

One Platform.
Endless Possibilities.

February 2022



NASDAQ: RCEL

ASX: AVH

## Legal Disclaimers



Certain statements in this presentation and the accompanying oral commentary are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this presentation, including statements regarding our future financial condition, technology platform, development strategy, prospective products, pipeline and milestones, regulatory objectives, expected payments from and outcomes of collaborations, and likelihood of success, are forward-looking statements. Such statements are predictions only and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, among others, the costs, timing and results of clinical trials and other development activities; the uncertainties inherent in the initiation and enrollment of clinical trials; the uncertainties associated with the COVID-19 pandemic; the unpredictability of the timing and results of regulatory submissions and reviews; market acceptance for approved products and innovative therapeutic treatments; competition; the possible impairment of, inability to obtain and costs of obtaining intellectual property rights; and possible safety or efficacy concerns, general business, financial and accounting risks and litigation. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. More information concerning AVITA Medical as well as the aforementioned risks and uncertainties is available in our public fillings with the U.S. Securities and Exchange Commission, including our most recent Transition Report on Form 10-KT pe

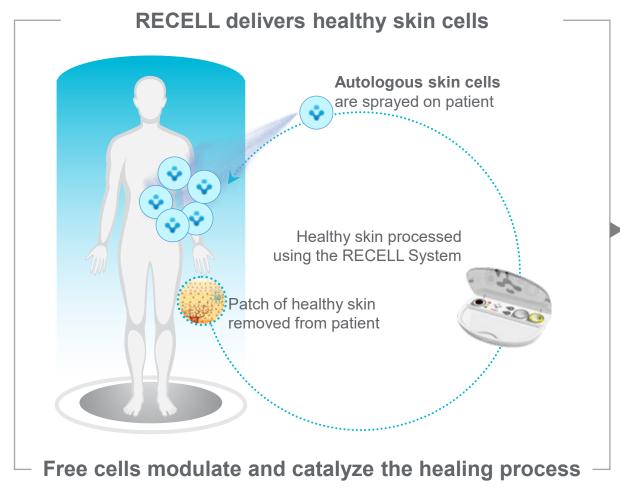
AVITA Medical's products are Rx only. Please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events.

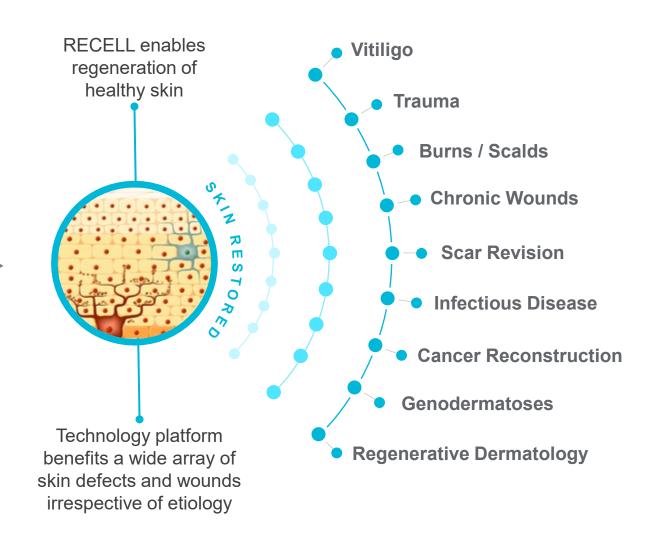
In the United States, RECELL® is approved for use in patients suffering acute thermal burns. Use of RECELL in other patient populations is either prohibited by United States law or may be made available pursuant to a relevant investigational device exemption granted by the FDA (and likewise limited by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

## One Platform. Endless Possibilities.









## Value Creation



## Recent Key Accomplishments



- Quarter Ending December '21, Total Revenue Growth of +35% vs Same Quarter Prior Year
- FDA Approval of New "Ease of Use" RECELL Device
- PMDA Approval of Burns in Japan
- Vitiligo Pivotal Trial: Enrollment Completed
- Soft Tissue Pivotal Trial: Enrollment Completed
- Transitional Pass-Through Payment Application Approved by CMS for Reimbursement in Outpatients
- EB: Initial Proof of Concept for Delivery of Genetically Modified Skin Cells in Suspension
- Telomerase/Rejuvenation: Initial Proof of Concept on Delivery of Reverse-Aged Skin Cells

## Projected Key Milestones



	<ul> <li>Top Line Results and Vitiligo FDA Submission / Vitiligo Commercial launch</li> <li>Top Line Results and Soft Tissue FDA Submission / Soft Tissue Commercial Launch</li> </ul>	H2 22 / H2 23
	<ul> <li>Outpatient Launch</li> <li>Launch of New "Ease of Use" RECELL Device</li> </ul>	H1 22
	<ul> <li>IND Enabling Studies (EB &amp; Rejuvenation)</li> <li>Reimbursement &amp; Launch of Burns in Japan</li> </ul>	H2 22



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 (U.S.)				APPROVED	<b>A</b>
RECELL® Japan				APPROVED	大
Vitiligo (U.S.)		ENF	ROLLMENT COMPLETE		
Soft Tissue Reconstruction (U.S.)		ENF	ROLLMENT COMPLETE		
Early-Stage Research Programs					ı
Epidermolysis Bullosa					
Rejuvenation					
Innovation	CONCEPT	DESIGN	SUBMISSION	APPROVAL	ı
New Device: Improved Ease of Use				APPROVED	*
New Device: Fully Automated					

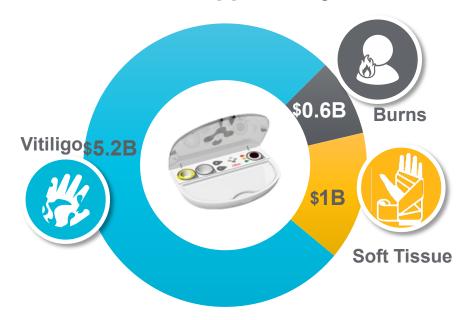
## **Focused Effort on Business Development to Supplement Pipeline**

## Market Opportunity of Pipeline Exceeds \$22 Billion



#### **EXISTING PLATFORM**

~\$6.8B Opportunity



#### NEW PLATFORMS: CELL BASED GENE THERAPY



> \$22 Billion in Combined TOTAL ADDRESSABLE MARKET

## Current Platform: Efficacy is Well Demonstrated



PRODUCT IS WELL STUDIED			
	Patients (in Published Studies)	Number of Publications & Presentations	
ACUTE WOUNDS (Including Thermal Burns)	1,772	206	
DEFECTS/ VITILIGO	453	57	
CHRONIC WOUNDS	143	17	

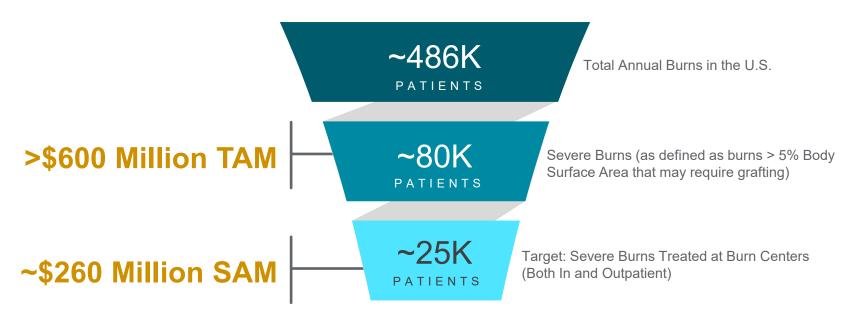
Highly De-risked
Pipeline with
>15,000 Patients
Treated Globally

A Common Goal: Full Skin Restoration (Re-epithelialization and Re-pigmentation)

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

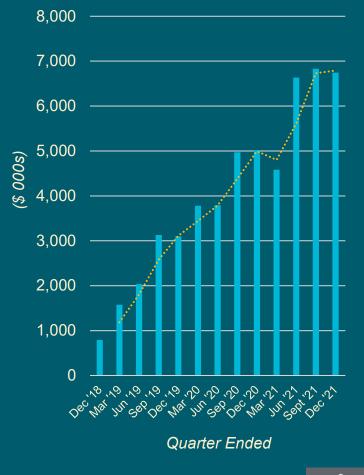


#### Patient Funnel and Addressable Market



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

# U.S. RECELL Commercial Sales Since Approval



## New C-Code Provides Additional Payment in the Outpatient Setting avita



The Centers for Medicare and Medicaid Services (CMS) created a new technology Transitional Pass-Through (TPT) Payment - C Code for billing RECELL devices when used in procedures performed in the hospital outpatient and ambulatory surgery center (ASC) settings as of Jan 1 2022

#### C1832:

Autograft suspension, including cell processing and application, and all system components

Code provides additional payment which offsets the cost of the device for Medicare beneficiaries over a 2-3 year period before converting to a permanent code

This is a Medicare specific code, which we estimate covers ~ 15% of patient lives



AVITA will ensure broad commercial payer acceptance & coverage before pursuing a full commercial launch

The New Code is not Indication (Burns) Specific and Lays the Foundation for Growth in Soft Tissue

## New Ease of Use Device Now FDA Approved





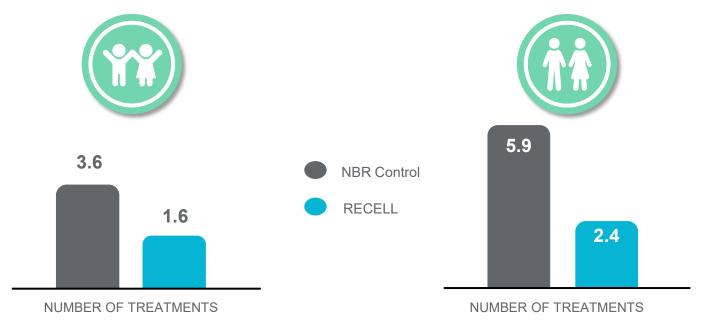
Only 1 Set of Hands Required in the Sterile Field; Steps Reduced By 1/3rd

\* Market Research March 2020 HCPs N=15

## FDA Approval in Pediatric Full-Thickness & Larger Burns



## FEWER PROCEDURES REQUIRED FOR DEFINITIVE CLOSURE VS CONVENTIONAL AUTOGRAFT<sup>1</sup>



**Pediatric Patients** 

**56% fewer** mean procedures with RECELL (N=284) p < 0.0001

#### Adults with >50% TBSA

**60% fewer** mean procedures with RECELL (N=318) p < 0.0001



~25% of all burns occur in children

80% of RECELL Customers Stated that these New Label Enhancements Will Positively Impact Their Usage of RECELL\*

<sup>1.</sup> Instructions for Use. RECELL® Autologous Cell Harvesting Device

<sup>2.</sup> NBR – National Burns Repository

<sup>\*</sup> N = 41, "will significantly or somewhat impact RECELL usage"

## Approval of Burns Received in Japan



#### **BACKGROUND**



**AVITA Commercial Partner:** 

COSMOTEC, an M3 Company



**INDICATION: Burns** 

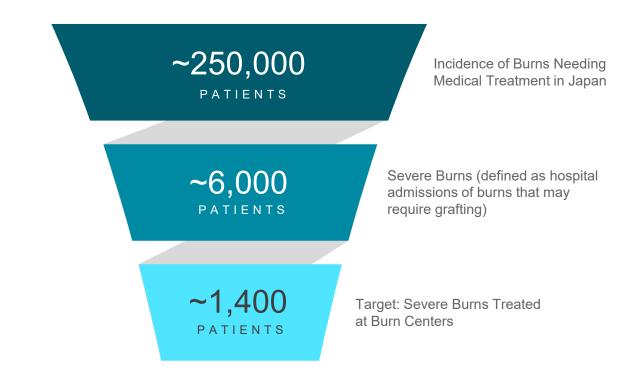
Soft Tissue and Vitiligo to Follow Based on U.S. Pivotal Clinical Data



LAUNCH:

Following Ministry of Health, Labour, and Welfare (MHLW) decision on reimbursement pricing, anticipated June 2022

#### PATIENT FUNNEL - BURNS ADDRESSABLE MARKET



#### Reimbursement Anticipated in June 2022 with Commercial Launch Following Thereafter

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

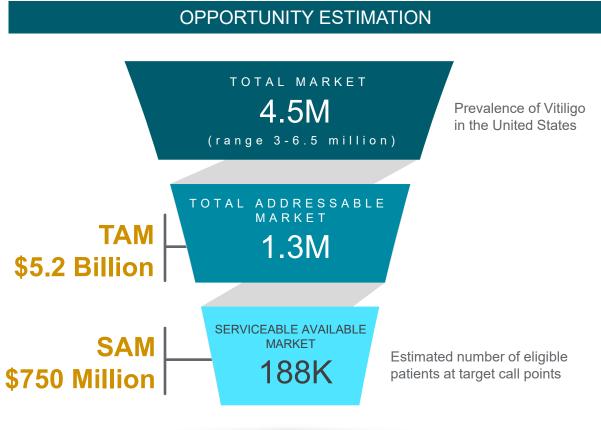




# No FDA-approved medical treatments; extremely low patient and physician satisfaction with existing products

#### Vitiligo impacts quality of life (QoL) -

25% of patients with vitiligo reported a DLQI >10, which indicates severe QoL reductions, compared with 34% in psoriasis patients

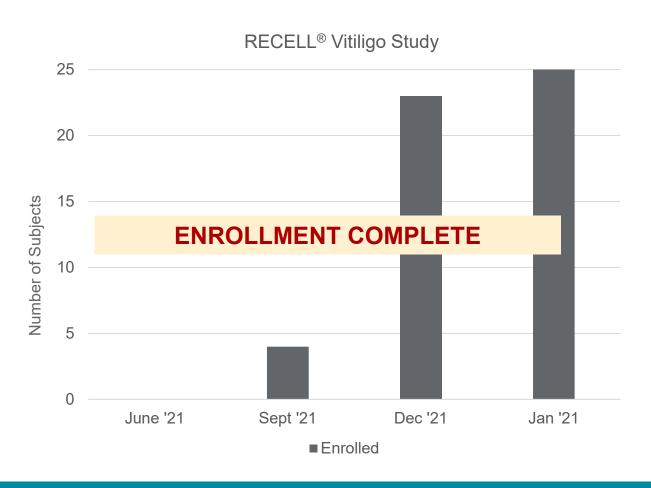


Concentrated HCP base: Estimating <1,000 procedural dermatologists and plastic surgeons with interest in treating vitiligo

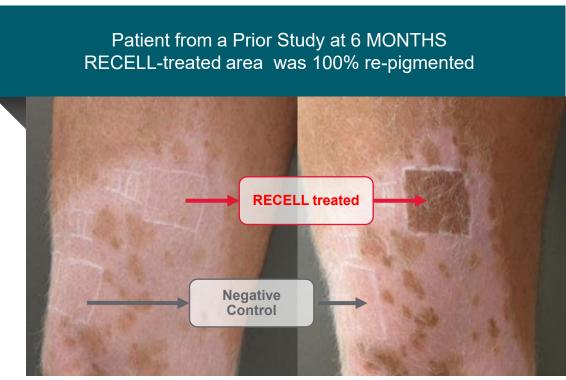
## Vitiligo Study Enrollment Complete



#### Blinded, Randomized, Study Evaluating RECELL for Repigmentation of Stable Vitiligo



FDA Submission Expected in H2 '22 with Approval in H2 '23



Komen L, Vrijman C, Tjin EP, Krebbers G, de Rie MA, Luiten RM, van der Veen JW, Wolkerstorfer A. Autologous cell suspension transplantation using a cell extraction device in segmental vitiligo and piebaldism patients: a randomized controlled pilot study.

Journal of the American Academy of Dermatology. 2015 Jul;73(1):170-2.

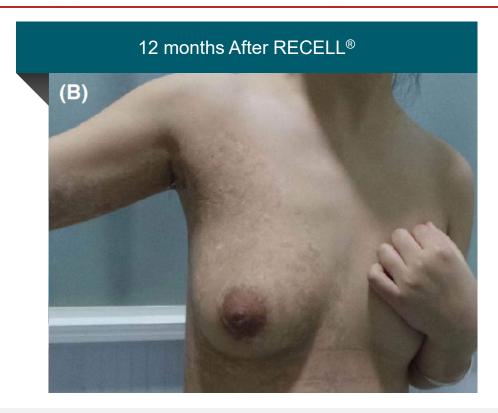
#### POTENTIAL RECELL BENEFITS

For Stable Vitiligo: Segmental & Non-Segmental **Durable:** One-time treatment

## RECELL Case: Repigmentation of the Nipple-Areola Complex







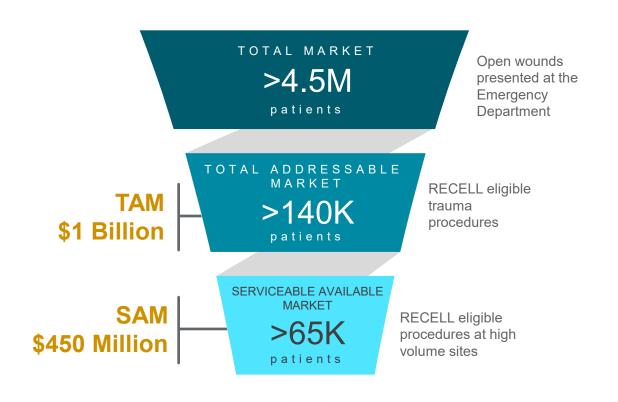
- 23 year old female with vitiligo.
- Donor skin was harvested from adjacent unaffected areas.
- Depigmented epidermis was removed using dermabrasion.
- The cellular suspension was then sprayed on both the recipient and donor areas (expansion ratio ranged from 1:20-1:40).

Established Track Record in Vitiligo: 1,000 patients treated internationally & 12 peer reviewed publications showing positive outcomes

# Soft Tissue Repair Will Expand the Burns Business to Encompass All Acute Wounds

## avita

#### **OPPORTUNITY ESTIMATION**



# Female, pregnant 28-year-old who suffered from a de-gloving Injury



POST DEBRIDEMENT OF INJURY

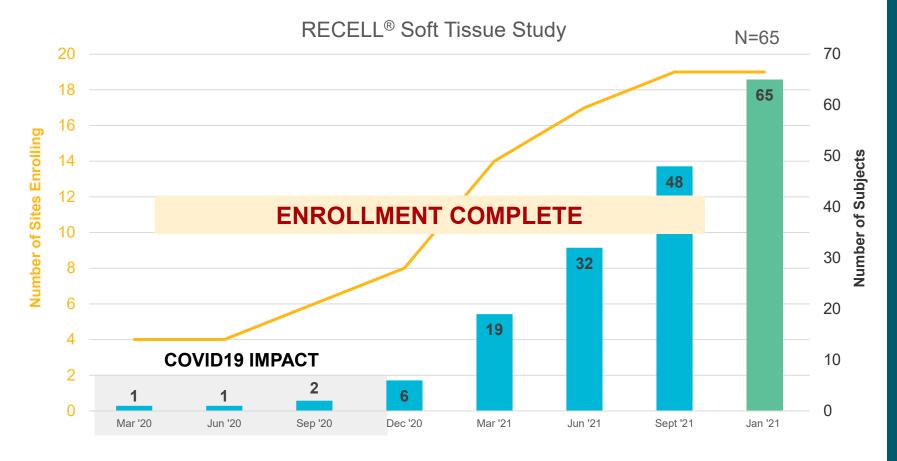


6 MONTH POST-RECELL TREATMENT

Poster: Use of regenerative suspension in the treatment of a complex de-gloving injury. Ian M Smith,

## Early Completion of Soft Tissue Reconstruction Trial

Clinical trial demonstrates use of less donor skin without compromising healing outcomes relative to conventional autografting



#### FDA Submission Expected in H2 '22 with Approval in H2 '23



#### Patient treated for necrotizing fasciitis



TREATMENT DAY



1 YEAR POST-RECELL TREATMENT

Photos courtesy of Kevin Foster, Valleywise Health Medical Center

## Soft Tissue Synergies with Current Commercial Burn Focus



## Expanded Acute Wounds Sales Team Will Target a Total of 366 Centers



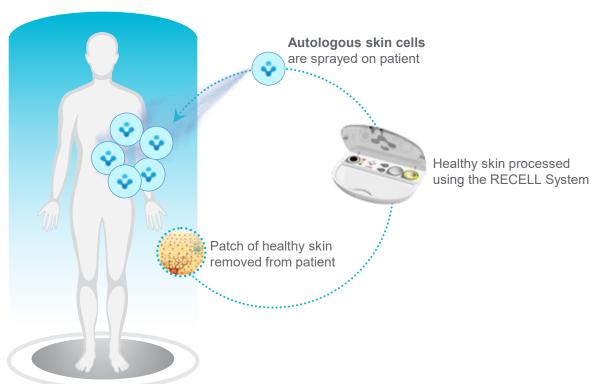
### Large opportunity that leverages existing burns infrastructure

## RECELL in Genetic Skin Defects and Rejuvenation



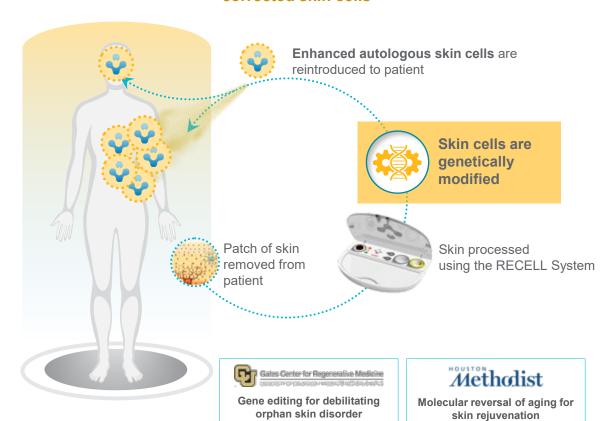
#### **CURRENT PLATFORM**

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



#### **FUTURE PLATFORM**

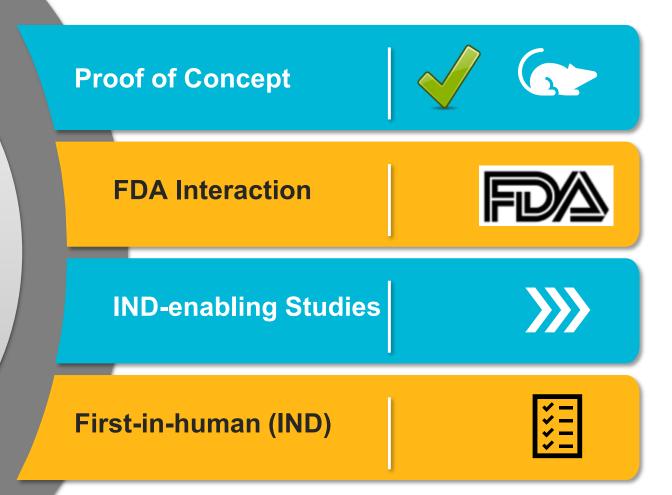
RECELL as a platform for treatment using the patient's corrected skin cells



## Cell and Gene Therapy Development Activity









Program Objective:

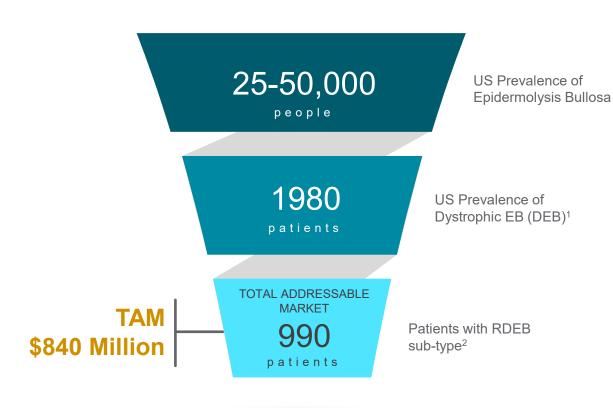
Optimize Spray-On Skin™
Cells with *modified* skin
cells and establish INDreadiness

# Sizeable Market Opportunity Estimated in EB, Given Orphan Pricing Potential



#### **OPPORTUNITY ESTIMATION**

#### POTENTIAL COMPETITIVE ADVANTAGES





Suspension is potentially more cost effective to generate, transport and apply vs cultured sheet grafts



iPSC-based technology enables banking of cells for future treatments

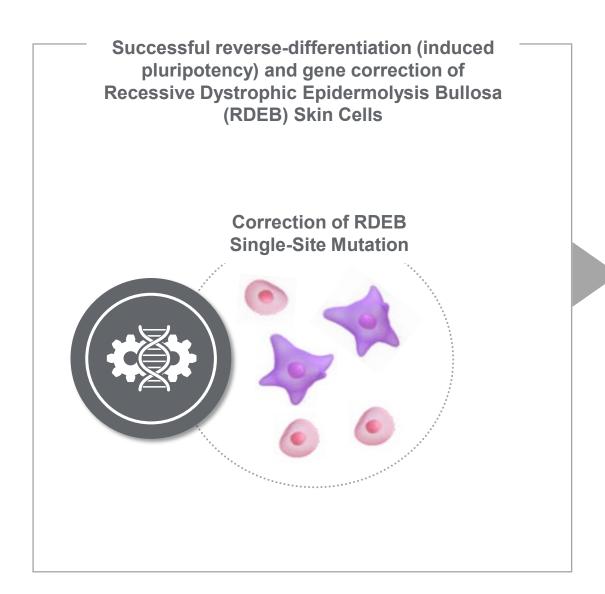


Ex vivo gene editing of skin cells has a safety advantage over *in vivo* gene therapeutics

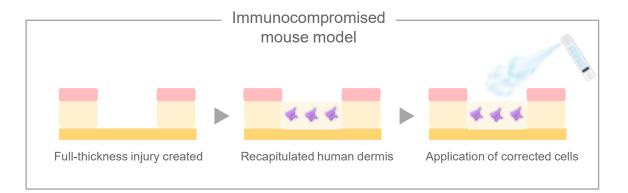
### ~\$840M target US market opportunity, assuming \$850,0004 per patient / treatment

## Skin Regeneration from Corrected Autologous Skin Cell Suspension





#### In Vivo Evaluation of Gene-corrected Skin Cells



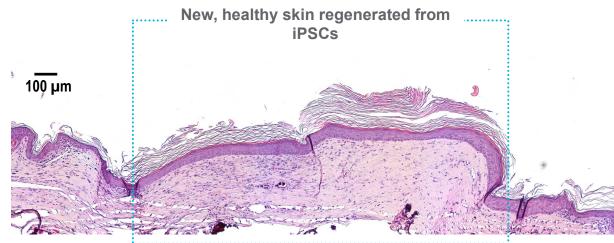


Image courtesy of Gates Center for Regenerative Medicine, University of Colorado

## Exploring Cell-Based Gene Therapy for Epidermolysis Bullosa



#### THE CHALLENGE



#### **DEBILITATING**

Skin fragility, disability, cancer



No FDA-approved treatment, only palliative measures

#### **COST BURDEN**

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

#### THE OPPORTUNITY



**CURATIVE**: Technology for precise correction of genetic defect & banking for future use (vs ameliorating symptoms)



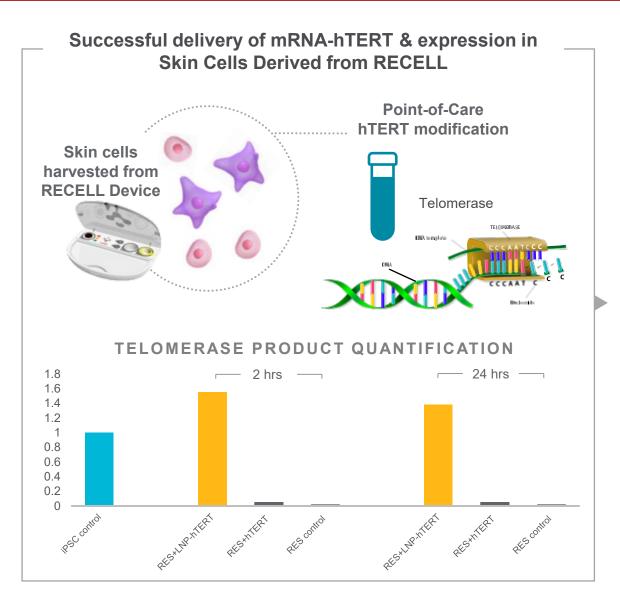
**EFFICIENT**: Suspension-based approach eliminates growth & transport of fragile skin sheets



**CONVENIENT**: Suspension-based product simplifies application onto patient wounds (vs surgical anchoring of epidermal sheets which can result in issues with "take rates")

## Reverse Aging of Skin Cells Derived using the RECELL Device





## In Vivo Evaluation of mRNA-hTERT Modified Skin Cells **Immunocompromised** mouse model Full-thickness injury created Recapitulated dermis Application of containing human fibroblasts modified human cells **On-going Characterization** Reverse-aged Human skin cells Reversal of fibroblast senescence Collagen & elastin markers Time to re-epithelialization

## Exploring Novel RNA-Based Approach for Rejuvenation





Methodist

LEADING MEDICINE

avita edical

- 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

Patient Funnel and Addressable Market

~8.3M

PEOPLE/Yr

People Who Underwent Facial Aesthetic Procedures Aimed at Improving Skin Tightness, Texture & Evenness in Skin Tone <sup>1</sup>

~1M

PATIENTS/Yr

Target: People Who Undergo Aggressive Facial Lifting & Tightening Procedures<sup>2</sup>

\$15 Billion TAM

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



Corporate



## **Financial Overview**



### 12 Months Ended

	June 30			
(USD in \$000s)	2018	2019	2020	2021
Commercial Sales	929	5,474	14,263	21,483
BARDA Sales	-	-	-	7,749
Total Revenue	929	5,474	14,263	29,232
Gross Profit	383	4,203	11,290	23,283
BARDA Income	7,734	5,921	3,926	2,055
Cash, cash equivalents				
and Marketable	10,986	20,174	73,639	110,746
Securities				

(Unaudited) 12 Months Ended	(Unaudited) 12 Months Ended
December 31	December 31
2020	2021
17,918	25,091
-	7,934
17,918	33,025
14,660	26,921
2,534	1,590
59,765	104,852

\$9.03 Share Price<sup>1</sup>

\$225.1 Million Market Capitalization<sup>1</sup>

> \$0.0 (Zero) Debt

#### Analysts

- Matt O'Brien, Piper (U.S.)
- Josh Jennings, Cowen (U.S.)
- Ryan Zimmerman, BTIG (U.S.)
- Brooks O'Neil, Lake Street (U.S.)
- Lyanne Harrison, BofA Global Research (AUS)
- Nicolette Quinn, MorningStar (AUS)

- Chris Kallos, MST (AUS)
- John Hester, Bell Potter (AUS)
- Shane Storey, Wilsons (AUS)

NASDAQ ticker symbol:

ASX ticker symbol:

1. RCEL as 2/25/2022

## A Global Total of 18 Granted Patents & 24 Pending Applications



#### 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 and method of production

Devices, Methods, and Kits for Preparing a Cell Suspension

All-in-one RECELL kit, system, and associated method of use

Methods for Identifying Cell Suspensions with Therapeutic Potential for Skin Regeneration

Method and system for validating the use of a cell suspension for administration to a patient

Bioactive Therapeutic Suspensions with Cellular-Based Supernatant

Bioactive suspension derived from freshly disaggregated tissue, and associated methods of preparation and use

## EXPANDING PORTFOLIO TO SUPPORT CURRENT AND FUTURE INDICATIONS



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



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



Potential to license technologies for suspensionbased delivery of genetically modified cells, with applications to genetic skin disorders

Robust and Expanding Patent Estate: Expiration from 2022 to 2040

## **AVITA Leadership Team**





Dr. Michael S. Perry CEO >30 years experience



Michael Holder CFO >30 years experience



Erin Liberto CCO >20 years experience



**Andrew Quick** CTO >25 years experience



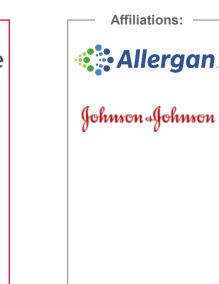
Kathy McGee COO >25 years experience



Donna Shiroma **General Counsel** >20 years experience













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## 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 in the United States as well as in Australia and internationally. Some of these companies have greater financial and other resources than the Company and, as a result, may be in a better position to compete for future business opportunities. There can be no assurance that the Company can compete effectively with these companies.
- Patent Protection: The patent protection that the Company may obtain varies from product to product and country to country and may not be sufficient, including to maintain product exclusivity. Patent rights are also limited in time and do not always provide effective protection for products and services: competitors may successfully avoid patents through design innovation, the Company may not hold sufficient evidence of infringement to bring suit, or the infringement claim may not result in a decision that the rights are valid, enforceable or infringed. Legislation or regulatory actions subsequent to the filing date of a patent application may affect what an applicant is entitled to claim in a pending application and may also affect whether a granted patent can be enforced in certain circumstances. Laws relating to biotechnology remain the subject of ongoing political controversy in some countries. The risk of changed laws affecting patent rights is generally considered greater for the biotechnology field than in other longer established fields.
- Change in government policy and legislation: Any material adverse changes in relevant government policies or legislation of Australia / United States may affect the viability and profitability of the Company, and consequent returns to investors. The activities of the Company are subject to various federal, state and local laws governing prospecting, development, production, taxes, labor standards and occupational health and safety, and other matters.

## Important Safety Information



- INDICATIONS FOR USE: The RECELL® Autologous Cell Harvesting Device is indicated for the treatment of acute thermal burn wounds. The RECELL device is used by an appropriately-licensed healthcare professional at the patient's point of care to prepare autologous RES® Regenerative Epidermal Suspension for direct application to acute partial-thickness thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients.
- 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, and in patients younger than 28 days of age (neonates).
- SPECIAL PATIENT POPULATIONS: The safety and effectiveness of RECELL have not been established for treatment of acute thermal partial-thickness burn wounds in pediatric patients younger than 18 years of age.

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



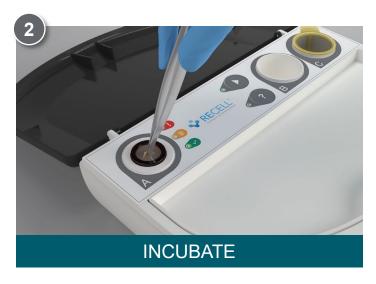


## RECELL Process For Autologous Cell Harvesting and Application















# RECELL Spray-On Skin<sup>TM</sup> 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

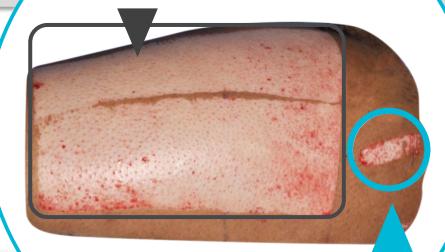
## SPLIT-THICKNESS SKIN GRAFT DONOR SITE

#### **COMPLETE**

Full range of skin cell types with re-pigmentation

#### **ACTIVATED**

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



#### SAFE & EFFECTIVE

2 randomized controlled trials supporting PMA 1st PMA burn product approval ~20 yrs 10K+ patients 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

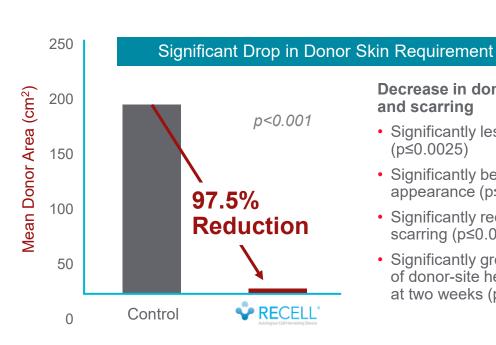
## 1st Premarket Approval Treatment in Burns in 20 Years



Dual multi-center, randomized, controlled premarket approval studies



Published in JBCR and Presented at ABA

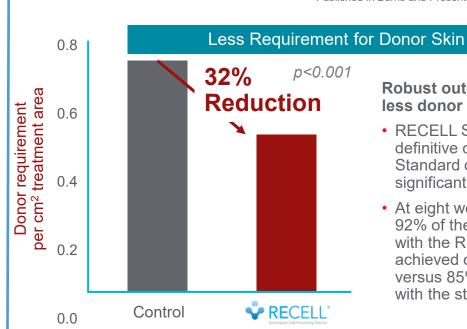


#### Decrease in donor site pain and scarring

- 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

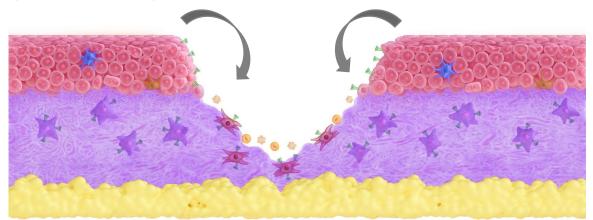
Comparable healing and long-term outcomes for burn sites with significantly less donor skin required

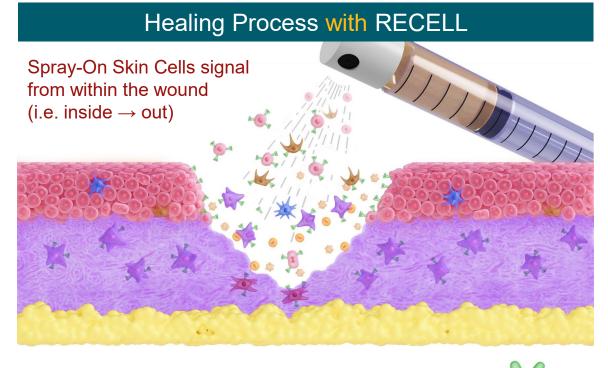
## RECELL "Free Edge" Advantage



### Healing Process without RECELL

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



















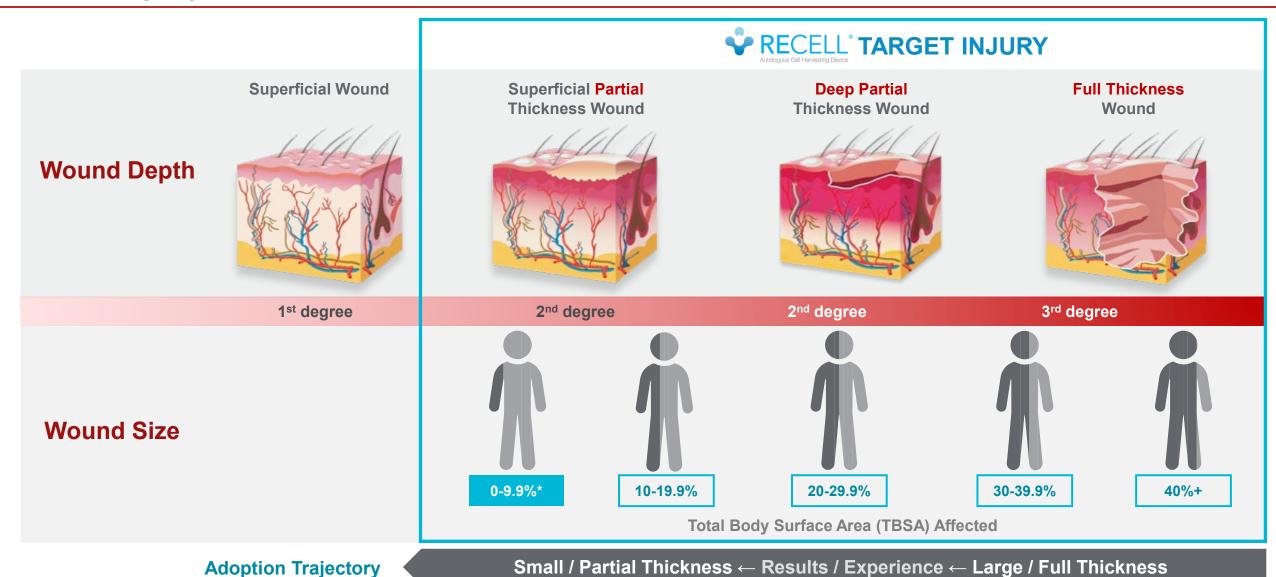






## Skin Injury Framework





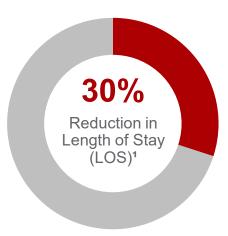
## Published Health Economic Model: Demonstrates Patient and Health Care System Benefits



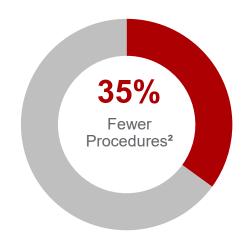
RECELL saves the hospital money in in-patient scenarios where the burn is 10% Total Body Surface Area (TBSA) or greater

#### **Transforming Care**

Can reduce costs and accelerate 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