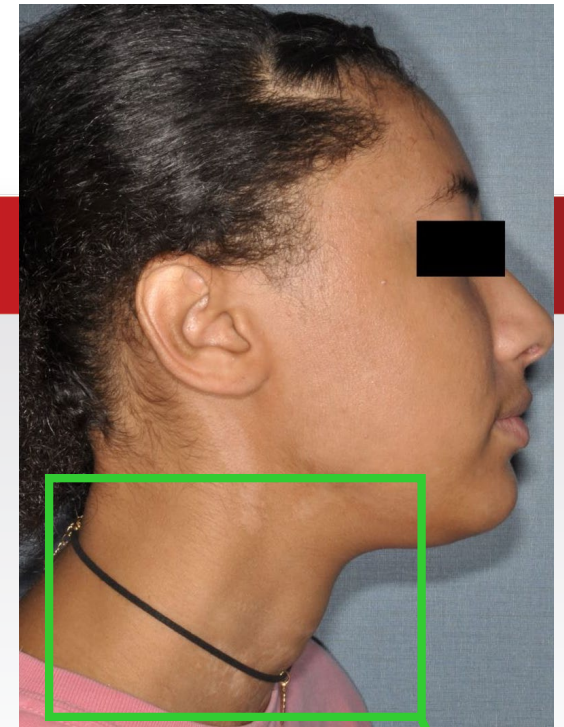
Day 21



3 Months



1 Year



1 Year

- Compassionate Use case
- 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

Skin +  
**Color**  
Restoration

RECELL's treatment area is **80 times larger** than the donor site

# Promote Healing in Challenging Areas

40-year-old male | <10% BSA | DPT Face | RECELL<sup>®</sup> alone

Treatment Day



*After 24 days of no progressive healing with allograft, Spray-On Skin<sup>™</sup> Cells were applied*

1 Week



*At 1 week, 95% re-epithelialization occurred*

5 Months



*At 5 months, minimal scarring and consistent pigmentation were seen despite an anatomically challenging area*



# Skin Injury

# 1st Premarket Approval Treatment in Burns in 20 Years

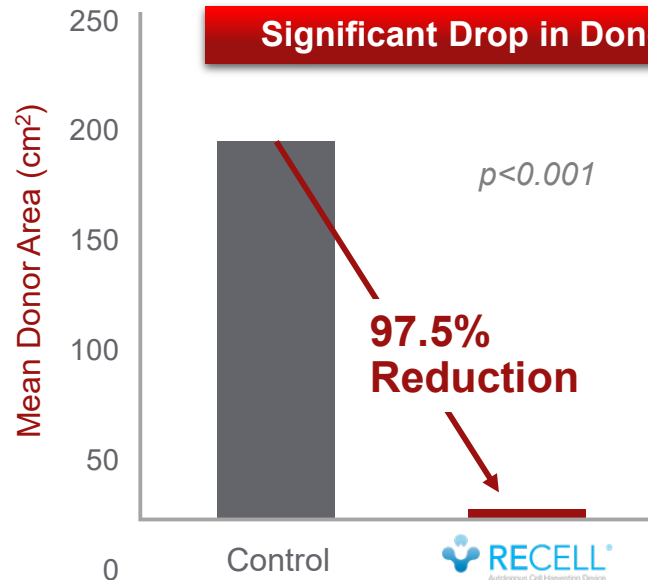
Dual multi-center, randomized, controlled premarket approval studies

## Pivotal Trial #1 (101 Patients) RECELL (alone) versus SoC (STSG) in Second-Degree Burns

Published in JBCR and Presented at ABA



### Significant Drop in Donor Skin Requirement



### Decrease in donor site pain and scarring

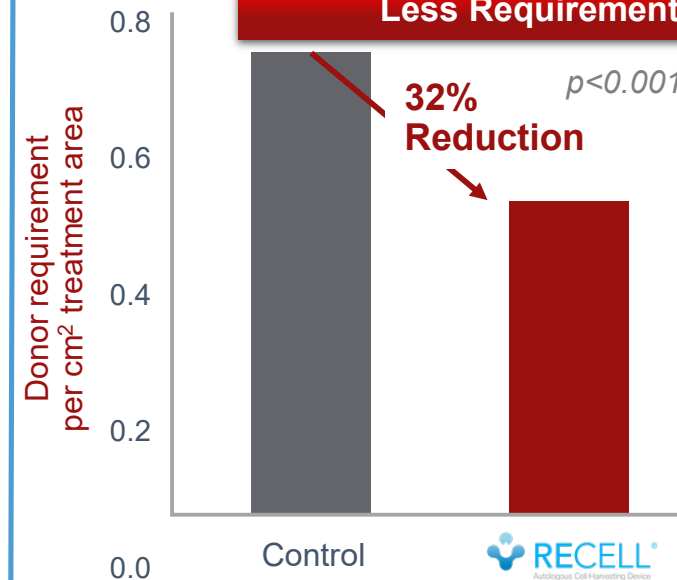
- Significantly less donor site pain ( $p \leq 0.0025$ )
- Significantly better donor site appearance ( $p \leq 0.0025$ )
- Significantly reduced donor site scarring ( $p \leq 0.0025$ )
- Significantly greater incidence of donor-site healing at two weeks ( $p < 0.001$ )

## Pivotal Trial #2 (31 Patients) RECELL (with widely expanded graft) versus STSG in Third-Degree Burns

Published in Burns and Presented at ABA



### Less Requirement for Donor Skin



### Robust outcomes despite less donor skin

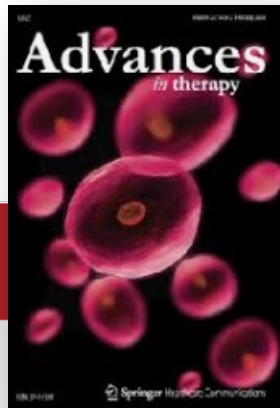
- RECELL System achieved definitive closure comparable to Standard of Care with significantly less donor skin
- At eight weeks post treatment, 92% of the burn sites treated with the RECELL System achieved complete healing versus 85% for the sites treated with the standard of care

Comparable healing and long-term outcomes for burn sites with significantly less donor skin required

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

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

# Published Health Economic Savings – Patient & Hospital Benefits

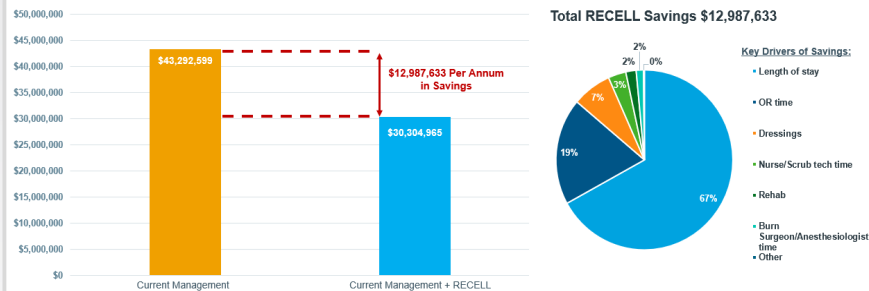


## RECELL Reduces Overall Hospital Costs

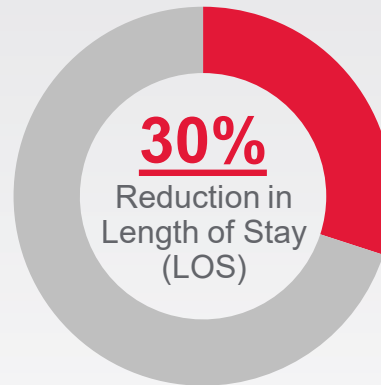
### Transforming Care

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

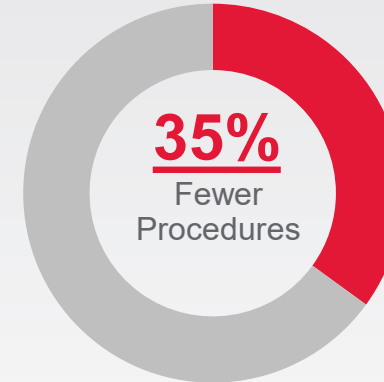
Annual budget impact of current management versus RECELL for a burn center with 200 patients



**Conclusion:** Considering the expected mix of patients entering a typical burn center each year (as informed by NBR data), use of RECELL is expected to reduce costs per treated patient and overall.



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

**RECELL saves money in all in-patient scenarios where TBSA burn is > 10%**

# Soft Tissue Grafting is 5 Times Larger Than Burns



Road rash



Traumatic Wounds



Iatrogenic  
(Surgically generated)



Skin cancer



Abrasions

## Significant Unmet Need

**Reduction of donor site morbidity** and donor site requirements are top unmet needs

## Strong Interest In RECELL

**89%** of respondents in surgeon research perceived the RECELL product profile as compelling

## 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



## Strong Success Indicators

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

**U.S. Pivotal Study (N=65) enrolling now**



# Pediatric Patients

## A unique subset

- **30%** of burns occur between 1 and 15 years of age **~45%** Estimated to be associated with scalds
- Scalds frequently present as “indeterminate depth” burns
- Skin defects healing > 3 weeks have a much higher rate of hypertrophic scarring
- Both painful donor sites and autografted areas can be disfiguring as the child grows

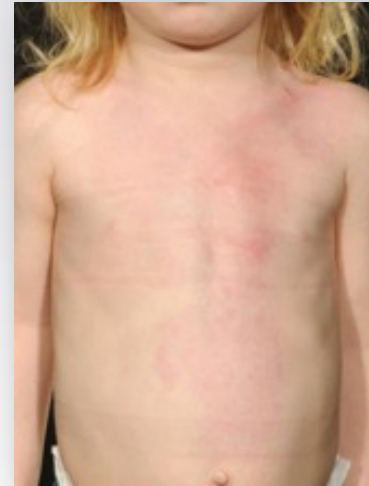
### Case Study: 2-year old with scald treated with RECELL



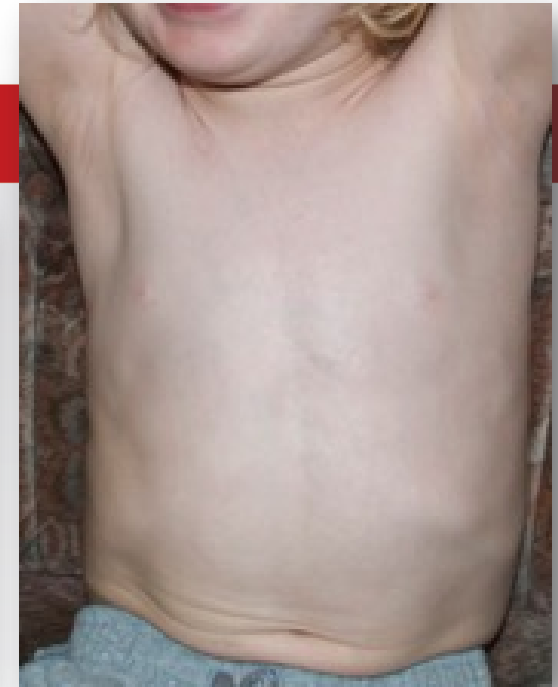
*Before Treatment*



*3 Weeks  
post RECELL treatment*

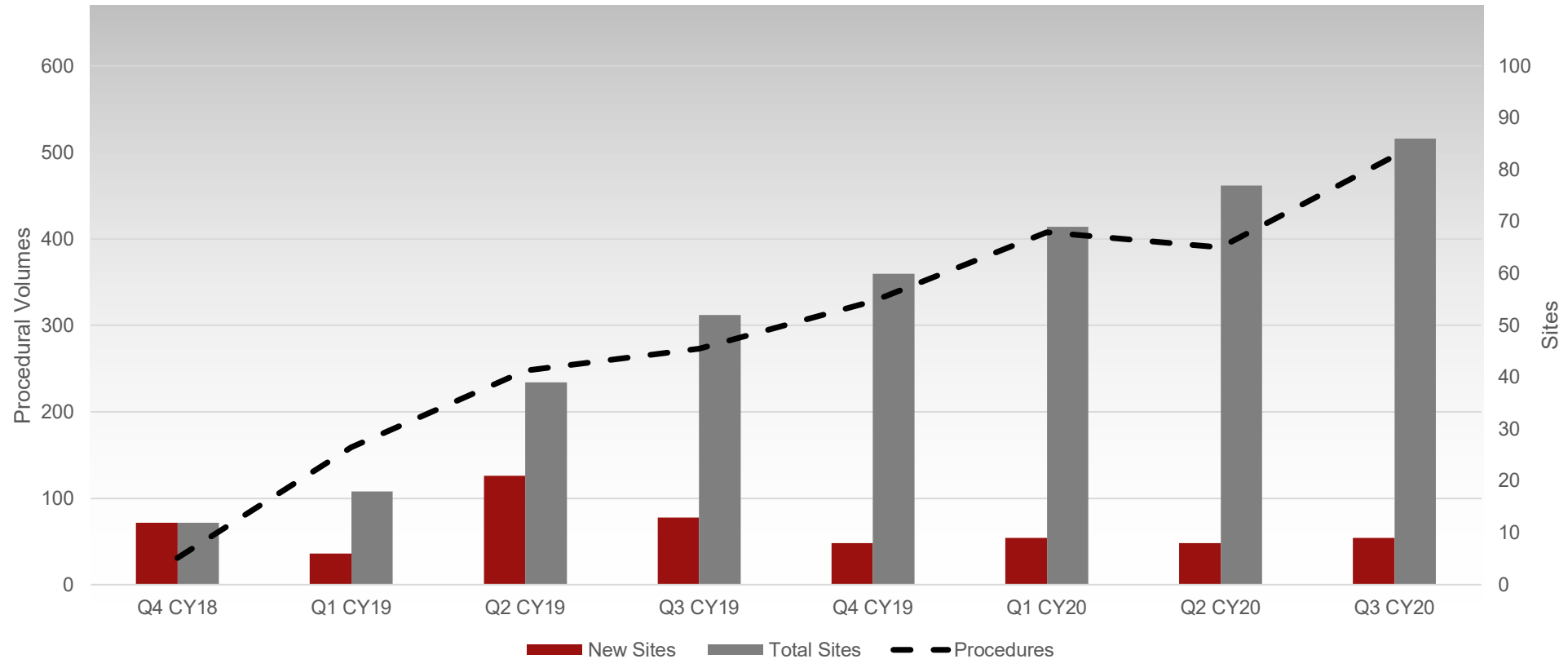


*10 Weeks  
post RECELL treatment*



*10 Months  
post RECELL treatment*

# Strong Adoption of the RECELL System\*



**RECELL System procedural growth since PMA**

# Skin Flaws / Defects

# 1,000 Vitiligo Patients & 8 Peer-Reviewed Publications Showing Benefits

## SIGNIFICANT UNMET NEED

Up to 2% of the population affected  
(~6.5M in the US)\*

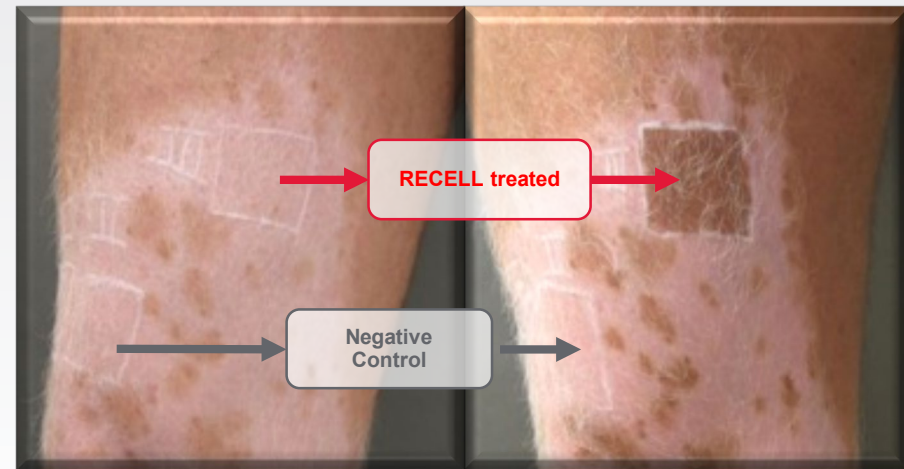
No FDA-approved medical treatments; extremely  
low patient & physician  
satisfaction with existing products

Vitiligo impacts quality of life (QoL)  
- 25% had severe QoL reductions,  
comparable to psoriasis

Growing reimbursement  
(\$24,000 – \$42,000 / year for phototherapy)\*

## RECELL VALUE PROPOSITION

- Over 1,000 vitiligo patients treated internationally with RECELL
- 8 publications of RECELL in vitiligo with positive outcomes
- Potentially indicated for stable vitiligo of all types (segmental & non-segmental vitiligo)
  - JAK inhibitors could significantly increase the number of patients with stable disease



**At 6 Months, RECELL-treated area was 100% re-pigmented**

**U.S. Pivotal Study enrolling; last patient (N=84) expected in H2 CY 2021**



# Cell / Gene Therapy

# Exploring Cell-Based Gene Therapy for Epidermolysis Bullosa (EB)

## The Challenge

### Debilitating

Skin fragility, disability, cancer

### High unmet need

No FDA-approved treatment

### Rare

~3-8 per million in the US

### Cost burden

Care of \$200k-\$500k/yr/patient\*



## The Opportunity

### Curative

Correct underlying genetic defect

### Efficient

Simplify manufacturing,  
shorten time to treatment

### Aesthetic

Scarless healing

### Durable

Long-term wound closure

\* Estimates and data based on information on file at AVITA Therapeutics, Inc.

**Proof-of-concept in EB could open doors to other genetically correctable skin disorders**

# Rejuvenation

## Sponsored Research to Investigate Telomerase in Reverse Aging of Skin Cells



- US: **>\$16.5B** in aesthetic procedures per year\*
- **>3M** aesthetic procedures per year (US) aimed to improve skin tightness, texture & evenness in skin tone\*
- Telomeres act as molecular clocks for cells and their length decreases over time with age
- Telomerase (hTERT) enzyme repairs telomeres
- Avita now has access to RNA technology to deliver telomerase (hTERT RNA) to aged skin cells
- Sponsored Research Agreement with option for an exclusive license to Houston Methodist Research Institute (HMRI) patented technology
- HMRI has already demonstrated reversal of aging and return of functionality in cells of progeria patients - a human model of accelerated aging

\* Estimates and data based on information on file at Avita Medical Limited

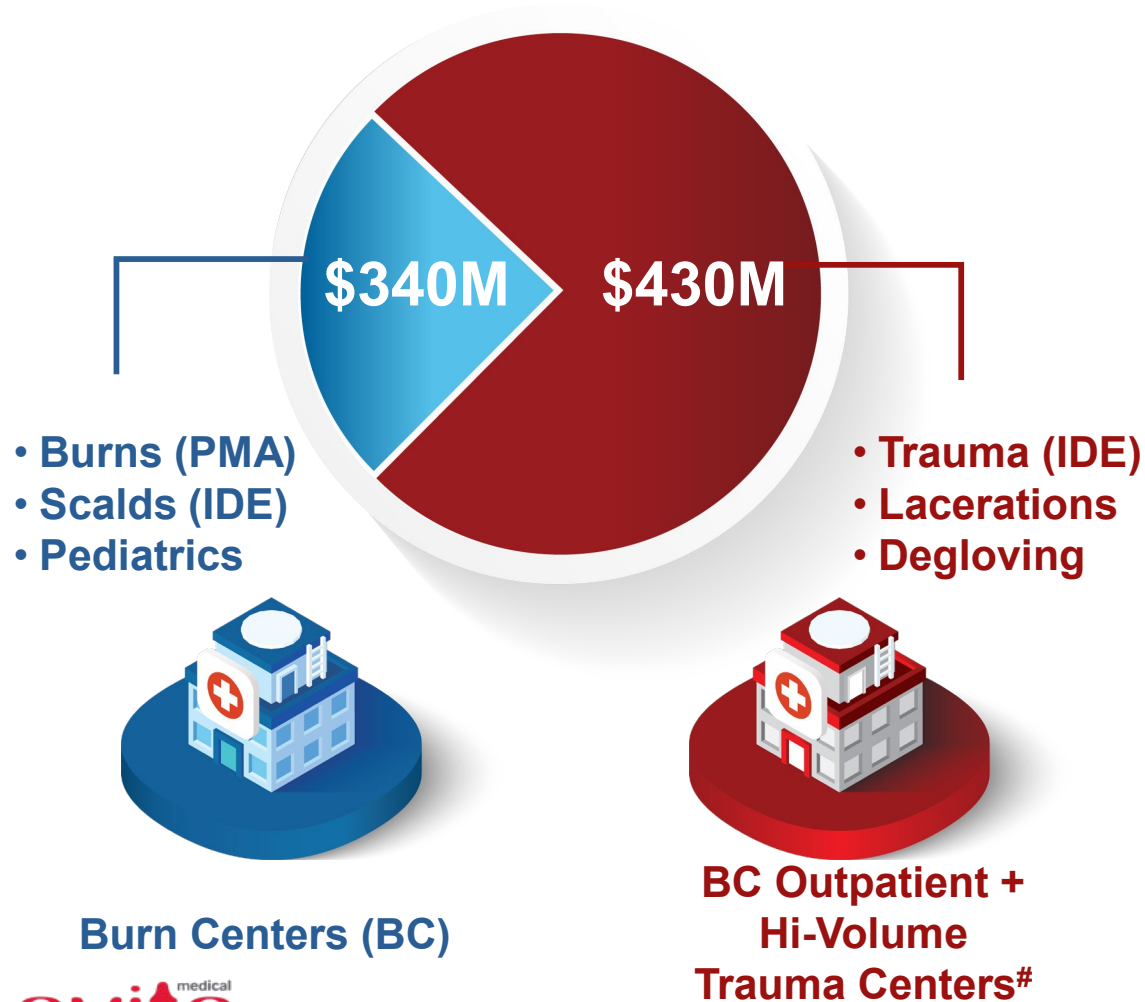
**Rejuvenation – Early R&D; represents a \$multi-B market opportunity**

# Corporate



# Leveraging Premarket Approval\* in a Multi-Billion Serviceable Market

## SKIN INJURY



## SKIN FLAWS / DEFECTS

**\$750M  
Vitiligo  
(IDE)**

**Cell & Gene  
Therapy**

**3 IDE registration studies in pediatric scalds, soft tissue reconstruction and vitiligo**

# Intellectual Property

## ROBUST PROTECTION...

### Cell Suspension Preparation Technique / Device

- Commercial RECELL device, composition of matter, and associated methods of use

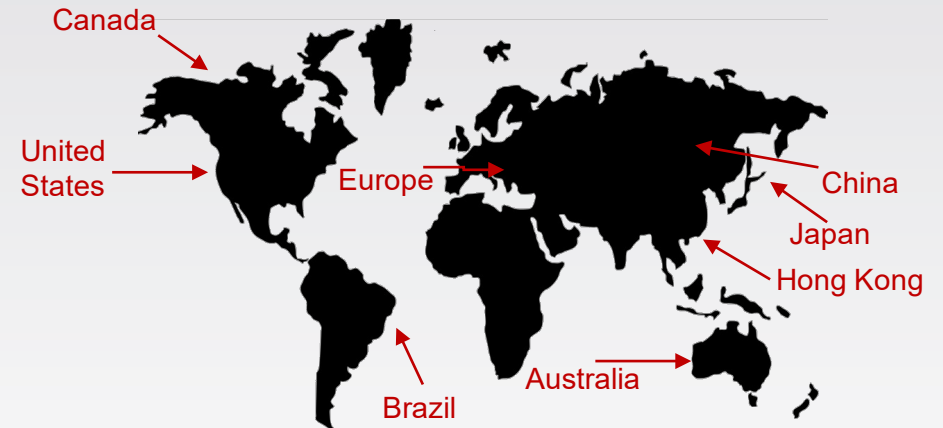
### Cell Suspension And Use Thereof

- Method of preparing cell suspension with exogenous agent to promote wound healing

### Method And Composition for Epithelial Regeneration

- Automated apparatus, next generation sprayer and method of production (pending)

## ...ACROSS GEOGRAPHIES



A global total of 26 issued patents,  
10 pending patent applications

**Patent and patent applications expiration from 2022 (2024 with Hatch-Waxman) to 2034**

# Thank you for your kind attention