

# AVITA Medical

Dr. Mike Perry, CEO

February 2020



**avita**<sup>medical</sup>  
*transforming lives*

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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 Medical: Transformation Through Regeneration

## 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 RCTs and 1<sup>st</sup> PMA in burns in > 20 years**
  - 8,000+ patients, 50+ publications
  - U.S. FDA approved for acute burns\*
- **Published health economic model demonstrating hospital cost savings**
- **\$2Bn + market opportunity**
  - Platform technology with numerous adjacent applications

## INJURIES



- **In-patient Burns**
- Out-patient Burns
- Pediatric Scalds



- Soft Tissue Reconstruction
- Traumatic Wounds

## DEFECTS



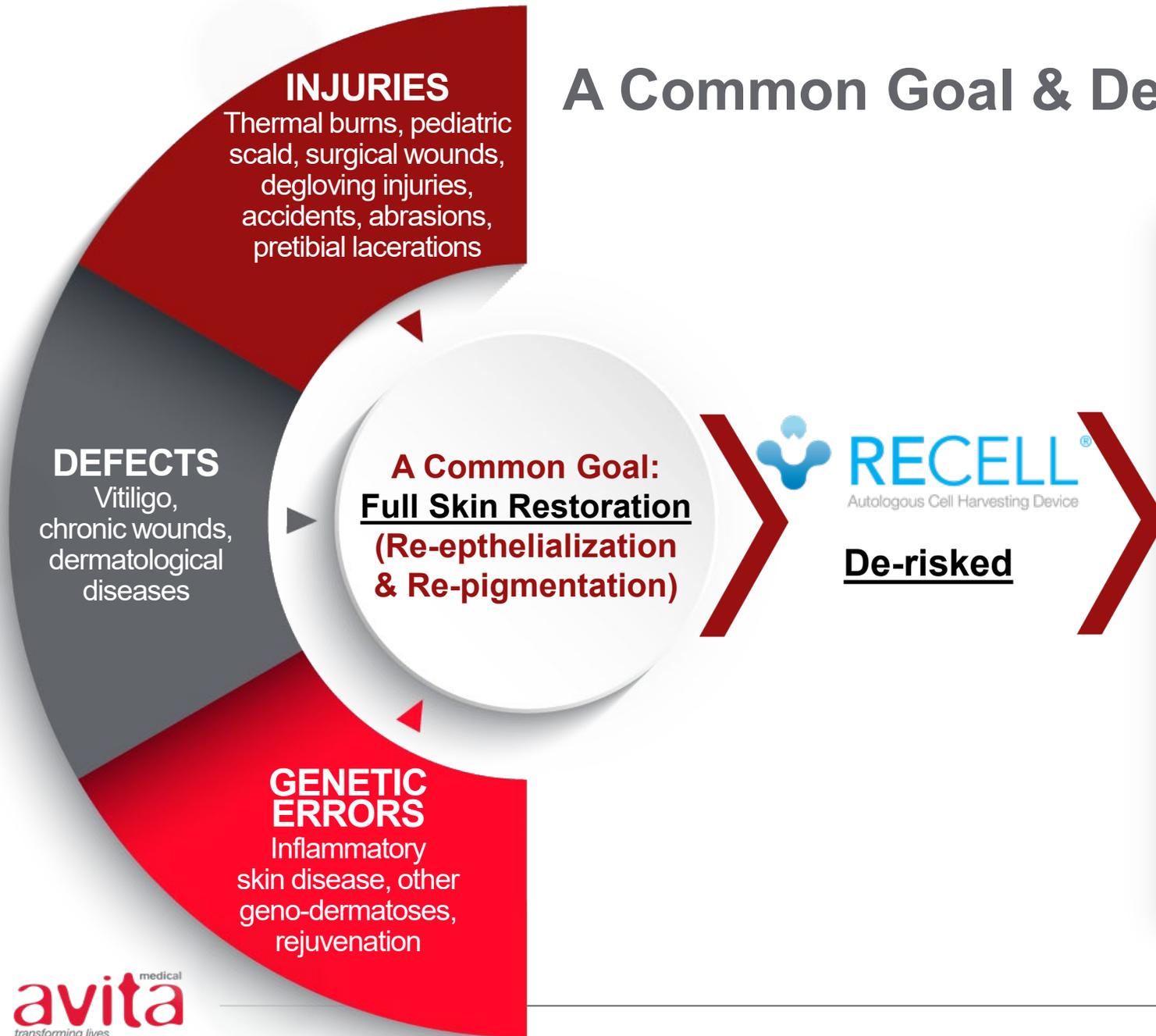
- Vitiligo
- Chronic Wounds (DFU + VLU)
- Dermatological Diseases

## GENETIC ERRORS



- University of Colorado Anschutz Medical Campus
  - Epidermolysis Bullosa
- New Sponsored Research
  - Rejuvenation

# A Common Goal & Deep Clinical Experience



| Patients (In studies)  |                               | Peer Reviewed Publications |
|--|-------------------------------|----------------------------|
| 858  | Burns                         | 75                         |
| <b><u>1st PMA approved burn product in &gt;20 years*</u></b> |                               |                            |
| 77   | Non-Healing Wounds (DFU, VLU) | 6                          |
| 120  | Defects / Vitiligo            | 14                         |
| 68   | Acute Wounds (Non-Thermal)    | 9                          |

**>8,000 Patients Treated Globally**

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# Skin Grafting is Unchanged for More Than 50 Years

## Split-Thickness Skin Grafts (STSG) are “Medieval”



*Dermatome skin harvesting from new donor site*



*New (second) donor wound created via skin harvesting*

### KEY SHORTCOMINGS OF STSG

- Large donor area required
- Pain associated with donor site
- Prolonged hospitalization + high costs
- Multiple complex, costly, surgical procedures
- Risk of infection
- Scarring

**STSG requires HCPs to create or “duplicate” the wound**

# 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*



Normal skin restoration (re-epithelialize and re-pigmentation) is the ultimate goal

# The RECELL Solution ... Spray-On Skin™



**AUTOLOGOUS**

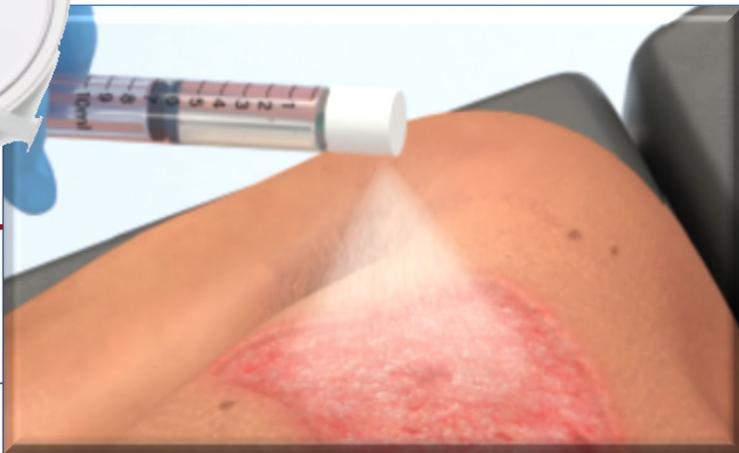
Cell Harvesting Device that delivers Spray-On Skin™ Cells within 30 minutes at the point of care

**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)



# The RECELL Solution ... Spray-On Skin™ (Continued)

 **RECELL**®  
Autologous Cell Harvesting Device

**COMPLETE**

Full range of skin cell types  
with re-pigmentation

**ESTABLISHED SAFETY  
& EFFECTIVENESS**

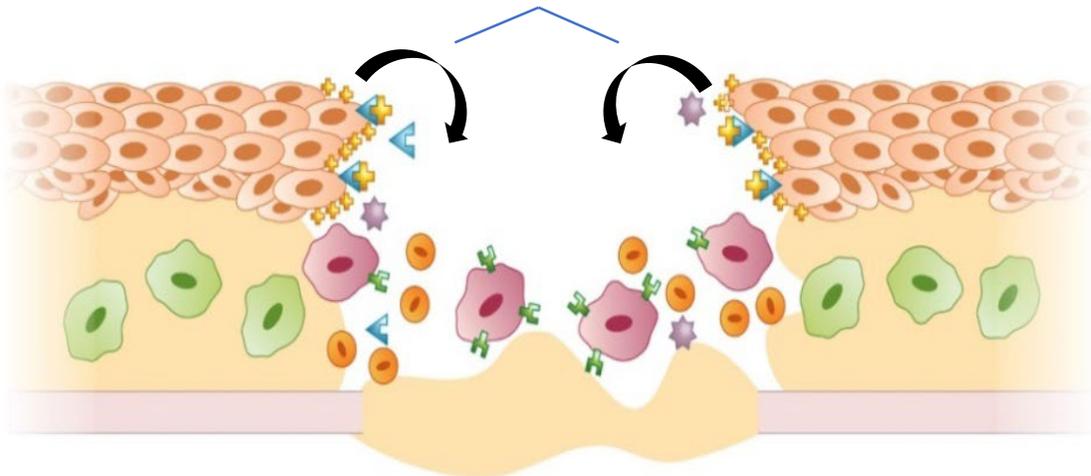
2x PMA randomized controlled trials  
1<sup>st</sup> PMA burn product approval in > 20 yrs  
8K+ clinical uses & 50+ Publications

**ROBUST HEALTH ECONOMIC DATA**  
Validated, published health economic data

# RECELL's "Free Edge" Advantage

## Healing Process without RECELL

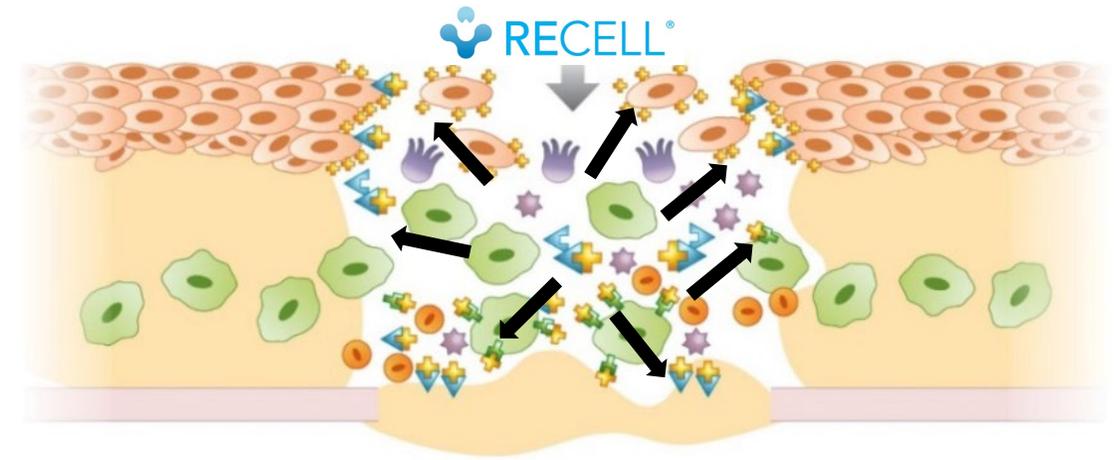
Free edge limits signaling to wound boundary (i.e. outside → in)



- The wound boundary acts as a "free edge" between injured and uninjured cells
- The absence of neighbor cells at the free edge triggers a healing signal which promotes cell proliferation and migration (myofibroblasts)
- New tissue growth is localized to the wound boundary (free edge)

## Healing Process with RECELL

Spray-On Skin™ signals from within the wound (i.e. inside → out)



- RECELL uses the patient's skin to create a cell suspension of disaggregated (autologous) cells that are sprayed across the entire wound
- RECELL creates a broader free edge effect with more numerous signaling cells thus unleashing the free edge effect across the wound surface area
- New tissue proliferates across the entire surface area of the wound bed, now unrestricted to the free edges of the wound



# RECELL Delivers Life-Changing Outcomes

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



Treatment Day



Day 7



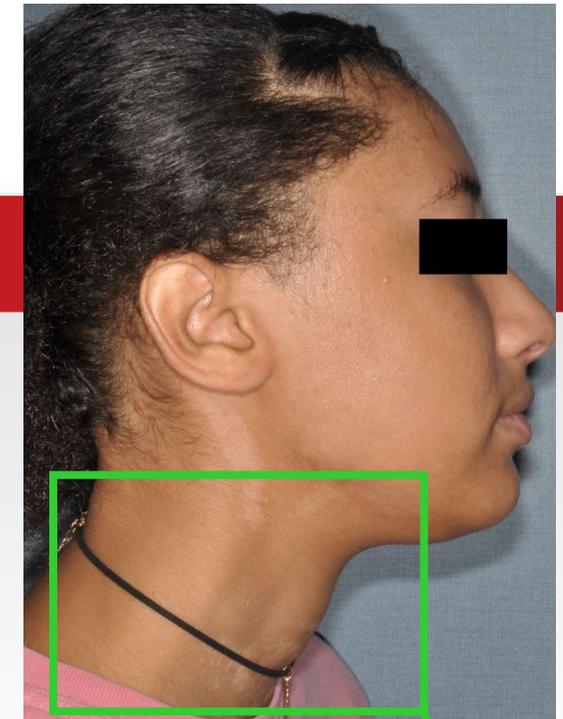
Day 21



3 Months



1 Year

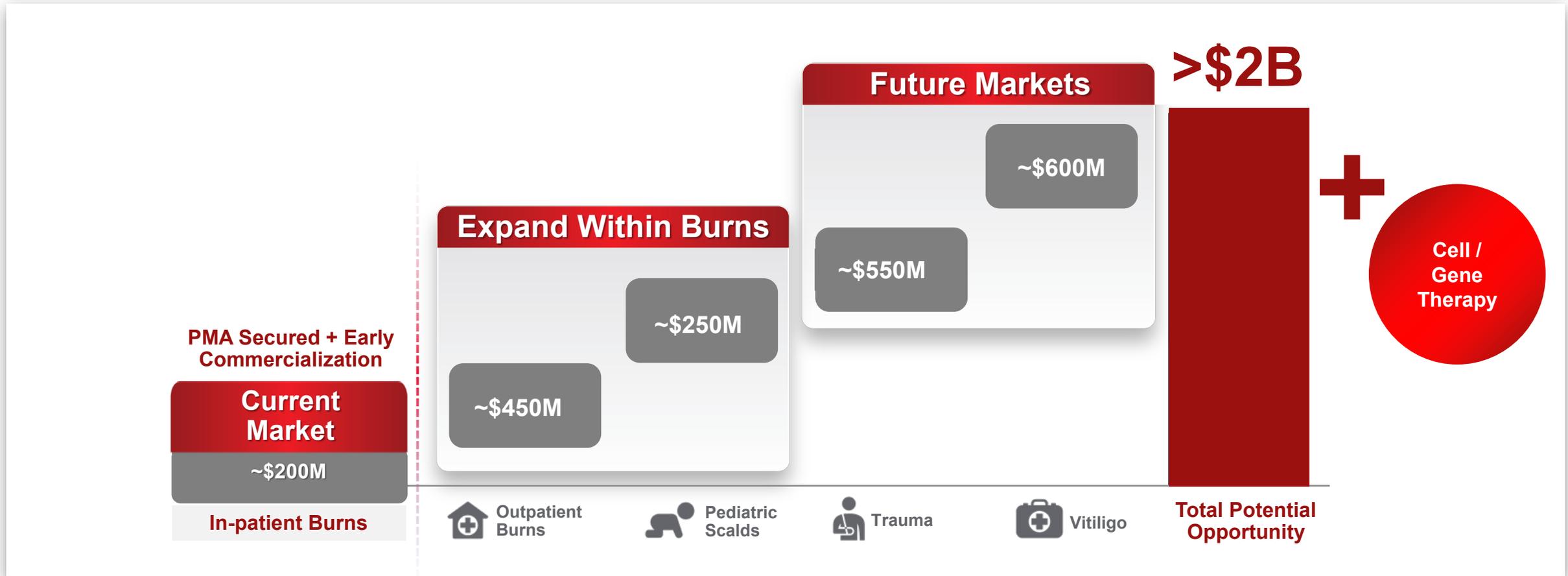


1 Year

- 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

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

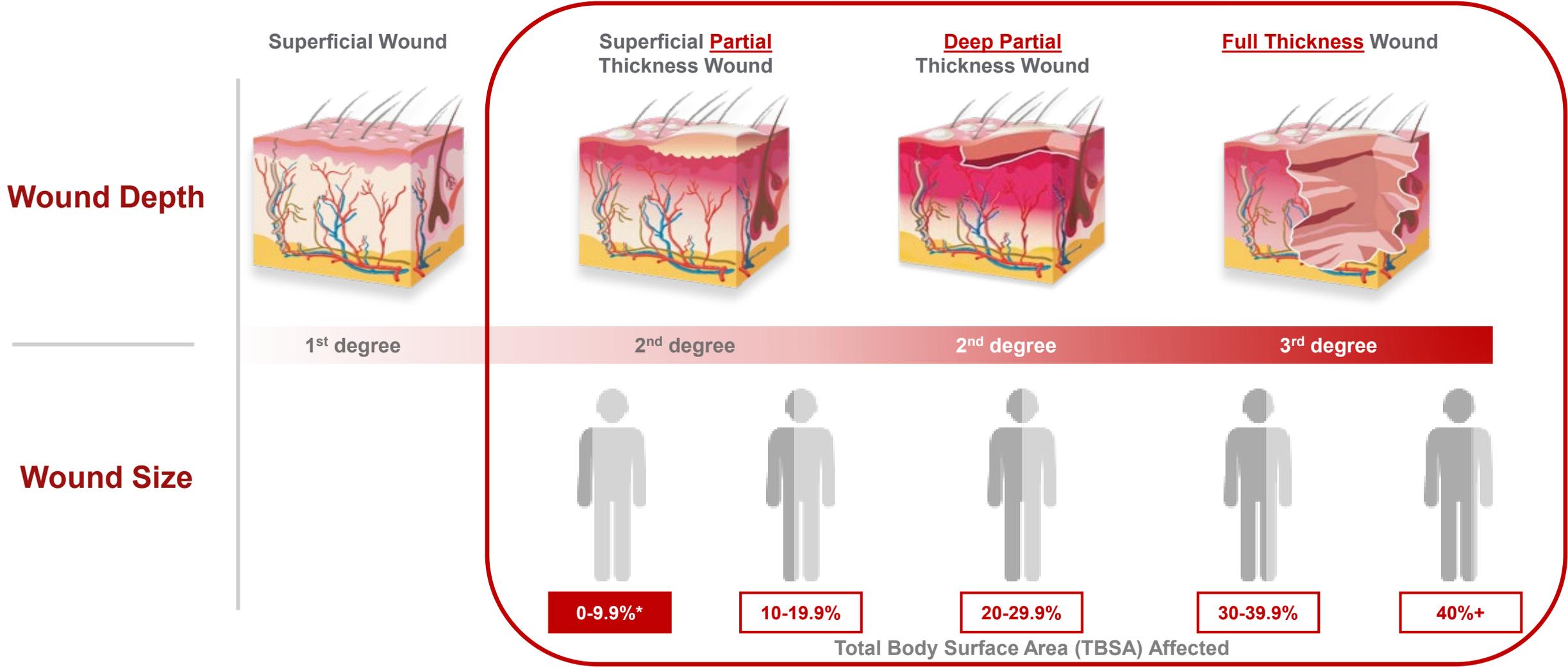
# \$2 Billion Opportunity\* and Existing U.S. Premarket Approval



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

# Burns Franchise

# Burn Injury Framework



# Burn Market Segmentation

**~14,000**  
RECELL Eligible Patients

**Current Burn Market**  
**\$200M**

**In-patient Burns:**  
FDA PMA secured /  
Commercializing



**~110,000**  
2<sup>nd</sup>/3<sup>rd</sup> Degree  
Adult Burn Injuries

**Future Burn Markets**  
**\$450M**

**Outpatient Burns:**  
Enhance Reimbursement  
& Launch



**~65,000**  
Pediatric Scalds Injuries

**\$250M**

**Pediatric Scalds:**  
PMA Studies (2)  
start in 2020

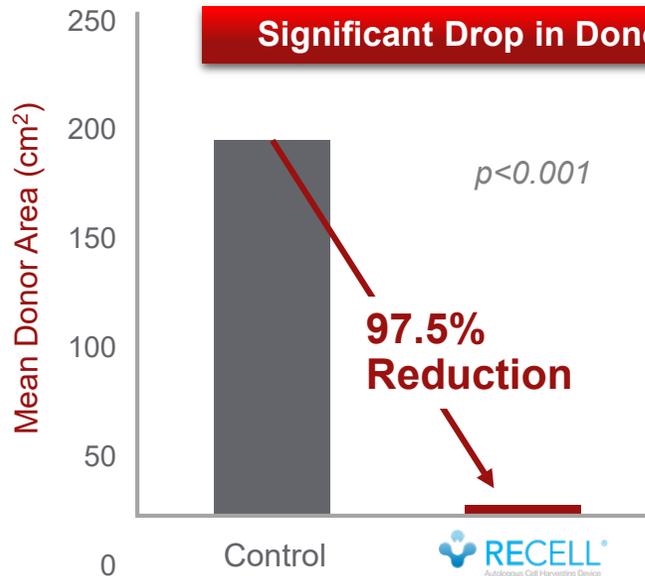


# 1st Premarket Approval Treatment in Burns in 20 Years

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



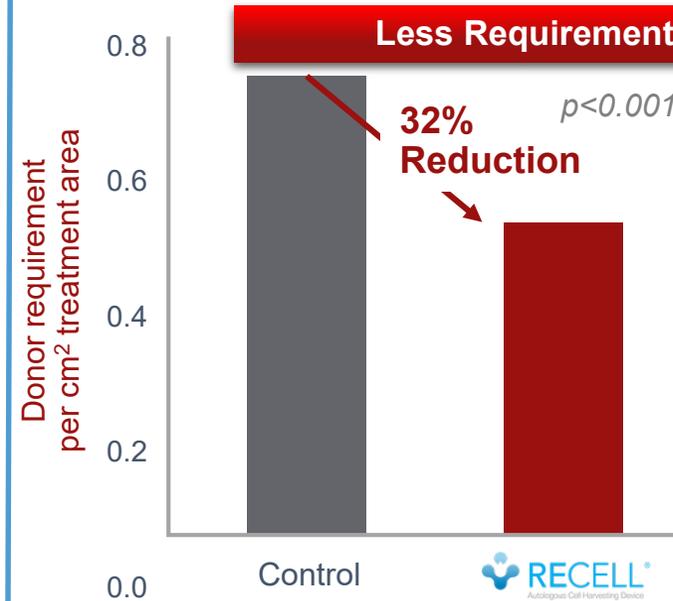
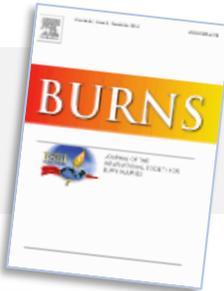
**Significant Drop in Donor Skin Requirement**

### 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

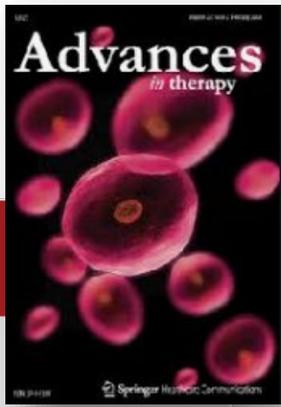
- RECELL System achieved definitive closure comparable to Standard of Care with significantly less donor skin
- At eight weeks post treatment, 92% of the burn sites treated with the RECELL System achieved complete healing versus 85% for the sites treated with the standard of care

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

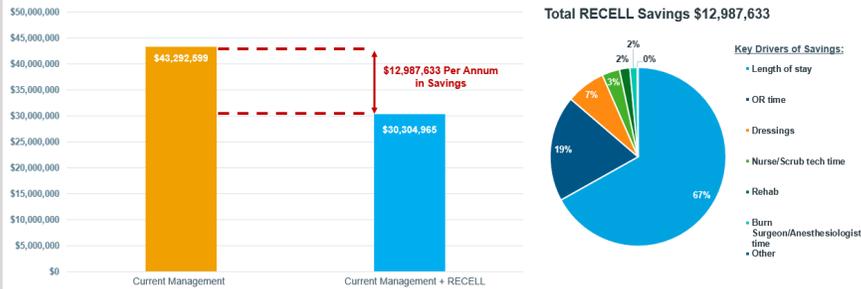


## RECELL Reduces Overall Hospital Costs

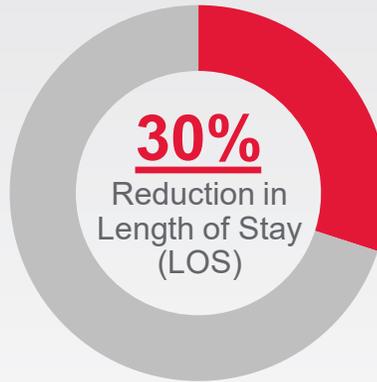
### Transforming Care

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

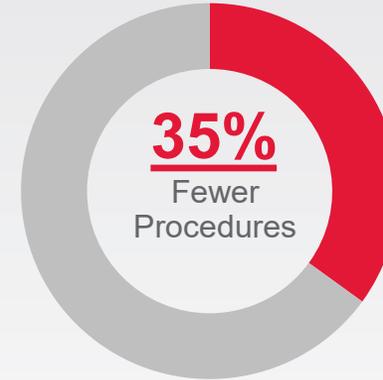
Annual budget impact of current management versus RECELL for a burn center with 200 patients



**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



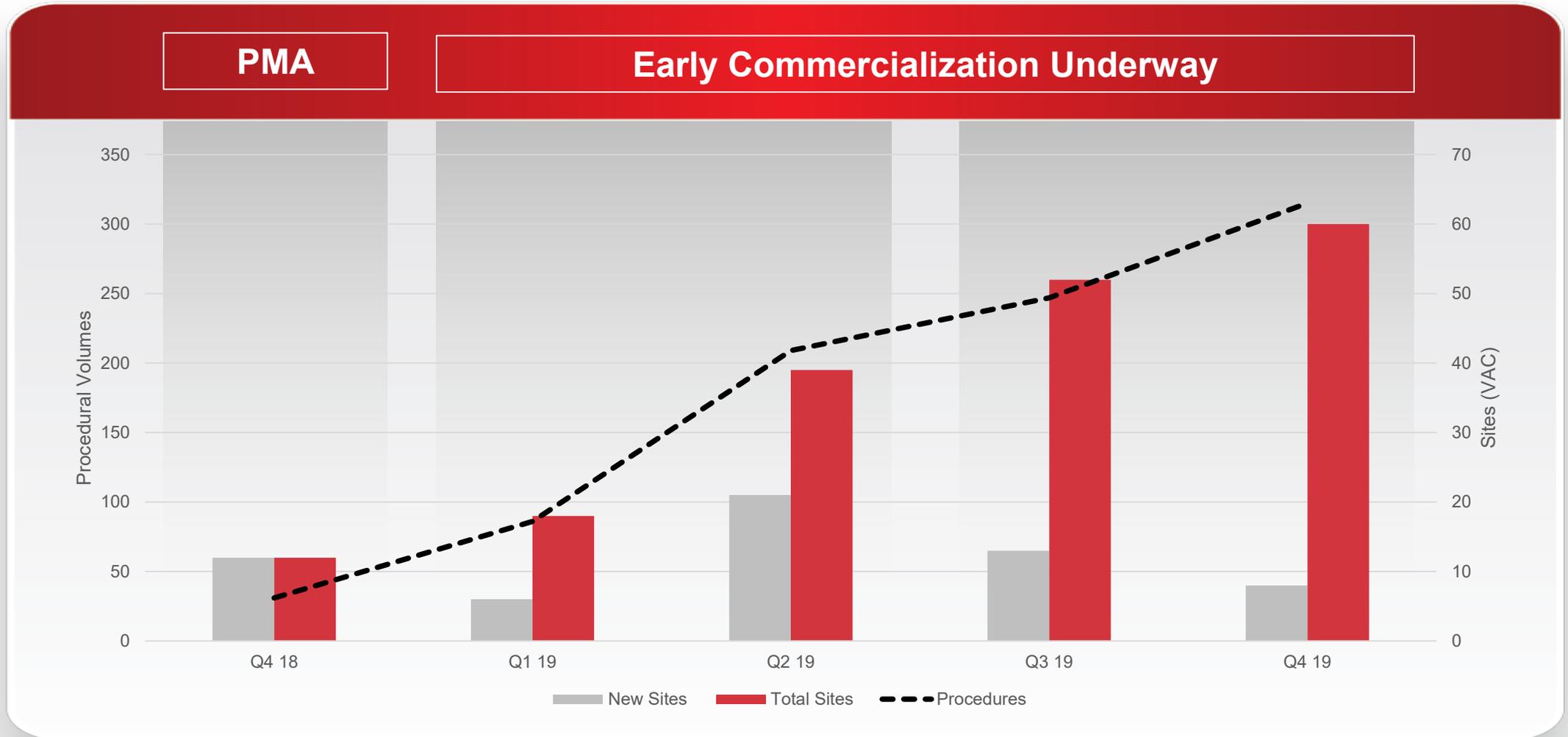
Reduced donor site size and greater meshing ratio enables permanent closure with fewer invasive autograft procedures



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%**

# Strong Adoption of the RECELL System



**RECELL System procedural growth increasing quarter-on-quarter since PMA**



Current Platform  
~\$450M TAM

## Second Target (Burn) Market

### Out-patient burns

**~430,000**

outpatient burns

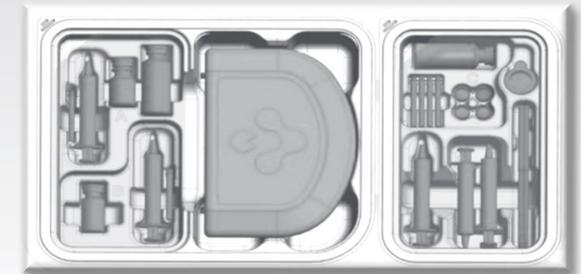
**~37%**

are 2nd and 3rd degree



## Next Generation Device

focused on improved efficiencies and ease of use



**Step 1:** Pursue more favorable reimbursement

**Step 2:** RECELL “2.0” approval for market access

Targeting RECELL System launch in late H1 2021



# Third Target (Burn) Market: 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*

**Enrollment of U.S. pivotal studies to commence in mid-2020**

# Soft Tissue Reconstruction



Current Platform  
~\$550M TAM

# 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

Enrolling for U.S. pivotal study (N=65)

# Soft Tissue Reconstruction Closely Aligned to Burns



Current Platform  
~\$550M TAM

Target Expands to ~250 Total Centers\*

Current  
AVITA Burn  
Target:  
**~132**  
High Volume  
Burn Dedicated  
Centers\*



Future  
AVITA Trauma  
Target:  
**~200**  
Level 1 Trauma  
Centers\*

> 1/2 of all U.S. burn centers are also Level 1 trauma centers

# Defects



# More Than 1,000 Vitiligo Patients Treated Internationally

## SIGNIFICANT UNMET NEED

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

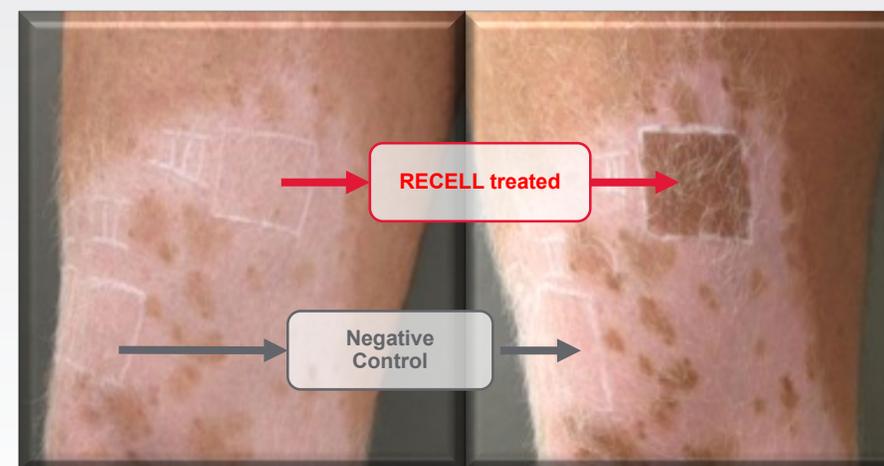
No FDA-approved medical treatments; extremely low patient & physician satisfaction with existing products

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

US feasibility study enrollment underway but exploring options for earlier pivotal study

# Deep Experience in Chronic (Non-healing) Wounds

## THE OPPORTUNITY

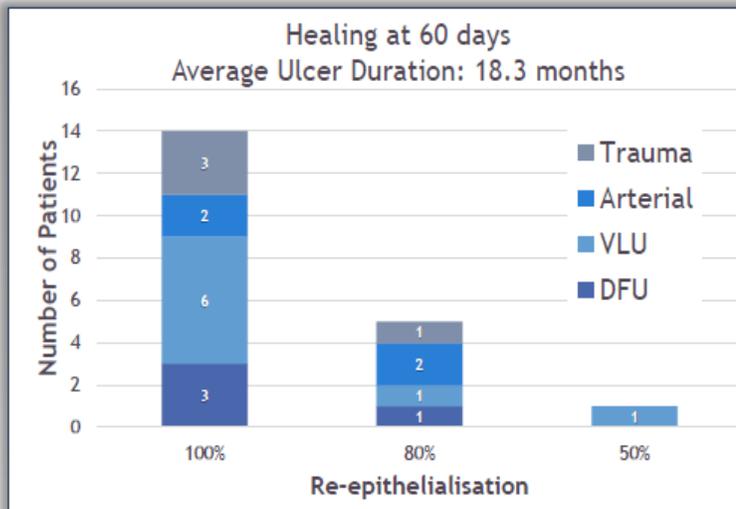
Chronic wounds fail to heal **50%** of the time

Failure to heal leads to pain, exudate (VLU), odor and infections

**Dramatic Quality of Life impact**  
(e.g. activity restrictions, mobility, hygiene, sleep disorder)

## RECELL VALUE PROPOSITION

- RECELL kick starts healing by providing healthy multi-phenotype single skin cells directly to the wound bed
- RECELL may provide faster & durable wound closure, reduced pain and positive QoL outcomes
- **Diabetic Foot Ulcer: 4 studies (2 RCTs) with 70 patients**
- **Venous Leg Ulcer: 4 studies (1 RCT) with 96 patients**



**16 patients treated at three UK hospitals with chronic DFUs from 5-33 cm<sup>2</sup> were followed for 26 weeks.**

### After RECELL:

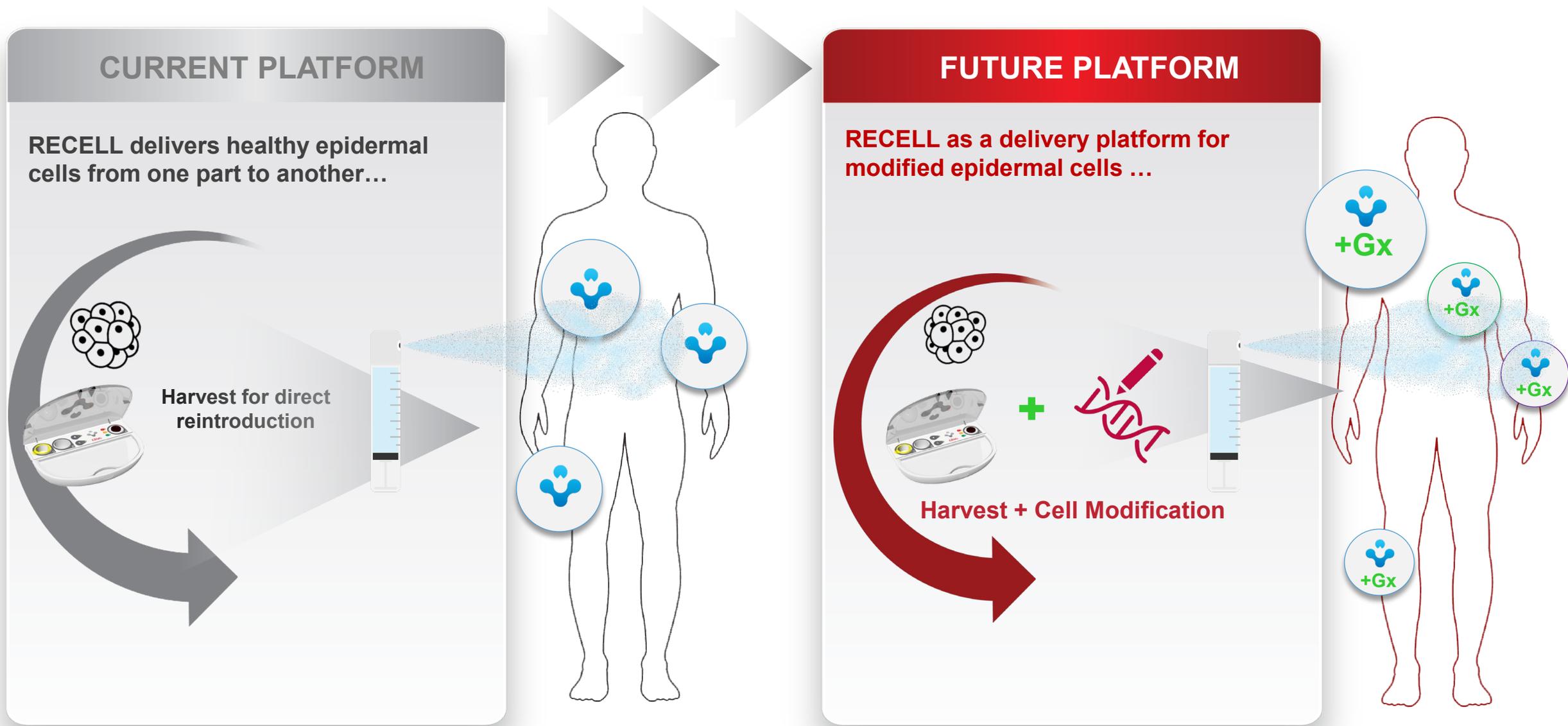
- **100%** of patients experiencing a reduction in DFU wound size
- Average wound size **reduction - 83%** at week 26
- **50% of patients had DFU wounds heal completely**, with a median time to healing of 14 weeks

**49% of all U.S. skin grafts are chronic wounds**

\* In the US, RECELL is approved for acute thermal burns in patients > 18 years ("ATB") only (see [www.avitamedical.com](http://www.avitamedical.com)). Use of RECELL in other indications is either (1) limited by United States law to investigational use; or (2) otherwise prohibited.

# Genetic Errors

# RECELL in Genetic Skin Defects



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# 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

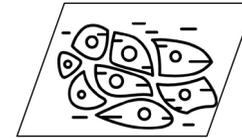
### Durable

Long-term wound closure

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

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

# Sponsored Research ... Combining RECELL + Gates Center Technologies



**Tissue sampling**

**Cell separation, isolation**

**Gene transfer / editing<sup>1</sup>**

**Cell selection, expansion**

**Maturation into skin sheets**

**Transplantation**

**Current Process**  
(Other products in development)



**avita**<sup>medical</sup>  
+

 Gates Center for Regenerative Medicine  
UNIVERSITY OF COLORADO / ANSCHUTZ MEDICAL CAMPUS



**Potential Benefit**  
Rapid, point of care process

**Potential Benefit**  
Corrects underlying genetic defect

**Potential Benefit**  
Eliminates growth & transport of skin sheets

**Potential Benefit**  
Spray-on delivery obviates skin grafting

**avita**<sup>medical</sup>  
transforming lives

Note: Schematic illustrates process for skin-related gene therapy products in development. Step duration and methodology varies across technologies currently in development, given different targeted cell types and gene transfer / editing methods. 1. Can be preceded by induction of pluripotency (CU Gates method)

# RECELL Well-Suited to Rejuvenation

## Skin Rejuvenation\*



- Americans spend **>\$16.5B** in aesthetic procedures annually
- **>3M** aesthetic procedures per year (US) aimed to improve skin tightness, texture & evenness in skin tone
- Consumers desire **superior results** over current offerings with a single treatment

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

**Avita is in late-stage discussions for a rejuvenation sponsored research agreement**

# Corporate

# 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 to 2034**

# Experienced Leadership Team



**Dr. Michael S. Perry**  
CEO

>30 years  
experience

Affiliations:



**David McIntyre**  
CFO

25 years  
experience

Affiliations:



**Tim Rooney**  
CAO

25 years  
experience

Affiliations:



**Erin Liberto**  
CCO

17 years  
experience

Affiliations:



**Andrew Quick**  
CTO

25 years  
experience

Affiliations:



**Donna Shiroma**  
General Counsel

20 years  
experience

Affiliations:



# AVITA Medical: Transformation Through Regeneration

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  - **2 RCTs and 1<sup>st</sup> PMA in burns in > 20 years**
  - 8,000+ patients, 50+ publications
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- **In-patient Burns**
- Out-patient Burns
- Pediatric Scalds



- Soft Tissue Reconstruction
- Traumatic Wounds

## DEFECTS



- Vitiligo
- Chronic Wounds (DFU + VLU)
- Dermatological Diseases

## GENETIC ERRORS



- University of Colorado Anschutz Medical Campus
  - Epidermolysis Bullosa
- New Sponsored Research
  - Rejuvenation

# Thank you

# References

Sources of certain information included in this presentation are set out below for convenience.

Page 4: Kowal, S et al. Cost-effectiveness of the Use of Autologous Cell Harvesting Device Compared to Standard of Care for Treatment of Severe Burns in the United States. *Adv Ther.* 2019; 36(7): 1715–1729.

Page 5: Images from <https://www.dailymail.co.uk/femail/article-3581558/Burns-survivor-bravely-bares-facial-scars-tells-emotional-story-driven-attempt-suicide-cruel-bullies-heart-wrenching-video.html>; <https://www.sciencedirect.com/topics/medicine-and-dentistry/burn-scar>;

Page 9: Kowal, S et al. Cost-effectiveness of the Use of Autologous Cell Harvesting Device Compared to Standard of Care for Treatment of Severe Burns in the United States *Adv Ther.* 2019; 36(7): 1715–1729.

Page 10: Out-patient: 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). Scalds: 486,000 burns per year x 30% pediatrics 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/>). Trauma: © 2017 Millennium Research Group, Inc. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission.; Vitiligo: American Academy of Dermatology- Vitiligo By the Numbers, 2017

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Page 14: 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); Holmes JH, Molnar JA, Shupp, JW, et al. Demonstration of the safety and effectiveness of the RECELL® System combined with split-thickness meshed autografts for the reduction of donor skin to treat mixed-depth burn injuries. *Burns.* December 2018.

Page 15: Park JH, Heggie KM, Edgar DW, Bulsara MK, Wood FM. Does the type of skin replacement surgery influence the rate of infection in acute burn injured patients? *Burns* 2013;39:1386-90. <https://doi.org/10.1016/j.burns.2013.03.015>; Kowal, S., Kruger, E., Bilir, P. et al. *Adv Ther* (2019). <https://doi.org/10.1007/s12325-019-00961-2> ; Foster, K., et al. Cost-effectiveness of RECELL® Autologous Cell Harvesting Device (ACHD) Versus STSG for Treatment of Severe Burns in the United States. Presented at ABA, April 2018, Chicago, IL.

Page 18: American Burn Association NBR Advisory Committee, National Burn Repository 2016 Report, [www.ameriburn.org/2016ABAFull.pdf](http://www.ameriburn.org/2016ABAFull.pdf); Chipp E, Charles L, Thomas C, Whiting K, Moiemmen N, Wilson Y. A prospective study of time of healing to healing of hypertrophic scarring in pediatric burns: everyday counts. *Burns & Trauma* 2017; 5:3. Published online 2017 Jan 19.

Page 21: 1. American Burn Association sources. In addition, see © 2017 Millennium Research Group, Inc. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission -number of sites performing skin grafts for burn injuries.

Page 23: Advances in Vitiligo: An Update on Medical and Surgical Treatments. A. Dillon, et al. *J Clin Aesth Derm.* 2017; KOL input; internal market research 2018; 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; KOL input; internal market research 2018-2019; 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.

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Page 29: [2017 Plastic Surgery Statistics Report](#)