# avita medical

# One Platform. Endless Possibilities.

39th Annual

J.P. Morgan Healthcare Conference

January 12, 2020

NASDAQ: RCEL

ASX: AVH



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AVITA Medical'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<sup>®</sup> 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: Investment Highlights

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#### RECELL System: FDA approved for the treatment of acute thermal burns

- Proprietary Spray-On Skin<sup>™</sup> Cells offers life changing benefits
   Point of care technology that is safe & effective
- Published health economic model demonstrates hospital cost savings

#### Deep scientific and clinical pedigree

- 2 randomized controlled trials and 1st PMA in burns in > 20yrs
- 10,000+ patients, 180+ publications and presentations

#### Ongoing platform expansion: \$1.5B U.S. serviceable market opportunity

- Platform technology with numerous adjacent applications
- PMA label expansion underway with 3 pivotal studies:
  - Vitiligo
  - Soft Tissue Reconstruction
  - Early Intervention for Pediatric Scalds

#### Further potential for cell-based gene therapy and aesthetics

Fiscal Q2 RECELL System reported revenue of \$5M; Cash of \$60M ending 2020



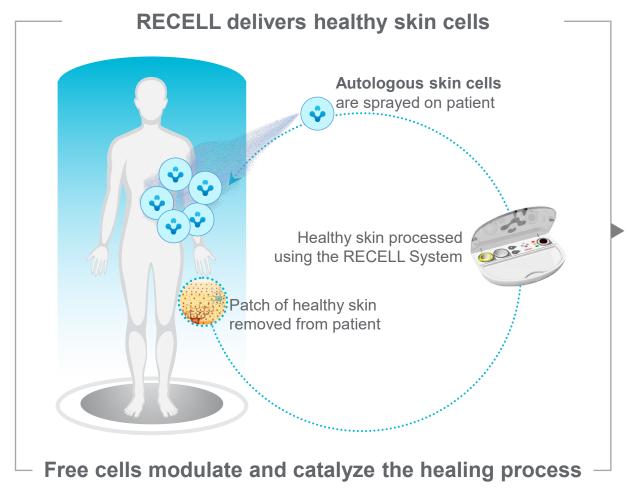
Zed, treated with the RECELL System

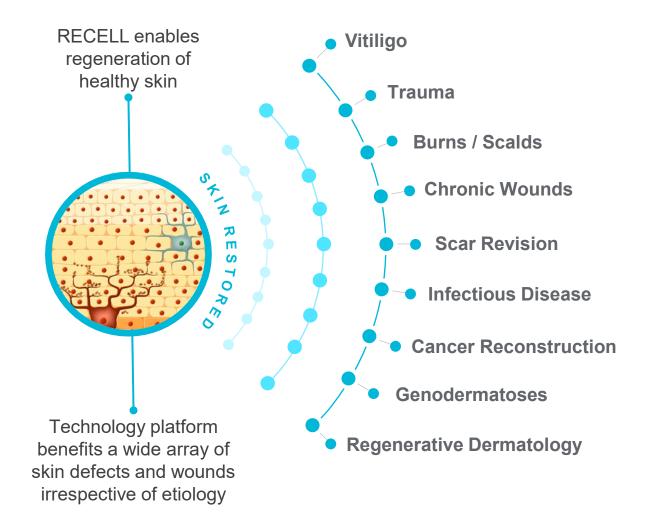
Revolutionary treatment using a patient's own skin for life-changing outcomes

### One Platform. Endless Possibilities.









## First Indication: Thermal Burns 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

- Extensive skin harvesting required
- Pain associated with donor site
- Extended hospitalization and costs
- Multiple complex, costly, surgical procedures
- Risk of infection
- Pigmentation and discoloration
- Scarring
- Atrophy
- Contracture

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>



## 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

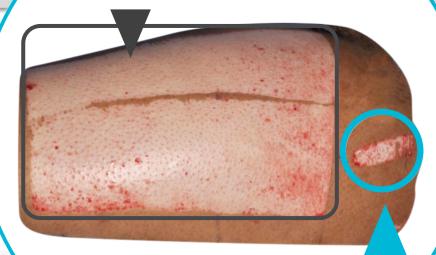
## SPLIT-THICKNESS SKIN GRAFT DONOR SITE

#### **COMPLETE**

Full range of skin cell types with re-pigmentation

#### **ACTIVATED**

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



#### SAFE & EFFECTIVE

2x PMA randomized controlled trials 1st PMA burn product approval ~20 yrs 10K+ clinical uses worldwide >150 peer reviewed articles

#### **DONOR SPARING**

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

#### **RECELL DONOR SITE**

## PUBLISHED HEALTH ECONOMIC DATA

Demonstrating significant savings to the health care system

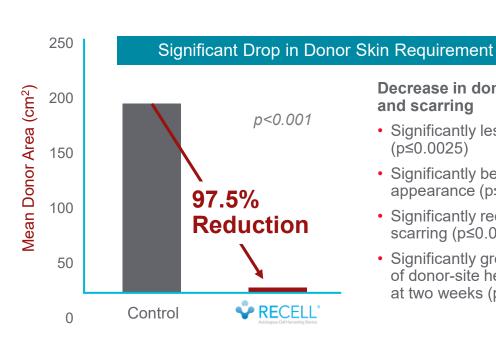
## 1st Premarket Approval Treatment in Burns in 20 Years



Dual multi-center, randomized, controlled premarket approval studies



Published in JBCR and Presented at ABA

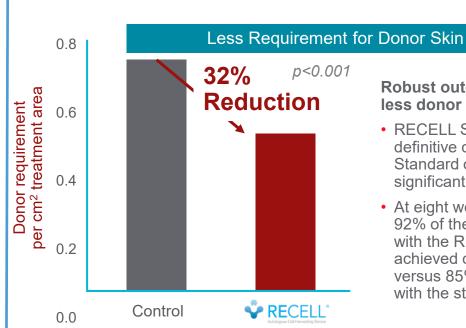


#### Decrease in donor site pain and scarring

- Significantly less donor site pain  $(p \le 0.0025)$
- 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)

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

Published in Burns and Presented at ABA



#### 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

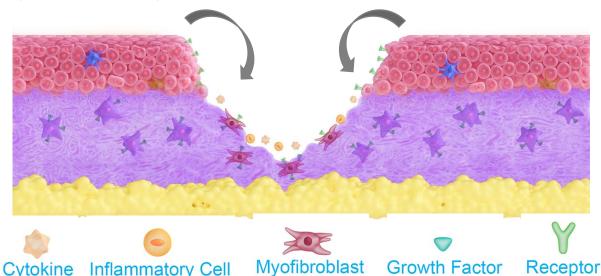
Comparable healing and long-term outcomes for burn sites with significantly less donor skin required

## RECELL "Free Edge" Advantage

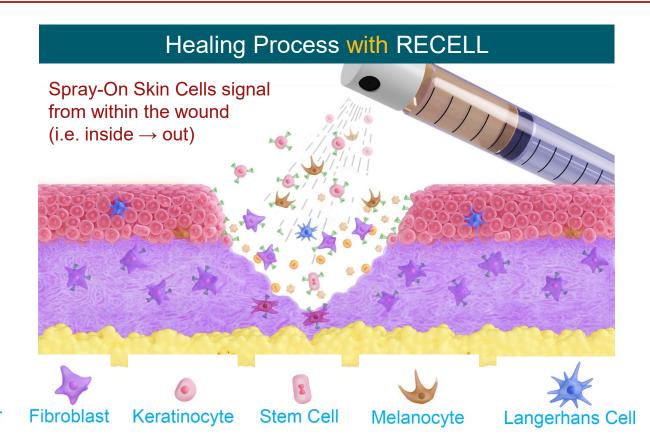


#### Healing Process without RECELL

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)



- 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, 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



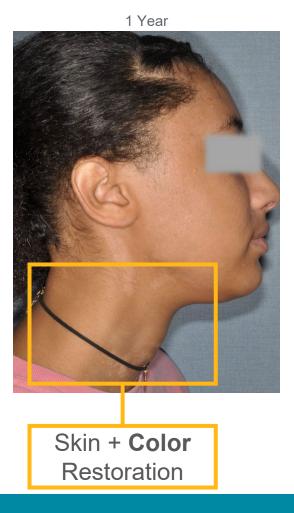
1 Year



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

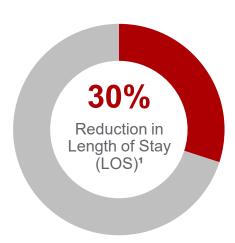
### Published Health Economic Model: Demonstrates Patient and Health Care System Benefits

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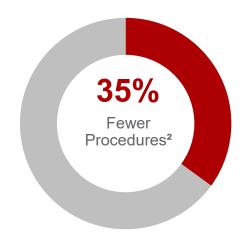
RECELL saves the hospital money in all in-patient scenarios where the burn is 10% Total Body Surface Area (TBSA) or greater

#### **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

#### **VALIDATED MODEL**

- 21 abstracts on RECELL health economics since launch
- 17+ Burn Centers contributing to the RECELL abstracts and publications
- Two publications
- Customized Budget Impact calculator
- Leader of health economics in burns

<sup>1.</sup> 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

<sup>2.</sup> Kowal, S., Kruger, E., Bilir, P. et al. Adv Ther (2019). https://doi.org/10.1007/s12325-019-00961-2



Development Pipeline and Growth Potential



## Focused Pipeline with Strong Growth Potential

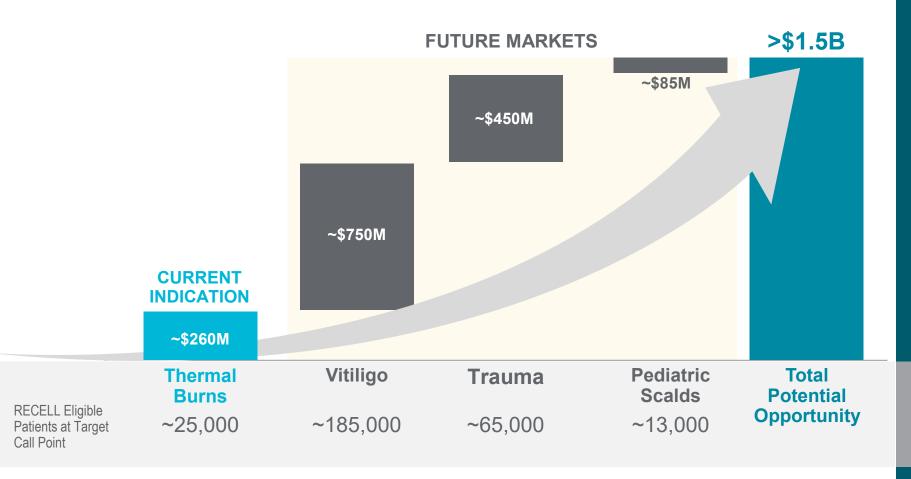


INDICATION	DISCOVERY	FEASIBILITY	PIVOTAL	APPROVAL		
Regenerative Therapeutics – Wounds & Dermatology (Current Platform)						
Acute Thermal Burns Adults (U.S.)			:			
Burns and Wounds (Japan)						
Vitiligo (U.S.)						
Soft Tissue Reconstruction (U.S.)						
Pediatric Scalds (U.S.)*						
Early-Stage Research Programs						
Epidermolysis Bullosa						
Rejuvenation						

<sup>\*</sup> Pediatric Scalds is a BARDA-funded study under contract HHS0100201500028C. Epidermolysis Bullosa and Rejuvenation programs are sponsored research programs in partnership with the CU Denver and Houston Methodist

## Current De-Risked Platform Enables Access to a Large Serviceable Market





Efficacy \	Vell [	Demon	strated
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	Patients (in studies)	Publications & Presentations
BURNS	1,281	121
DEFECTS/ VITILIGO	481	39
ACUTE WOUNDS	108	15

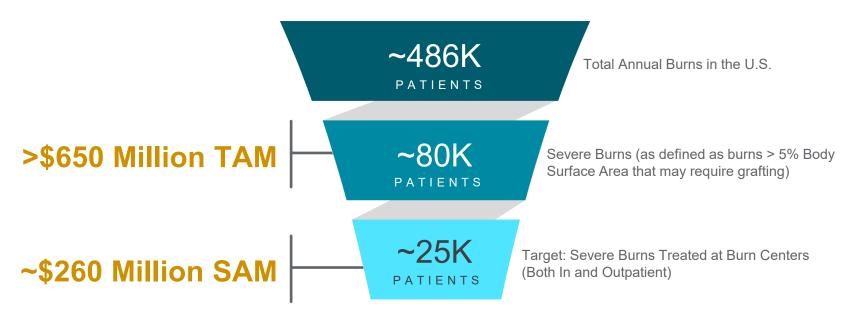
Highly De-risked Pipeline with > 10,000 Patients Treated
Globally

A common goal: Full skin restoration (Re-epithelialization and re-pigmentation)

## Thermal Burns: U.S. Target Market Expanded to Include Small Burns and Outpatient

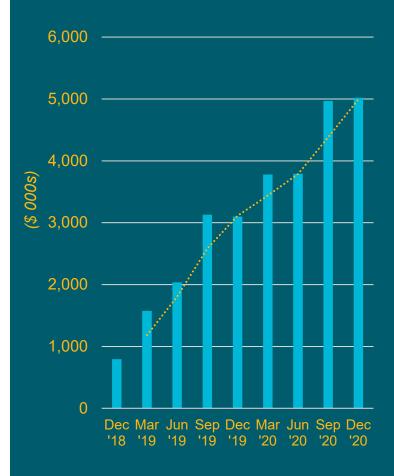


#### Patient Funnel and Addressable Market



Outpatient Pass Thru Code Opens Doors to Small Burns and Expands Serviceable Market Opportunity

## Quarterly U.S. RECELL Sales Since Approval



## Strong Adoption of the RECELL System





Over \$28 Million in U.S. RECELL Revenue Since Approval

## Pathway to the Outpatient Market



The current indication for RECELL is valid for all sites of service

Physician coding a reimbursement has been established and is the same inpatient and outpatient

AVITA has applied for a Transitional Pass Thru Payment for Outpatient Medicare Patients, which represent ~15% of patients



AVITA will partner with our accounts via our RECELL Access Program to support reimbursement payment

#### STEP 1

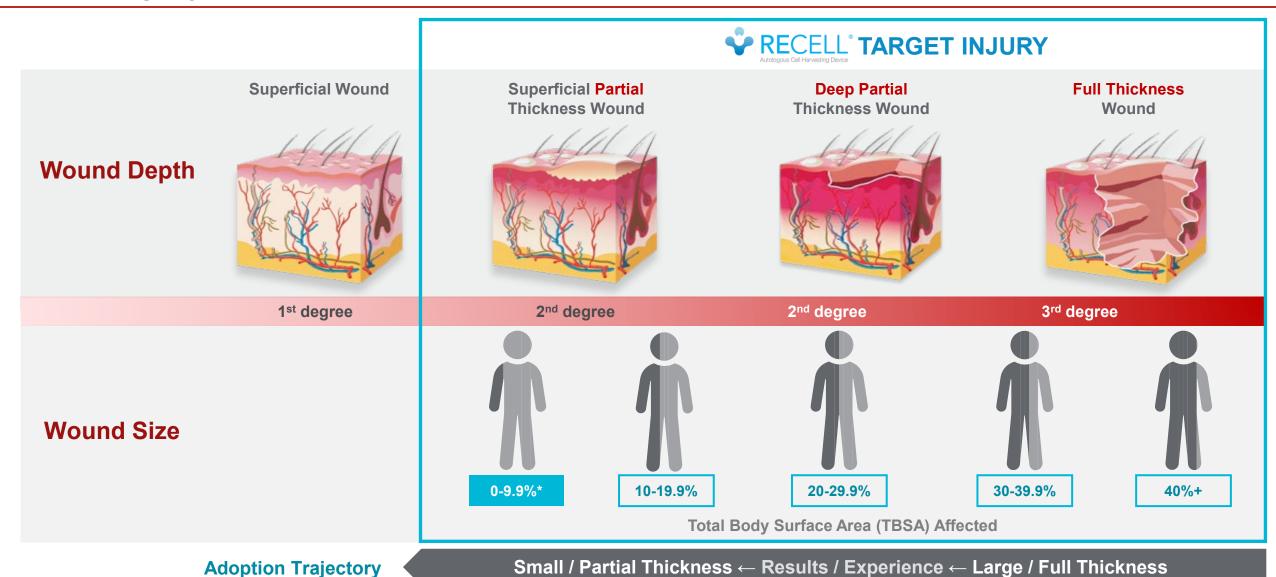
Pilot Launch to ensure private payers expand coverage using CMS established code.

#### STEP 2

Full launch to remaining burn centers who perform skin grafting in the outpatient setting.

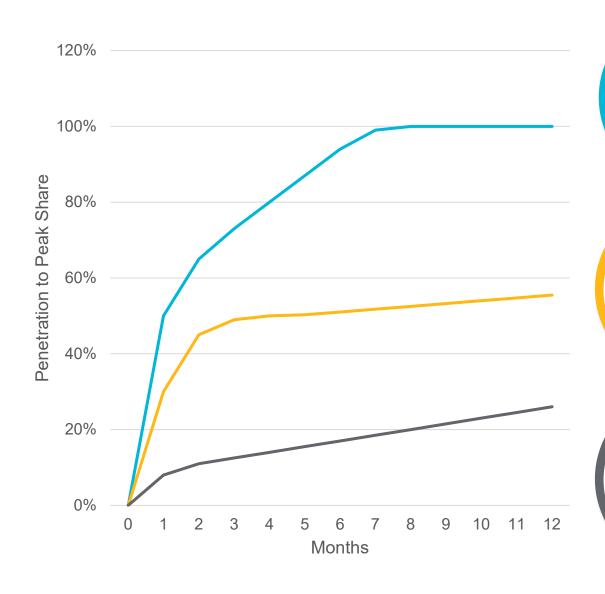
## Skin Injury Framework





### Account Adoption Varies By User Type





Super User ~25% Sales

- RECELL used by all surgeons.
- Consistent use across all burns which may require a skin graft"
- Burn Dedicated Team

Standard User ~50% Sales

- Consistent use on a subset of burn types
- Hesitation to expand usage across all burn types and sizes
- Values benefit in large burns

Slow User ~25% of Sales

- Not fully integrated, cautious and use as treatment of last resort
- Often only 1 doc trained, rotating staff, physician turnover
- Often constrained by procurement

## Promotion and Education Amplified During The Pandemic





~1,900 RECELL training events reaching ~1,300 healthcare providers in 2020

## Vitiligo: Unmet Need, No FDA-Approved Products



## SIGNIFICANT UNMENT NEED Up to 2% of the population affected (~6.5M in the US)

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

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

## LIMITED EFFICACY OF TREATMENT OPTIONS DRUGS AND PHOTOTHERAPY

#### Medical management

For disease stabilization: Corticosteroids, calcineurin inhibitors

2 treatments per week for 3-6 months

- Limited efficacy Poor compliance
- Potential skin atrophy, cancer risk

#### **Phototherapy**

For disease stabilization: UVB. excimer laser

2-3 treatments / week for a few months to over a year

- Typically combined with topicals
- Not durable

**Combination PUVA** (psoralen with phototherapy)

#### SURGICAL

#### Skin grafting

For repigmentation of stable lesions (rarely performed): Punch & suction blister grafting

Transplantation of small sections of pigmented skin to depigmented areas

#### Melanocytekeratinocyte transplantation

For repigmentation of stable lesions: Requires substantial laboratory equipment

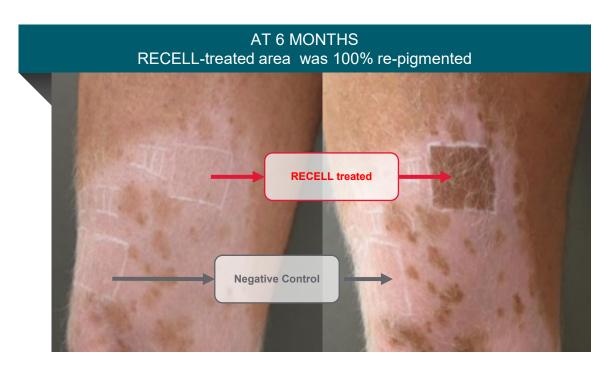
Note: Surgical approaches are performed very rarely and only at very specialized academic centers

Advances in Vitiligo: An Update on Medical and Surgical Treatments. A. Dillon, et al. J Clin Aesth Derm. 2017

## Established RECELL Track Record in Vitiligo



1,000 patients treated internationally and 8 peer-reviewed publications showing positive outcomes



#### POTENTIAL RECELL BENEFITS



For stable vitiligo of all types (segmental & nonsegmental)



**Durable:** One-time treatment to regenerate pigmentation



Complementary to existing products and pipeline (e.g., immunomodulating drugs and phototherapy that stabilize the disease)

Very exciting and novel. Preliminary efficacy rate looks very impressive.

This would be a hero product to these patients.

Nothing works today.

- Medical Dermatologist

- Vitiligo Specialist

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

## Significant Market Opportunity in Repigmenting Stable Vitiligo



#### MARKET TAILWINDS OPPORTUNITY ESTIMATION Payers with coverage for vitiligo treatments (e.g., phototherapy) TOTAL MARKET Growing 4.5M Prevalence of Vitiligo United reimbursement **Paetna**® in the United States Healthcare (up to \$38,000 / BlueCross BlueShield (range 3-6.5 million) patient annually) **Coverage Update: Cigna to Cover Excimer Laser Treatment for Vitiligo** TOTAL ADDRESSABLE MARKET Not exhaustive Patients with Stable Vitiligo\*. **TAM** 1.3M eligible for surgical treatment **5.2 Billion** Number of patients seeking treatment in 2013 150k Increasing SERVICEABLE AVAILABLE treatment-seeking SAM MARKET behavior Estimated number of eligible 188K patients at target call points 300k Number of patients seeking treatment in 2019 750 Million

Concentrated HCP base: Estimating <1,000 procedural dermatologists and plastic surgeons with interest in treating vitiligo

Advancing pipeline of disease stabilizing treatments

JAK inhibitors are in late-stage development. Potential to help build market and expand eligible patients

## Traumatic Soft Tissue Injury: High Confidence in Positive Outcomes



#### RECELL used by multiple surgeons in traumatic wounds with **positive outcomes**



Patient treated for necrotizing fasciitis.



Excellent healing, with very good cosmetic and functional outcomes.

RECELL demonstrated a compelling value proposition in these **particular wound** types:



**Abrasions** 



**Degloving Injuries** 



Infectious Disease (e.g., Necrotizing Fasciitis)

Soft tissue injuries are associated with large areas of skin loss. As such, the unmet needs are closely aligned with burns.

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

## Soft Tissue Injury Repair: Significant Strategic Overlap to Burns



#### Synergistic with current commercial focus



#### Significant Unmet Need

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

## Same Treatment Protocol to Burns

Consistent treatment protocol across acute injuries

## Strong Interest In RECELL

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

## Synergistic with Current Commercial Efforts

80% of accounts currently purchasing RECELL also treat for trauma

#### Reimbursement in Place

Able to leverage existing CPT & outpatient codes

#### Same Commercial Sales Team

Manageable expansion to cover an additional 222 accounts

## Early Intervention for Pediatric 2nd Degree Burns (Scalds)



#### A unique subset of burns

- 30% of burns occur between 1 and 15 years of age of which 45% are estimated to be associated with scalds
- Scalds frequently present as "indeterminate depth", for which conventional treatment involves waiting several weeks and only autografting if necessary
  - With RECELL early intervention, the aim is to prevent autografting and avoid scarring and disfigurement









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

## Early Intervention May Avoid Scarring and Disfigurement





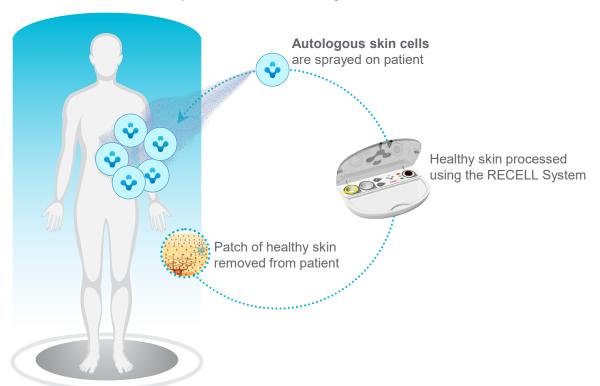


## RECELL in Genetic Skin Defects and Rejuvenation



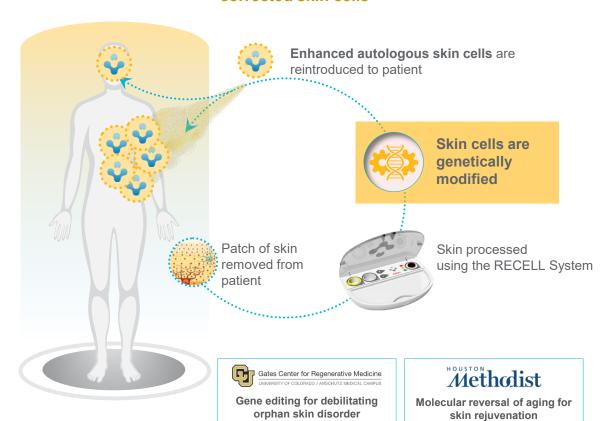
#### **CURRENT PLATFORM**

Treatment using RECELL for harvesting and direct reintroduction of the patient's own healthy skin cells



#### **FUTURE PLATFORM**

RECELL as a platform for treatment using the patient's corrected skin cells



## Exploring Cell-Based Gene Therapy for Epidermolysis Bullosa



#### THE CHALLENGE



#### **DEBILITATING**

Skin fragility, disability, cancer

## HIGH UNMET

No FDA-approved treatment, only palliative measures

#### COST BURDEN

Care of \$200K-\$500K per year per patient

#### THE OPPORTUNITY

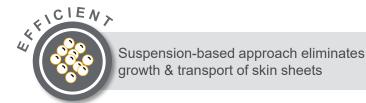
Preclinical research partnership underway, exploring the combination of a novel gene correction approach with AVITA's Spray-On Skin<sup>TM</sup> Cells technology

AVITA AND GATES CENTER COLLABORATION

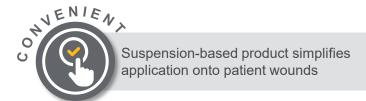
**COMPETITOR PIPELINE PROGRAMS** 



Majority focused on ameliorating symptoms, or based on foreign DNA insertion, which could have negative long-term effects



Some competitors focused on growth of geneedited skin sheets, which suffer from fragility



Epidermal sheets require surgical anchoring and can result in complex procedures and issues with 'take rates'

Proof-of-concept for delivering genetically modified cells in suspension expected in Q2 '21

## Epidermolysis Bullosa Could Be a Meaningful Opportunity and Open Doors to Other Genetically Correctable Skin Disorders



#### Estimated ~\$750M Total Addressable Market in RDEB

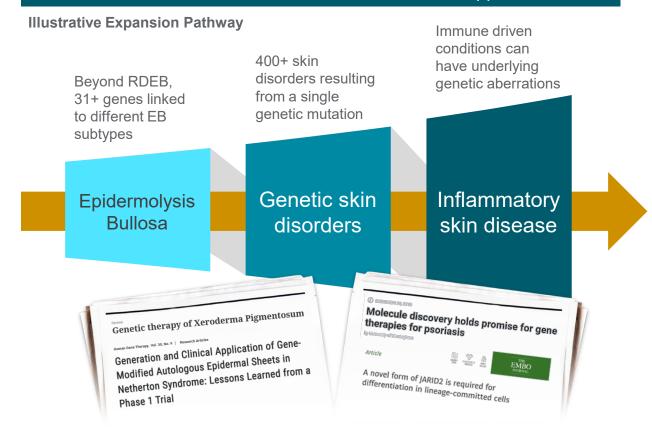


Prevalence of Recessive Dystrophic EB in the United States



Per Patient / Treatment Price Range of Marketed Cell & Gene Therapies

## Multi-Billion Dollar Market for Potential Future Indications in Skin, Which Could be Amenable to Gene Correction Approaches



Has et al, "Consensus reclassification of inherited epidermolysis bullosa and other disorders with skin fragility." Br J of Dermatology. 2020. Range 1,100-2,500. 2. DEB prevalence estimated as 6/million. RDEB estimated to be approximately half of DEB prevalence = 3/million. Range: 1.35- 8/million. Fine et al, "Epidemiology of Inherited Epidermolysis Bullosa..." JAMA, 2016.3. Pricing derived from publicly released information on list price of approved cell & gene therapy products. 4. (RHS) Pubmed searches for publications as noted.

In the U.S., RECELL is approved for acute thermal burns in patients > 18 years only (see www.recellsystem.com). Use of RECELL in other indications is either (1) limited by United States law to investigational use; or (2) otherwise prohibited. In the United States, RECELL is not approved for use in pediatrics. Use of RECELL in this case was performed internationally where the indication is approved.

## Exploring Novel RNA-Based Approach for Rejuvenation





- Patented RNA technology for delivery of telomerase enzyme to aged cells
- Demonstrated reversal of aging and return of functionality in cells of progeria patients (human model of accelerated aging)
- Patented and proprietary Spray-On Skin Cells technology and device (RECELL)
- **Expertise in skin** regeneration, including in preclinical models
- Strong track record and expertise in clinical development and commercialization

#### Multi-Billion Dollar Market Presents a Sizeable Opportunity

- >\$16.5B spent in aesthetic procedures per year (US)\*
- >3M aesthetic procedures per year (US) aimed to improve skin tightness, texture & evenness in skin tone\*
- Consumers desire superior results over current offerings
- Personalized, cellular-level approaches to skin rejuvenation, developed with robust evidence, is an area of significant interest

Sponsored research underway exploring use of telomerase for molecular reversal of skin cell aging



Corporate



## Intellectual Property: Robust and Expanding Patent Estate



#### ROBUST PROTECTION ACROSS PATENT FAMILIES

Cell Suspension
Preparation Technique
and Use

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

Systems and Methods for Tissue Processing and Preparation of Cell Suspension Therefrom

Automated system for preparing cell suspension, next generation sprayer and method of production

A global total of 48 granted patents, 17 pending patent applications Expiration from 2022 (2024 with Hatch-Waxman) to 2034

## EXPANDING PORTFOLIO TO SUPPORT CURRENT AND FUTURE INDICATIONS



Next Generation RECELL devices to improve ease of use in burns and pipeline indications



Option to license patented technology for telomerase mRNA that has the potential to reverse aging of skin cells



Option to license technologies for suspension-based delivery of genetically modified cells, with applications to genetic skin disorders

### **Experienced Leadership Team**





Dr. Michael S. Perry CEO >30 years experience



CCO
20 years experience

Erin Liberto



Andrew Quick CTO 25 years experience



Kathy McGee COO 25 years experience



Donna Shiroma General Counsel 20 years experience

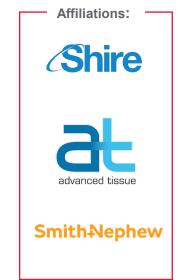


Sean Ekins
V.P. of Finance
19 years experience

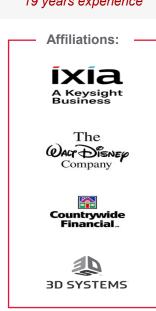












## Financial Overview (USD)



(in \$000s)	FY 2018	FY 2019	FY 2020
U.S. Sales	<del>-</del>	4,404	13,800
Total Revenue	929	5,474	14,263
BARDA Income	7,734	5,921	3,926
Cash	10,986	20,174	73,639

12 Months Ended June 30

#### Analysts

- Josh Jennings, Cowen (U.S.)
- Brooks O'Neil, Lake Street (U.S.)
- Kevin DeGeeter, Oppenheimer (U.S.)

- Ryan Zimmerman, BTIG (U.S.)
- John Hester, Bell Potter (AUS)
- Chris Kallos, MST (AUS)

\$19.11 Share Price<sup>1</sup>

\$411 Million Market Capitalization<sup>1</sup>

> \$0.0 (Zero) Debt

Nasdaq ticker symbol: RCEL

ASX ticker symbol:

AVH

1. RCEL as of 1-4-2021

## Value-Creating Milestones



#### Key Accomplishments in CY '20



- RECELL U.S. revenue growth YoY of 78%
- Cumulative U.S. product revenue since
   September 2018 FDA approval exceeding \$28M
- U.S. Redomiciliation
- First patient enrolled in 3 pivotal studies (Pediatric Scalds, Soft Tissue Repair and Vitiligo)
- Executed two sponsored research agreements with options to license IP globally

## Upcoming Key Milestones in CY '21



- Vitiligo: Last patient enrolled in clinical study H2
- EB: Initial proof of concept for delivery of genetically modified cells in suspension - H1
- Telomerase: Initial proof of concept on impact of telomerase on skin in a mouse model - H2
- Delivery of RECELL devices into BARDA Vendor Managed Inventory in H2
- Japan: PMDA Approval H2

## AVITA Medical: Transforming Lives with Skin Regeneration

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- Revolutionary treatment using a patient's own skin for life-changing outcomes
- Published health economic model demonstrating hospital cost savings

- FDA-approved RECELL System for the treatment of acute thermal burns
- Platform expansion into a \$1.5B U.S. serviceable market opportunity
  - Vitiligo; Soft Tissue Reconstruction; Pediatric Scalds
- Further potential for cell-based gene therapy and aesthetics
- Successful commercial launch
- Fiscal Q2 RECELL System reported revenue of \$5M; Cash of \$60M ending 2020

Life-Changing
Outcomes



Platform Technology



Significant Expansion Potential



#### Risk Factors and Disclosures



- 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.
- "Millennium Research Group, Inc. ("MRG") makes no representation or warranty as to the accuracy or completeness of the data ("MRG Materials") set forth herein and shall have, and accept, no liability of any kind, whether in contract, tort (including negligence) or otherwise, to any third party arising from or related to use of the MRG Materials by Customer. Any use which Customer or a third party makes of the MRG Materials, or any reliance on it, or decisions to be made based on it, are the sole responsibilities of Customer and such third party. In no way shall any data appearing in the MRG Materials amount to any form of prediction of future events or circumstances and no such reliance may be inferred or implied."

## Important Safety Information



- INDICATIONS FOR USE: The RECELL® Autologous Cell Harvesting Device is indicated for the treatment of acute thermal burn wounds in patients 18 years of age and older. The RECELL® device is used by an appropriately-licensed healthcare professional at the patient's point of care to prepare autologous Regenerative Epidermal Suspension (RES™) 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® 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® 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® Enzyme is animal derived and freedom from infectious agents cannot be guaranteed.
- PRECAUTIONS: RECELL® is not intended for use without meshed autograft for treatment of full-thickness burn wounds. The safety and effectiveness of RECELL® without meshed autograft have not been established for treatment of partial-thickness burn wounds: on the hands and articulating joints, >320 cm2, in patients with wounds totaling >20% total body surface area (TBSA). The safety and effectiveness of RECELL® 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® 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 <a href="https://www.RECELLSYSTEM.COM">www.RECELLSYSTEM.COM</a>



Appendix



#### **AVITA Medical Board of Directors**





Dr. Michael S. Perry
CEO, AVITA Medical



Non-Executive Director Sonic Healthcare Limited, Non-Executive Director Unison Housing Ltd

Lou Panaccio, Chairman



Professor Emeritus Burnet Institute,
Principle Research Fellow of the
Australian National Health & Medical
Research Council, Principal
Specialist in Infectious Diseases at

Specialist in Infectious Diseases at the Alfred Hospital, Adjunct Professor of Medicine and Infectious Diseases at Monash University, Member of Australian Institute of Company Directors, Director of St Vincent's Health Australia, Non-Executive Board Member of Sonic

Healthcare Ltd

**Professor Suzanne Crowe** 



Jeremy Curnock Cook

Managing Director of
Bioscience Managers Pty
Ltd, Chairman of
International Bioscience
Managers Ltd., NonExecutive Director of
Adherium Ltd., Director of
AmpliPhi Biosciences
Corporation, Inc., Director
for Sea Dragon Limited



Louis Drapeau

## **BARDA** Program



- U.S. Biomedical Advanced Research and Development Authority
  - Mandate: disaster preparedness and response
- The RECELL System was the first FDA approved product in the BARDA portfolio
- Providing sizable non-dilutive funding
  - Total estimated contract value \$80.1 million
  - Procuring RECELL systems into Vendor Managed Inventory
- Major programs supported:
  - PMA
  - Health Economic Model
  - Pediatric Clinical Trials
  - Disaster Preparedness Inventory







## Japan Is an Attractive Opportunity for AVITA Medical



- On March 3, 2019, AVITA announced a collaboration with COSMOTEC Company, Ltd, an M3 Group company to market and
  distribute the RECELL System for the treatment of burns and other wounds in Japan. M3 Inc. is a publicly traded company on
  the Tokyo Stock Exchange providing services to key global markets in healthcare and life sciences.
- Cosmotec is pursuing a broad label in Japan which could cover both acute & chronic wounds as well as Vitiligo. They are in active consultations with the PMDA and we anticipate approval to market the RECELL System in Japan on H2 of CY 2021.
- Japan is the second largest healthcare market in the world. Large patient populations coupled with generally attractive reimbursement coverage makes Japan an attractive market for the RECELL System

#### KEY PATIENT POPULATIONS IN JAPAN

Burn

~6,000
Patients treat

Patients treated severe burns per year

Vitiligo

~2 million

Patients Suffer from Vitiligo

Trauma

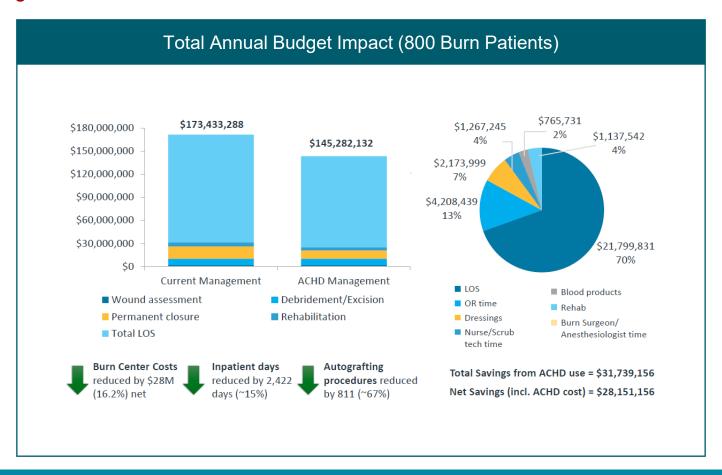
~22,000

RECELL Eligible Trauma Procedures

# Health Economic Model Demonstrates RECELL Cost Savings



2019 ABA presentation using Arizona Burn Center data



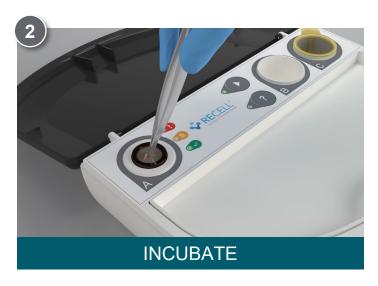
Estimated savings of \$28 million (16%) annually for single burn center

## RECELL Process For Autologous Cell Harvesting and Application

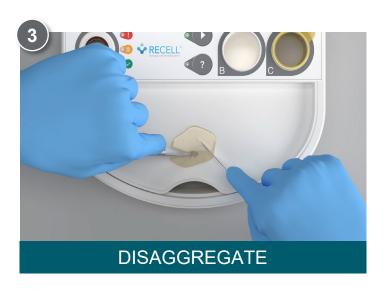














## Flexible Treatment Offering – Small Burns & Pigmentation



31-year-old female | -11% TBSA | DPT Face | RECELL alone



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 alone



After 24 days of no progressive healing with allograft, 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

### Point-of-Care Treatment for Fast Treatment



#### 85-year-old female | ~5% BSA | Mixed-Depth Burn to Forearm | RECELL + 2:1 STSG



Mixed-depth flame burn injury

Wound bed debrided



Spray-On Skin Cells were applied in combination with 2:1 STSG for immediate treatment



100% wound closure by week 2



Excellent pigmentation match and function of forearm.

No additional surgeries required.

## Restoration of Pigmentation in Full-Thickness Facial Burn



#### 56-year-old male | ~5% BSA | FT Burn to Face | RECELL Alone



Patient treated with Spray-On Skin Cells 12 days after traditional standard of care (xenograft) failed.



100% wound closure by post-RECELL treatment day 6.



Restoration of pigmentation by one month, without significant areas of hyper/hypopigmentation.

## Treatment of Full-Thickness Injury with Bone and Tendon Exposed **avita**



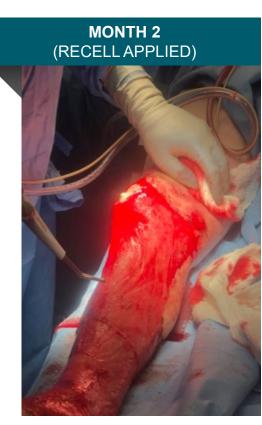
#### 73-year-old male | ~12% BSA | FT Burn to Leg | RECELL + 3:1 STSG



Tibia and tendon exposed after 38 days of traditional standard wound care (SOC)



Wound excised and covered with Biodegradable Temporizing Matrix (BTM)



BTM removed, wound cleaned, Spray-On Skin Cells applied after 5 weeks of BTM

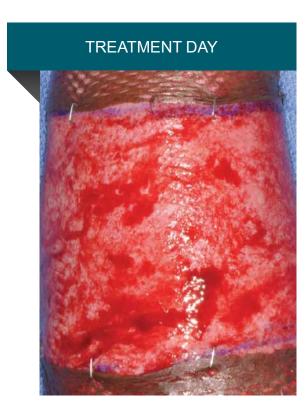


Patient fully ambulatory with absence of durability issues

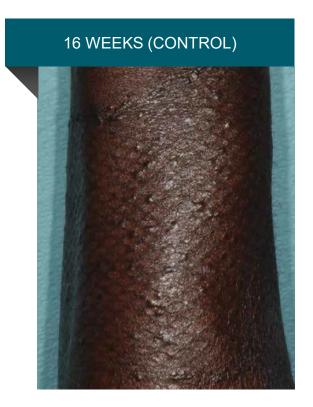
## Reduced Donor Skin Requirements Compared to Control



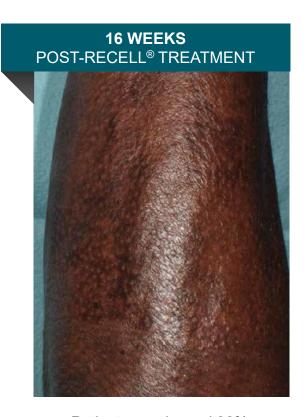
#### 48-year-old male | <10% BSA | DPT Forearm | RECELL alone



Patient part of randomized clinical trial. Spray-On Skin Cells were applied to treatment area and compared to control area with 2:1 STSG.



Vancouver Scar Scale had poorer scores in pigmentation and scar height for the control area.



Patient experienced 98% reduction in donor skin requirements with RECELL and better pigmentation and scar scores.