# **AVITA Therapeutics, Inc.**

Dr. Mike Perry, CEO

November 2020



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AVITA's products are Rx only. Please reference the Instructions for Use (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).

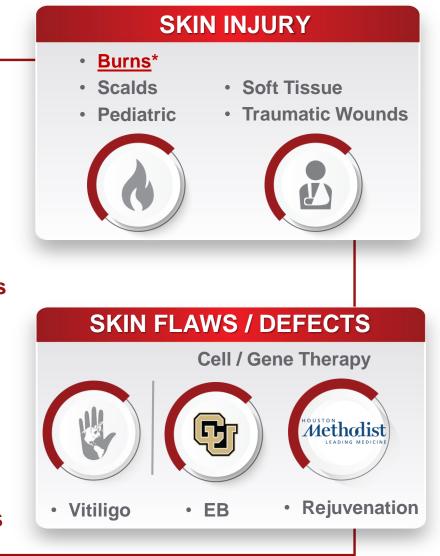


## **AVITA** Therapeutics: Spray-On Skin<sup>™</sup>

#### 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

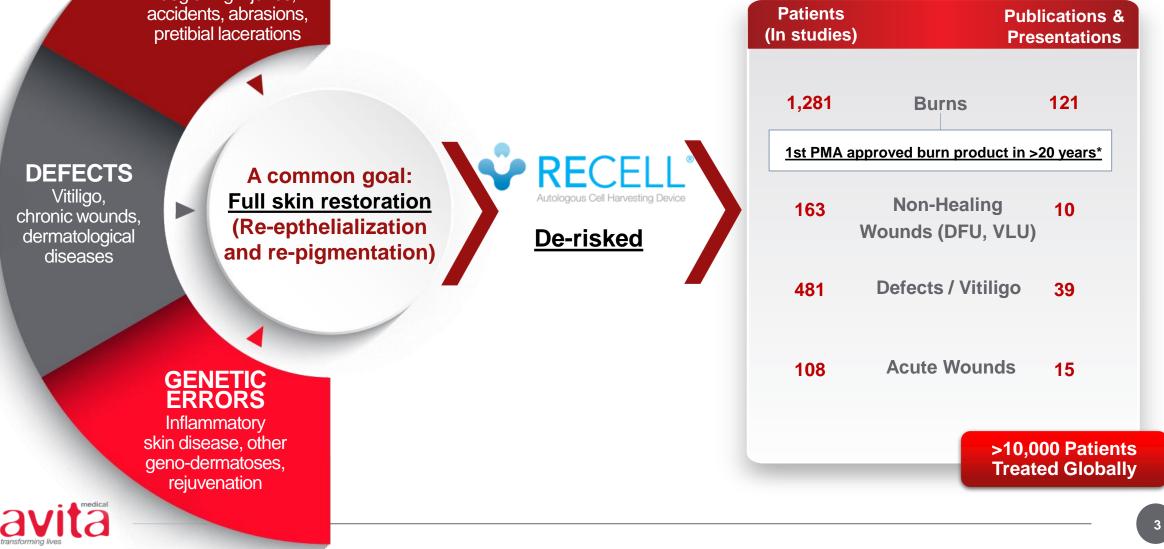


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#### INJURIES Thermal burns, pediatric scald, surgical wounds, degloving injuries, accidents, abrasions, pretibial lacerations

PMA Label Expansion & 10,000 Patients Treated Globally



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## **Treating "Skin Injury" is Unchanged for More Than 50 Years**

#### Split-Thickness Skin Grafts (STSG) are "Medieval"



Dermatome skin harvesting from <u>new</u> 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 is the Standard of Care and requires physicians to create a new (donor) 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**

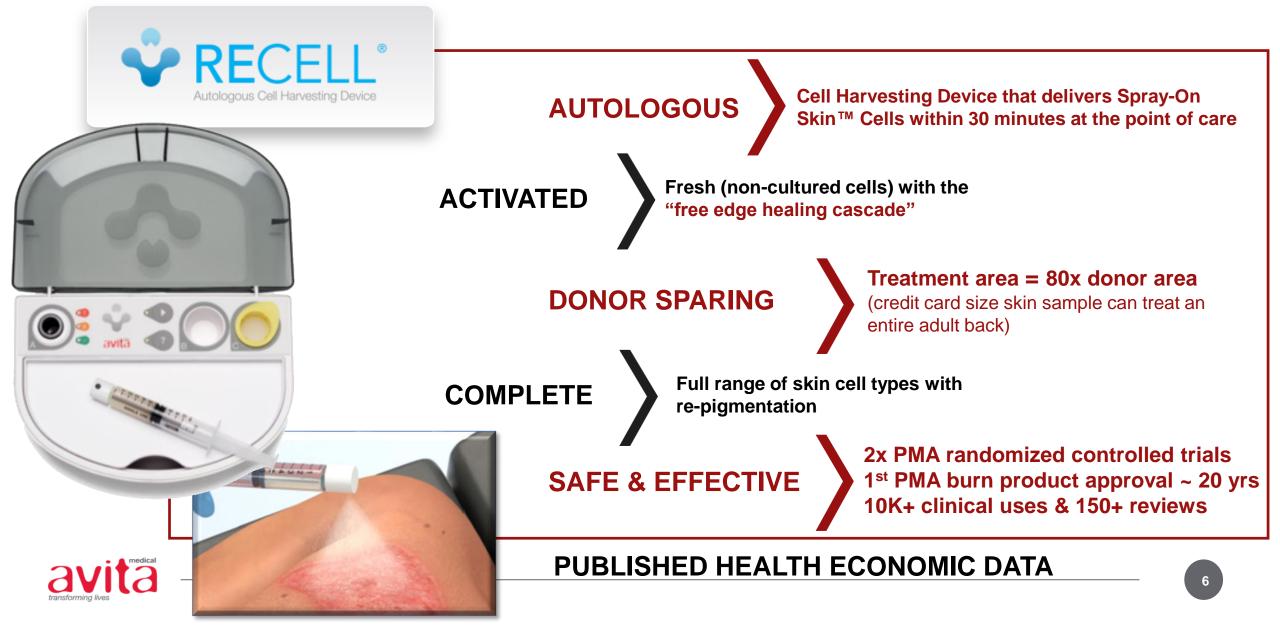


#### Scarring, Atrophy, Contracture



Scarring, re-operations, excessive pain, infection, contracture ...

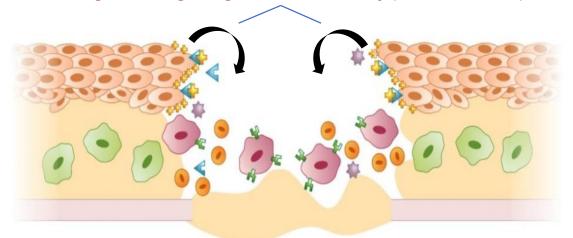
## **RECELL Spray-On Skin<sup>™</sup> Treats 80cm<sup>2</sup> of Skin from a 1cm<sup>2</sup> Biopsy**



## **RECELL's "Free Edge" Advantage**

#### Healing Process without RECELL

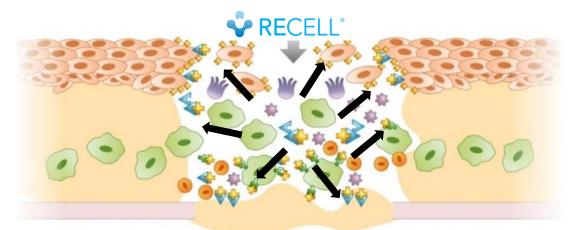
Free edge limits signaling to wound boundary (i.e. outside  $\rightarrow$  in)



- 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<sup>TM</sup> signals from within the wound (i.e. inside $\rightarrow$ 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

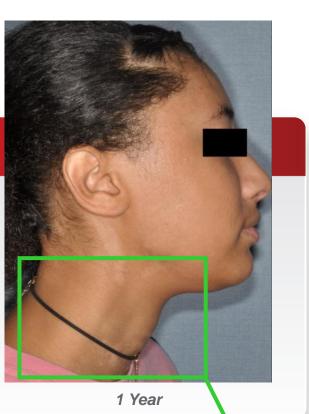




**Day 21** 



1 Year



Compassionate Use case

Day 7

- 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

3 Months



Skin +

Color

Restoration

## **Flexible Treatment Offering – Small Burns & Pigmentation**

### 31-year-old female | ~11% TBSA | DPT Face | RECELL<sup>®</sup> alone

#### **Treatment Day**



After 7 days of no progressive healing with allograft, Spray-On Skin™ Cells were applied



Day 11, patient was discharged with 100% re-epithelialization and no signs of infection or inflammation



2 months post-op, patient continued to show re-pigmentation

## **Promote Healing in Challenging Areas**

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



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



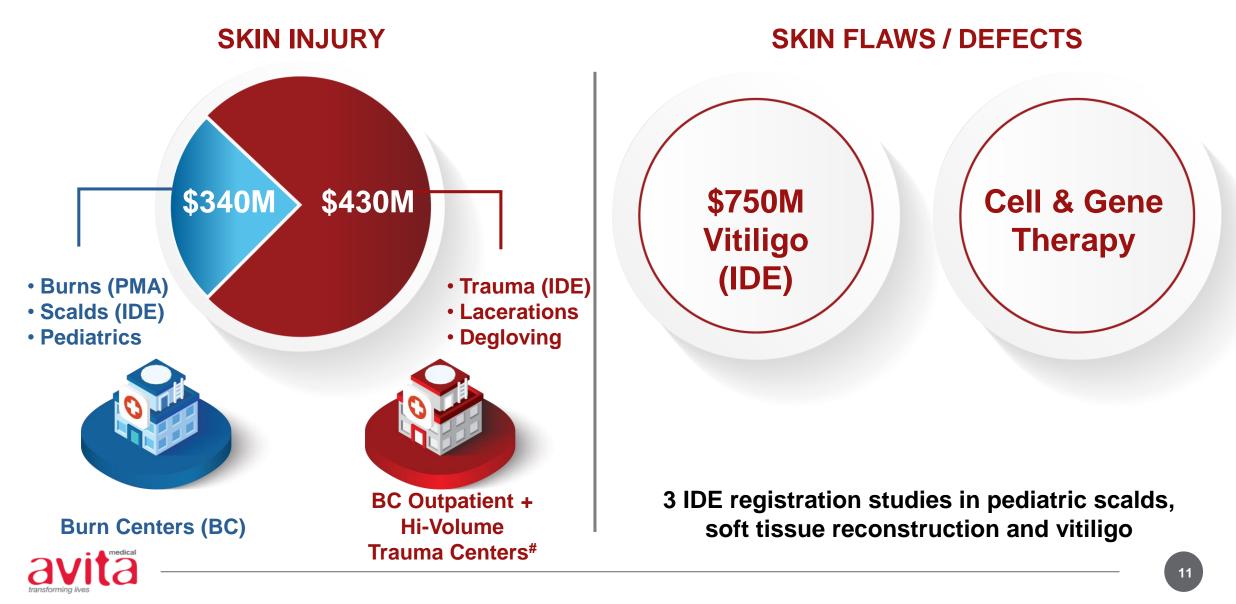
At 1 week, 95% re-epithelialization occurred



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



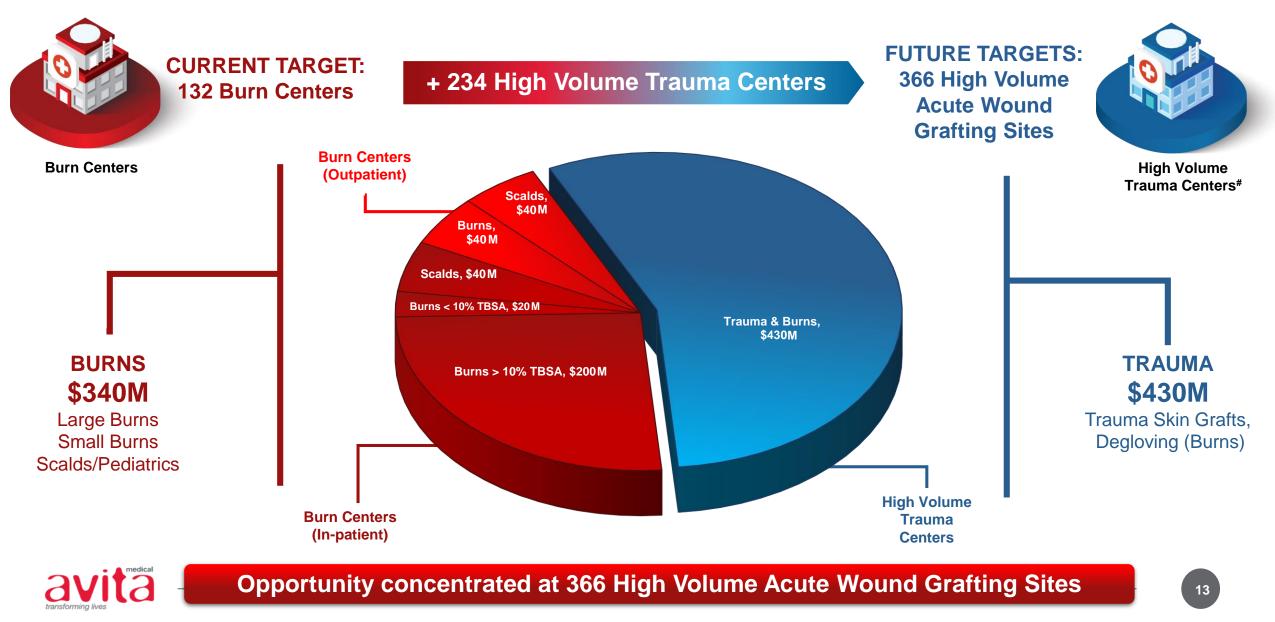
## Leveraging Premarket Approval\* in a Multi-Billion Serviceable Market



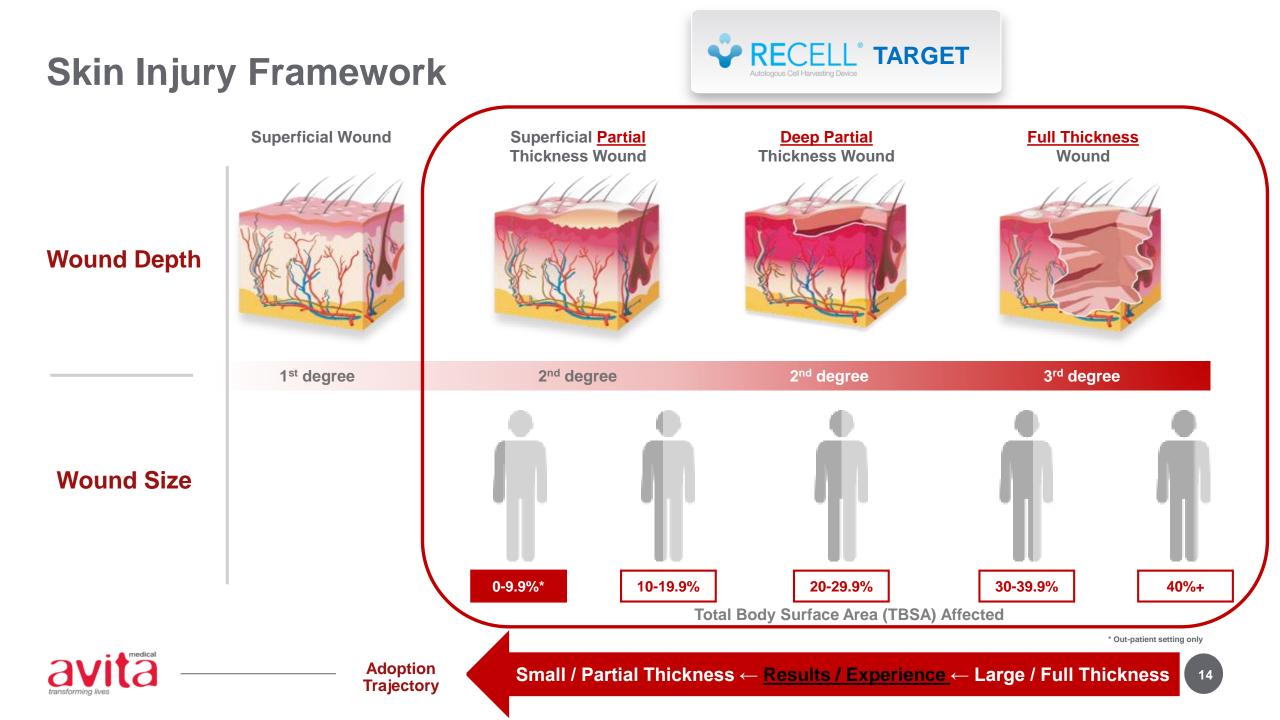
# Skin Injury



## Skin Injury: Significant Opportunity + Concentrated Target



# Decile 6+ trauma grafting sites; \* In the US, RECELL is approved for acute thermal burns in patients > 18 years (("ATB") only (see www.avitamedical.com)). Use of RECELL in other indications is either (1) limited by United States law to investigational use; or (2) otherwise prohibited



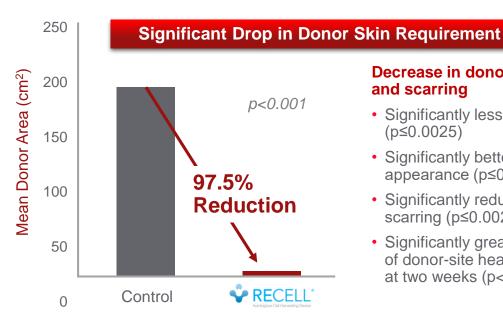
## **1st Premarket Approval Treatment in Burns in 20 Years**

Dual multi-center, randomized, controlled premarket approval studies

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

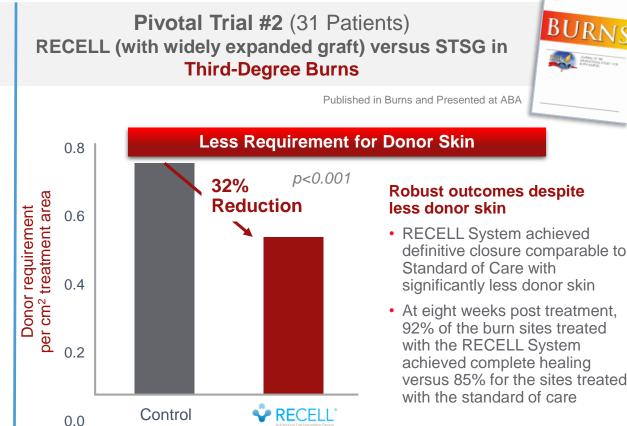


Published in JBCR and Presented at ABA



#### Decrease in donor site pain and scarring

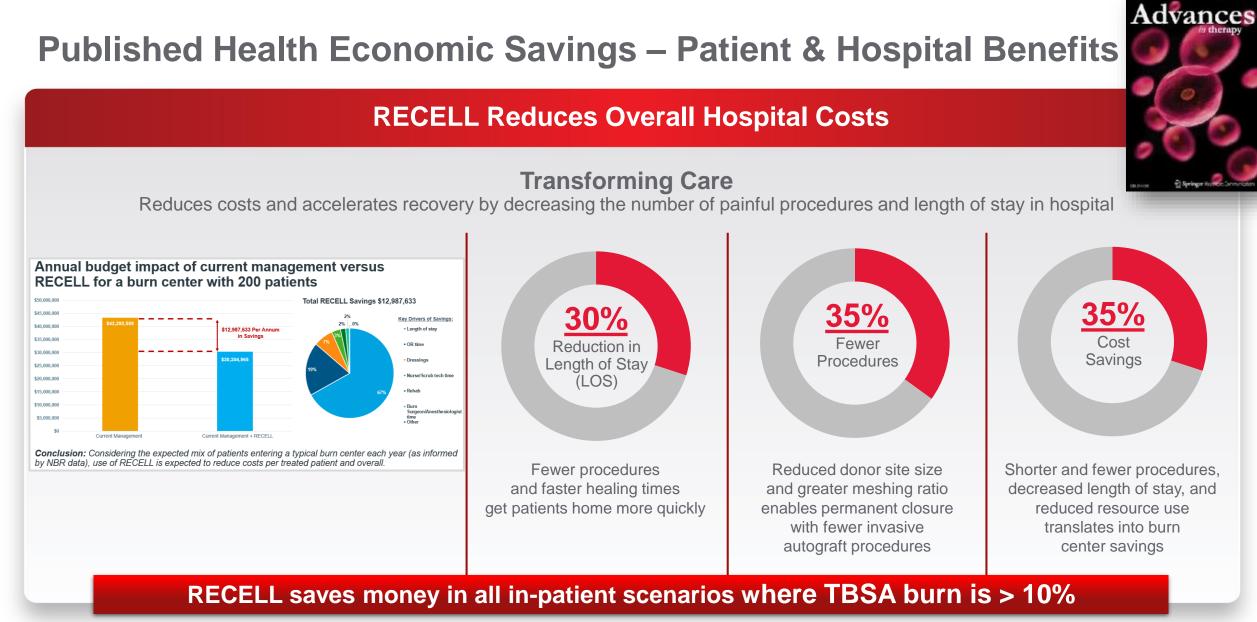
- Significantly less donor site pain (p≤0.0025)
- Significantly better donor site appearance (p≤0.0025)
- Significantly reduced donor site scarring (p≤0.0025)
- Significantly greater incidence of donor-site healing at two weeks (p<0.001)



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

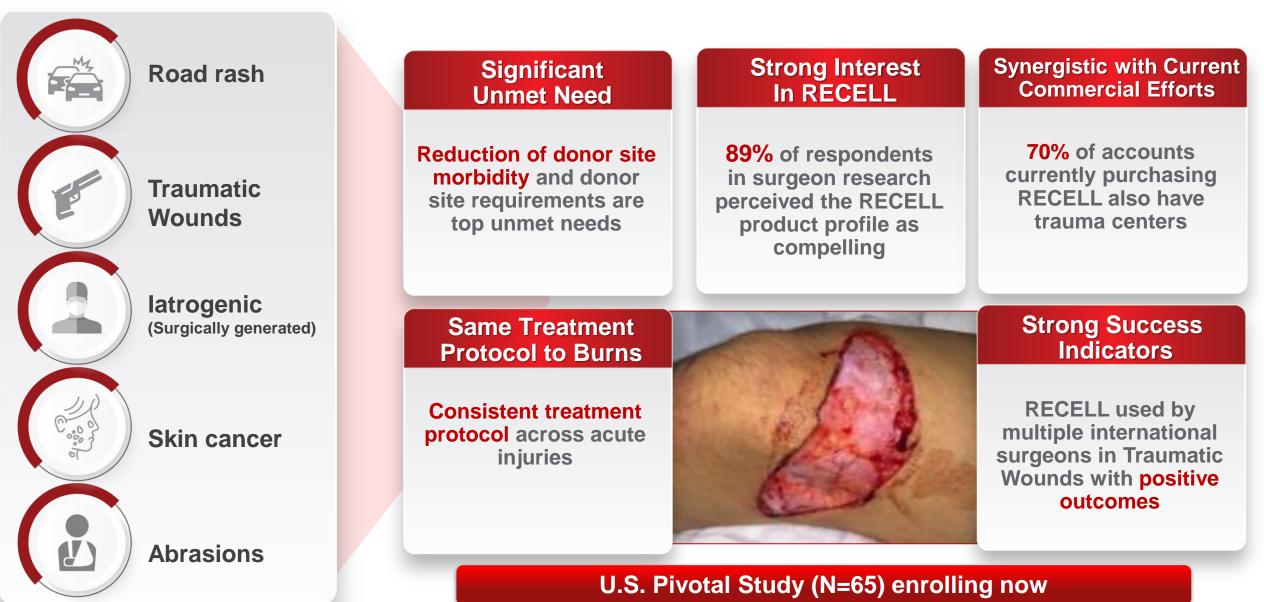
FDA Compassionate Use Investigational Device Exemption (IDE) Program (100 Patients)

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





## Soft Tissue Grafting is 5 Times Larger Than Burns



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## **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

3 Weeks post RECELL treatment



10 Weeks post RECELL treatment

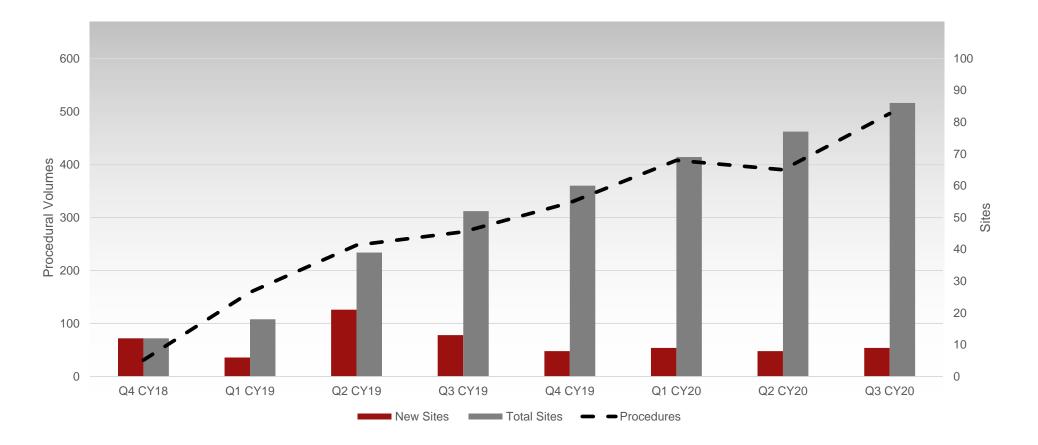






\* In the United States, RECELL is not approved for pediatric use and is an investigational device, limited by United States law to investigational use for those patients

## **Strong Adoption of the RECELL System\***



#### **RECELL System procedural growth since PMA**



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## **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)\*

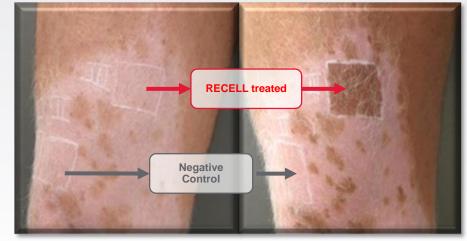
No FDA-approved medical treatments; extremely low patient & physician satisfaction with existing products

> 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

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



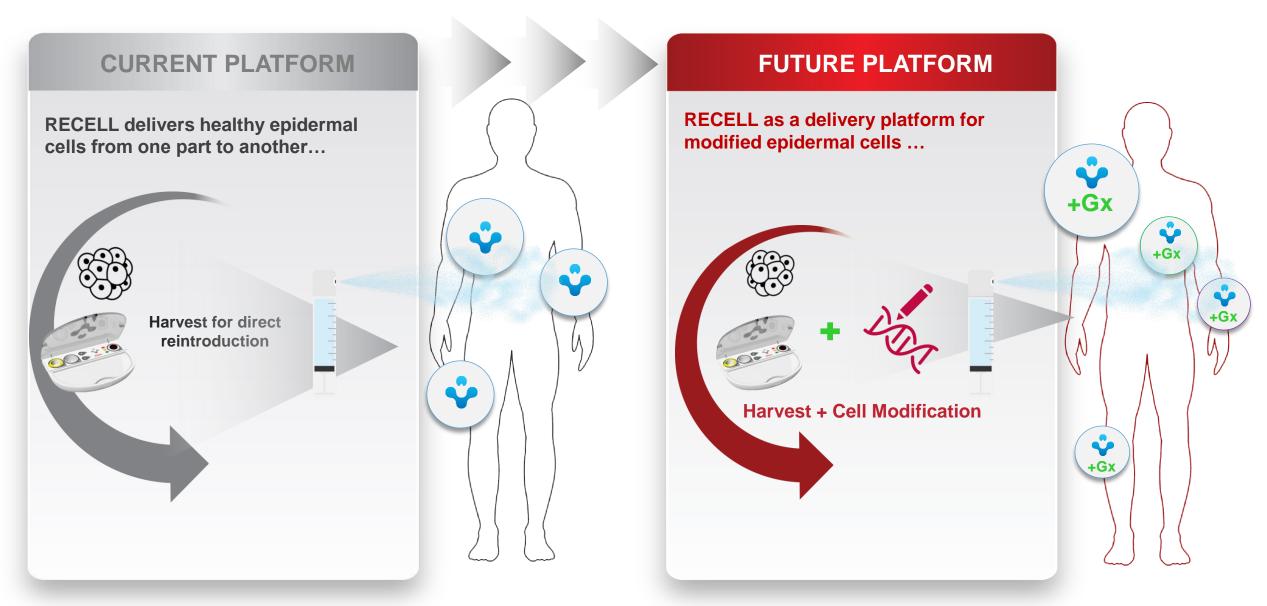
## Significant Opportunity for a Single, Curative Therapy

FIRST LINE	SECOND LINE	THIRD LINE	100% Re-pigmentation Observ
<ul> <li>Medical Management With Topicals* (Corticosteroids, Calcineurin inhibitors)</li> <li>2 treatments per week for 3-6 months</li> <li>4 Limited efficacy (45% regain some color)</li> <li>Poor patient compliance</li> <li>Potential skin atrophy</li> <li>Potential cancer risk</li> </ul>	<section-header><list-item><list-item><list-item></list-item></list-item></list-item></section-header>	<section-header><text><text><text><text></text></text></text></text></section-header>	<ul> <li>Week 12</li> <li>Yeek 12</li></ul>

# **Cell / Gene Therapy**



## **RECELL in Genetic Skin Defects**



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

# 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**



#### Research Program

## 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**







## **COVID-19 Pandemic Update**

#### **BURN BUSINESS**

#### **Non-Elective Procedure**

- Patients suffering acute thermal burns require immediate treatment
- Burn procedures are not elective, and cannot be deferred
- Burn patients take up hospital beds, including ICU beds

#### **Commercial Implications**

- Q2 CY20 disrupted due to COVID but growth restored (30%+) in Q3 CY20
- Procedural volumes vary regionally depending on local COVID dynamics
- New site ramp slightly slower but improving amid site access restrictions

#### **OPERATIONS**

#### Employees

- Implemented comprehensive work from home and social distancing policy
- Travel limited to essential travel
- Manufacturing uninterrupted

#### **Supply and Distribution**

- No anticipated disruptions to supply chain or distribution network
- Sufficient raw materials to meet expected demand

#### **Business "idling" and Well Capitalized**

 Tightly focused on existing objectives and managing expenses

#### **STUDIES & SUPPORT**

#### **Field Participation and Support**

- Comprehensive digital and audio outreach program implemented
- Virtual case support and site training implemented
- Clinical onsite hospital support highly restricted, and often solely at "physician request"

#### **Clinical Studies**

- Investigational studies have been deprioritized at all institutions
- Enrollment in all studies slow, especially in the emergency setting (where COVID capacity is needed)



Safety and welfare of employees, patients, HCPs and stakeholders are paramount

## Adapting to Meet the Needs of Patients and Customers





## **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



## **Experienced Leadership Team**



Dr. Michael S. Perry CEO

>30 years experience

Affiliations:









Erin Liberto CCO

17 years experience

Affiliations:

Johnson Johnson

🐔 Allergan.



Andrew Quick CTO

25 years experience

Affiliations:





Sean Ekins V.P. of Finance

19 years experience

Affiliations:

ÍXÍA A Keysight Business

The Water Disnep Company

Countrywide Financial...





Donna Shiroma General Counsel

20 years experience

Affiliations:



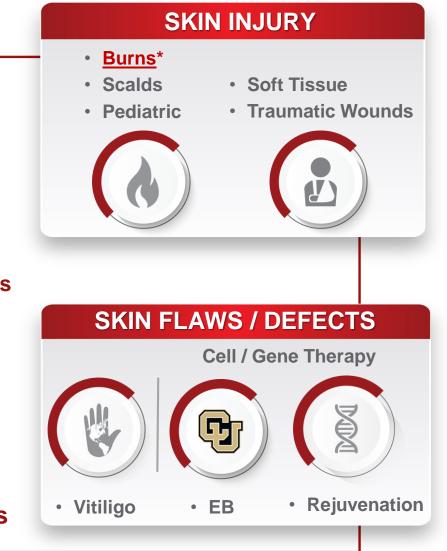
avit ansforming lives

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  - 2 randomized controlled trials + and 1<sup>st</sup> PMA in burns in > 20yrs
  - 10,000+ patients, 100+ publications and presentations
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- Published health economic model demonstrating hospital cost savings
- Multi-billion serviceable market opportunity
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# Thank you for your kind attention

