



# One Platform. Endless Possibilities.

Company Update  
Dr. Michael Perry

December 14, 2021

NASDAQ: RCEL

ASX: AVH



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 us and such risks and uncertainties is available in our public filings with the U.S. Securities and Exchange Commission, including our most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 and our most recent Annual Report on Form 10-K for the year ended June 30, 2020. We are providing this information as of its date and do not undertake any obligation to update or revise it, whether as a result of new information, future events or circumstances or otherwise, except as required by law. Additional information may be available in press releases or other public announcements and public filings made after the date of this presentation.

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<sup>®</sup> 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).

# Key Accomplishments Since Last Shareholder Meeting

## Accomplishments



- Fiscal 2022 RECELL<sup>®</sup> total net revenue growth of 105% vs prior year
- Cumulative U.S. commercial sales since September 2018 FDA approval exceeding \$46M
- Soft Tissue Pivotal Trial: 94% Enrolled
- Vitiligo Pivotal Trial: 83% enrolled and the remaining 17% scheduled before year-end
- Transitional Pass-Through Payment Application Approved by CMS for Reimbursement in the Outpatient Setting Effective January 1<sup>st</sup>, 2022
- FDA Approval of Pediatric Label Expansion
- New Ease of Use RECELL Device Submitted to FDA for Review
- Completion of RECELL Systems delivery to Biomedical Advanced Research and Development Authority (BARDA) under Vendor Managed Inventory Plan for emergency preparedness (\$7.6M revenue)
- AVITA completed \$69.1M Public Offering of Stock on NASDAQ
- Key Additions of Executives: Michael Holder, CFO & Kathy McGee, COO

# 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

**Affiliations:**

NOVARTIS  
Schering-Plough  
BAY CITY CAPITAL  
Baxter  
GENETIC THERAPY, INC.

**Affiliations:**

Immune Cyte  
PREMIER  
CAROLINA LONGEVITY INSTITUTE

**Affiliations:**

Allergan  
Johnson & Johnson

**Affiliations:**

Boston Scientific  
AB  
sonova  
SonaMed Corp

**Affiliations:**

Shire  
at advanced tissue  
SmithNephew

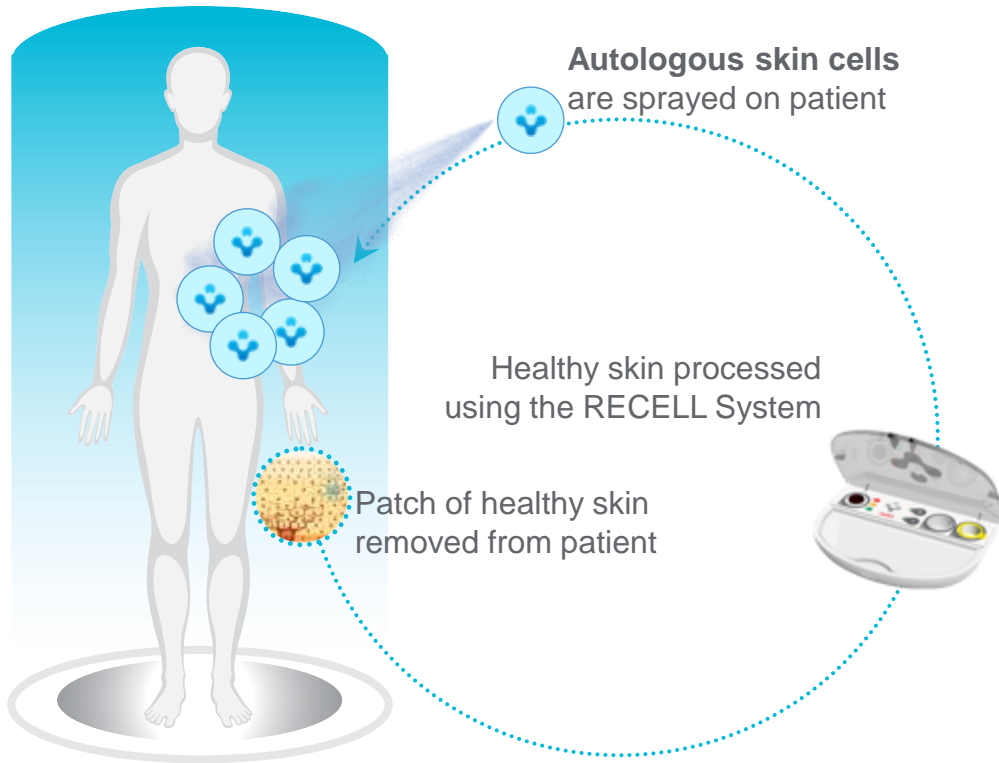
**Affiliations:**

ASCEND THERAPEUTICS  
A BESINS HEALTHCARE Company  
Innovators in Women's Health  
PDL BioPharma  
Johnson & Johnson

# One Platform. Endless Possibilities.

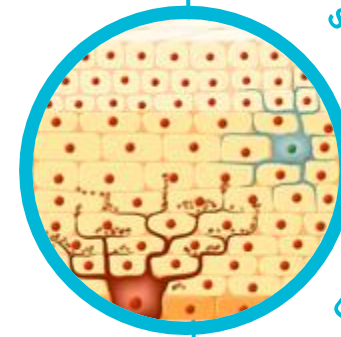


## RECELL delivers healthy skin cells



Free cells modulate and catalyze the healing process

RECELL enables regeneration of healthy skin



Technology platform benefits a wide array of skin defects and wounds irrespective of etiology

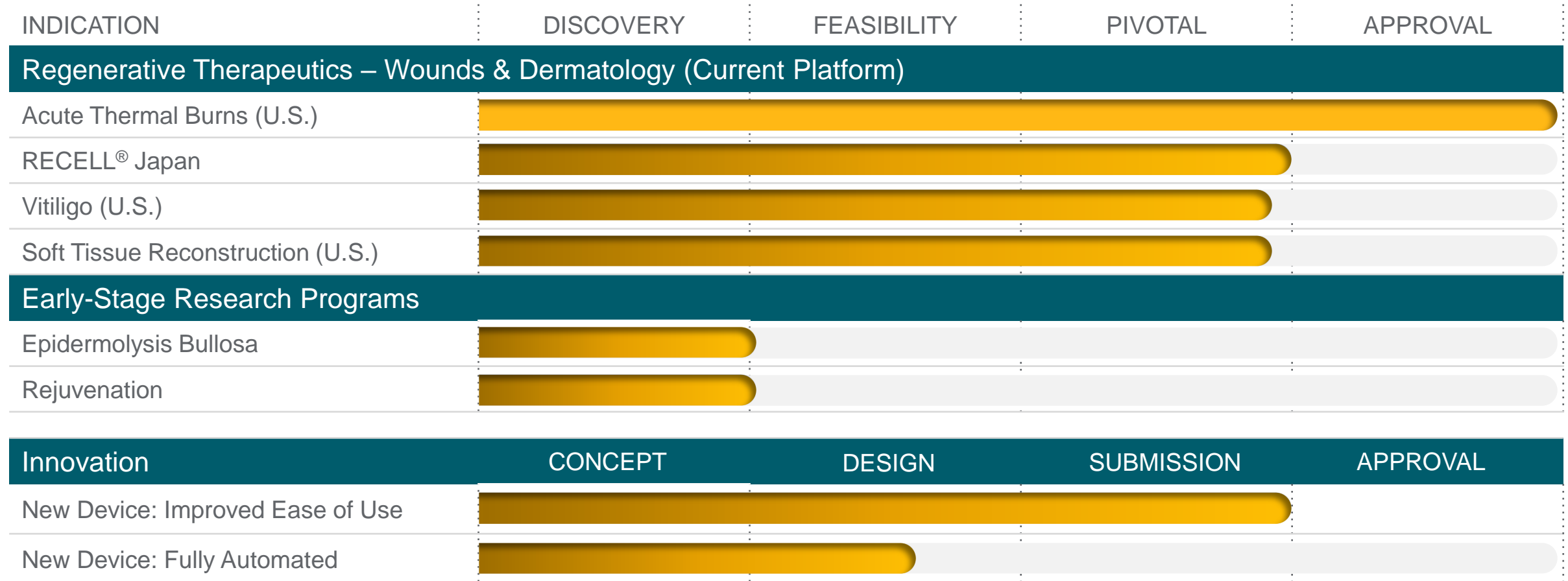
- Vitiligo
- Trauma
- Burns / Scalds
- Chronic Wounds
- Scar Revision
- Infectious Disease
- Cancer Reconstruction
- Genodermatoses
- Regenerative Dermatology



Development Pipeline and Growth Potential

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# Focused Pipeline with Strong Growth Potential

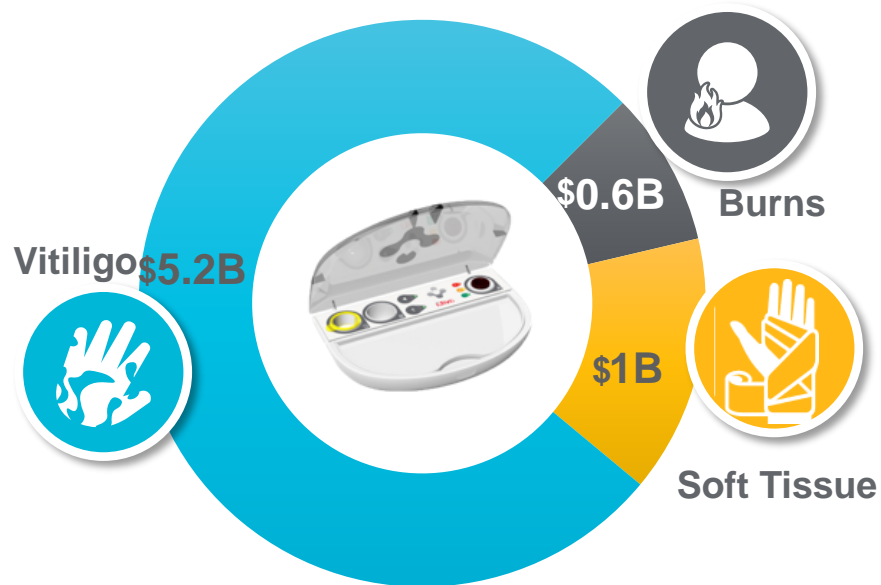


## Focused Effort on Business Development to Supplement Pipeline

# Market Opportunity of Pipeline Exceeds \$22 Billion

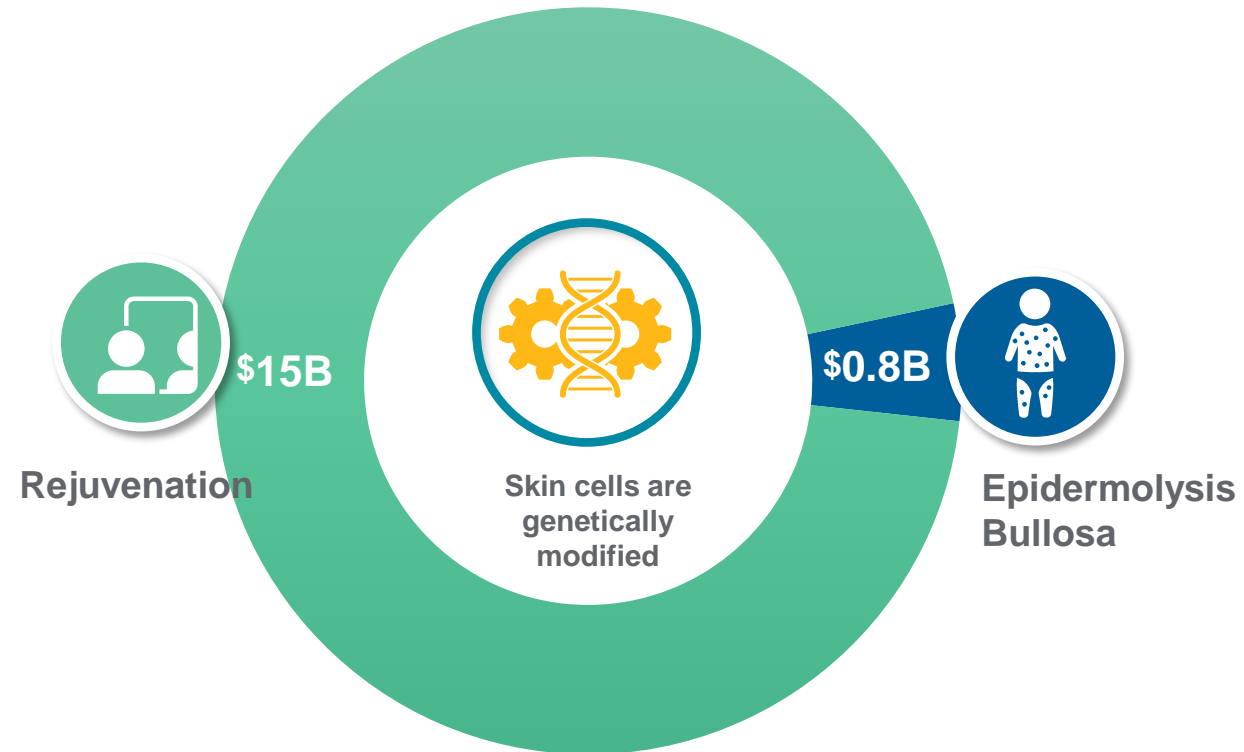
## EXISTING PLATFORM

~\$6.8B Opportunity



## NEW PLATFORMS: CELL BASED GENE THERAPY

~\$15.8B Opportunity



> \$22 Billion in Combined TOTAL ADDRESSABLE MARKET



# Current Platform: Efficacy is Well Demonstrated

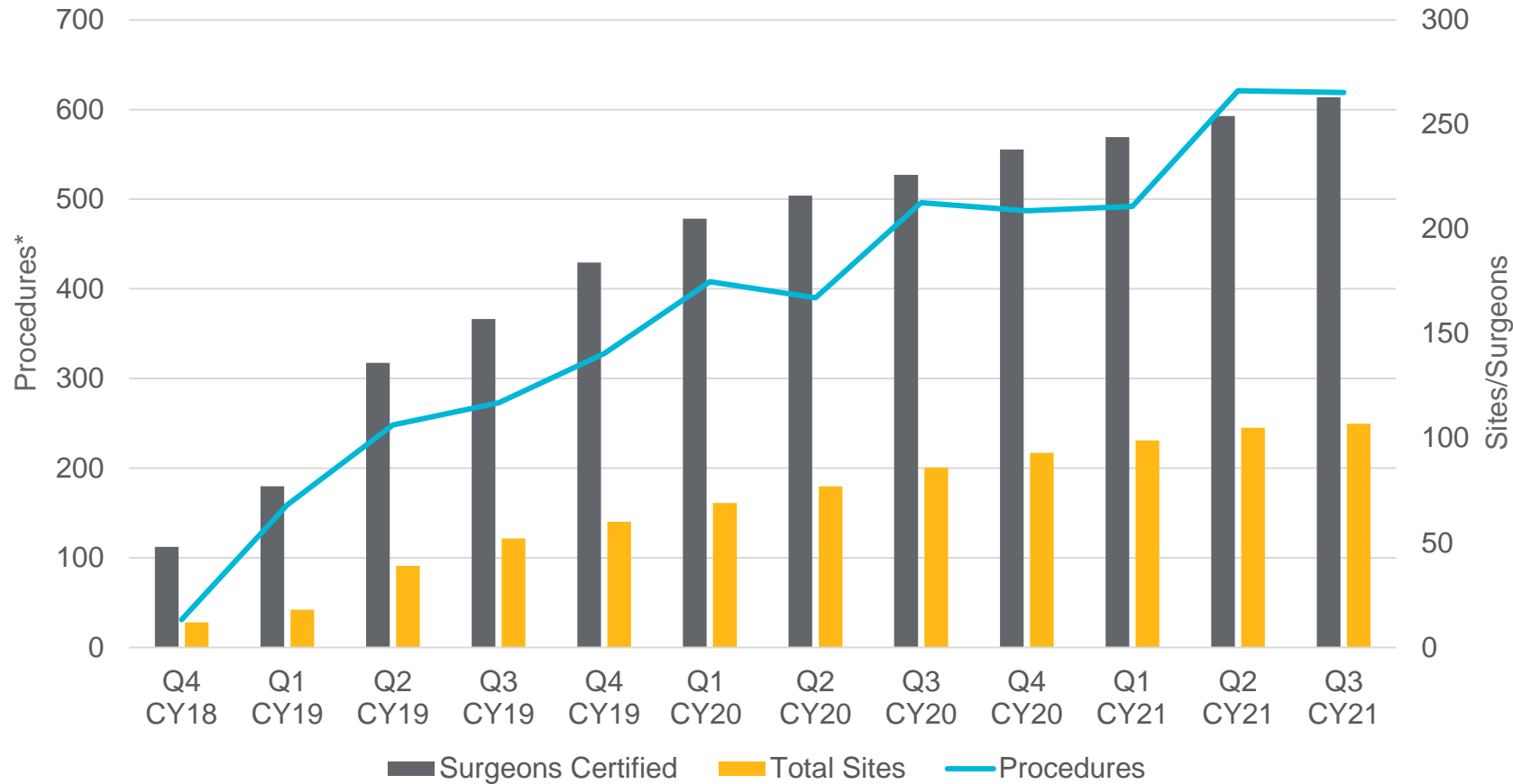
## PRODUCT IS WELL STUDIED

	Patients (in Published Studies)	Number of Publications & Presentations
<b>ACUTE WOUNDS</b> <i>(Including Thermal Burns)</i>	1,772	206
<b>DEFECTS/ VITILIGO</b>	453	57
<b>CHRONIC WOUNDS</b>	143	17

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

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

# Continued Strong Adoption Despite COVID Headwinds



## Accomplishments Since Approval

- 87% Burn Surgeons Certified**
- 78% Burn Sites Activated**
- >4,500 Procedures\***

> \$46 Million in U.S. RECELL Revenue Since Approval

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

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

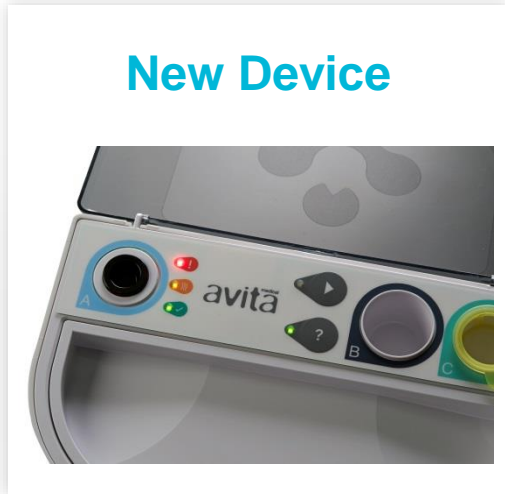
This is a Medicare specific code, which we estimate covers ~ 15% of patient lives



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 Submitted for FDA Approval



Reduced number of steps

Simplified Process

Improved Usability

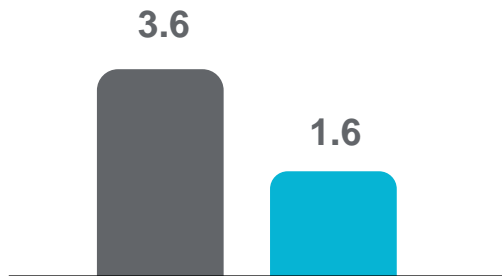


94% of users of the RECELL System believe it will **reduce their workload/allow them to perform other duties\***

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

# FDA Approval in Pediatric Full-Thickness & Larger Burns

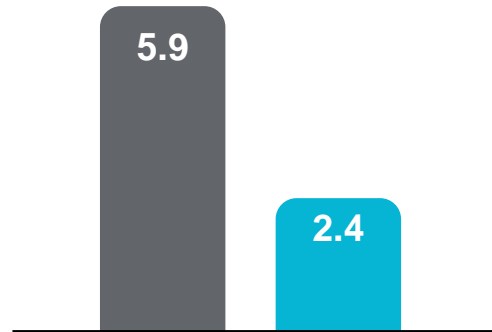
## FEWER PROCEDURES REQUIRED FOR DEFINITIVE CLOSURE VS CONVENTIONAL AUTOGRAFT<sup>1</sup>



NUMBER OF TREATMENTS

### Pediatric Patients

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



NUMBER OF TREATMENTS

### 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**

1. Instructions for Use. RECELL® Autologous Cell Harvesting Device  
2. NBR – National Burns Repository  
\* N = 41, “will significantly or somewhat impact RECELL usage”

# Japan – PMDA Review in the Final Phases

## BACKGROUND



AVITA Commercial Partner:  
COSMOTEC, an M3 Company

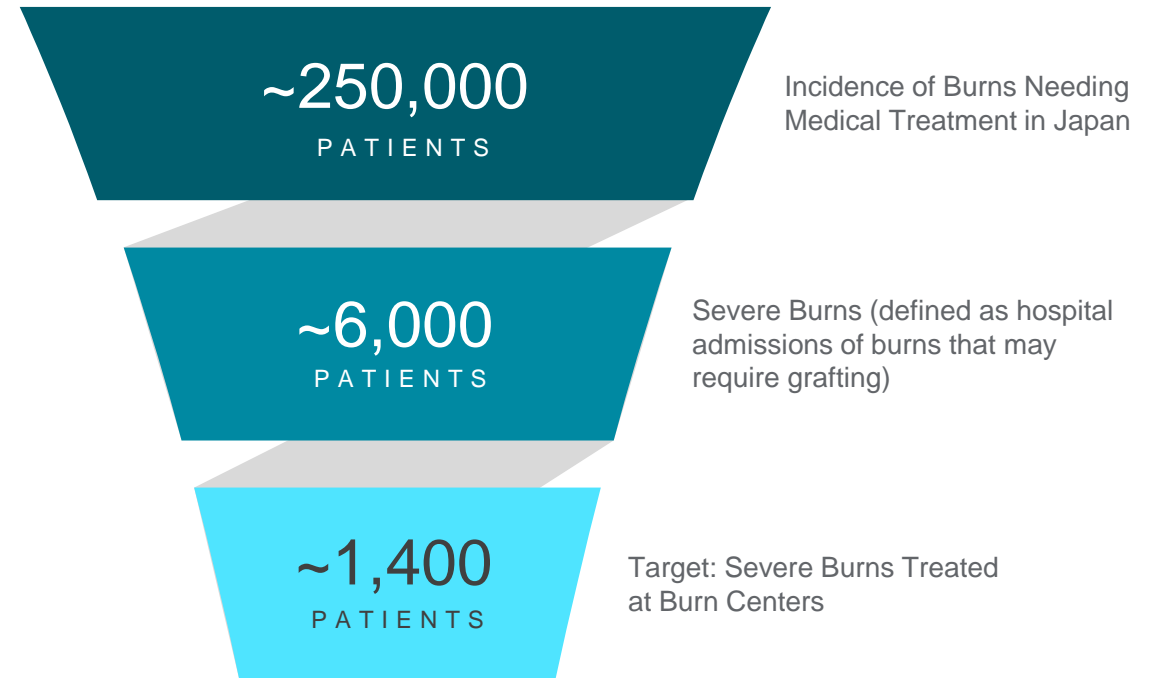


INDICATION: Burns  
Soft Tissue and Vitiligo to Follow Based on U.S.  
Pivotal Clinical Data



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: Unmet Need, No FDA-Approved Products

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

## LIMITED TREATMENT OPTIONS

### Phototherapy

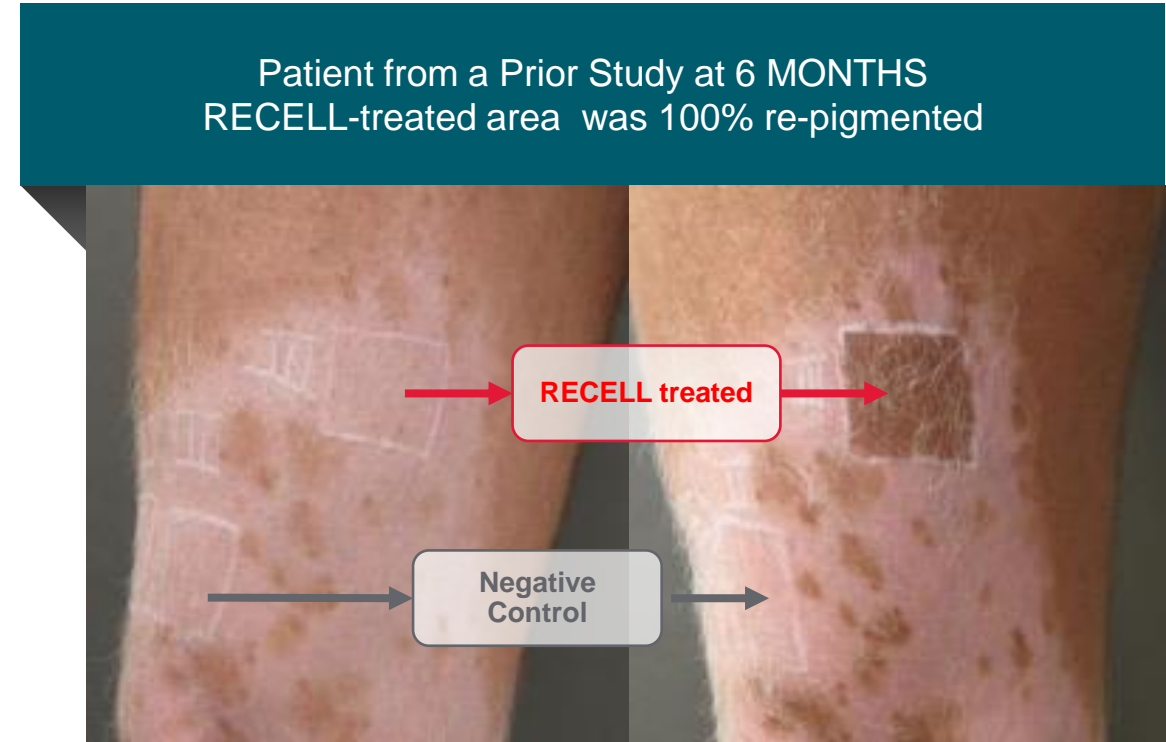
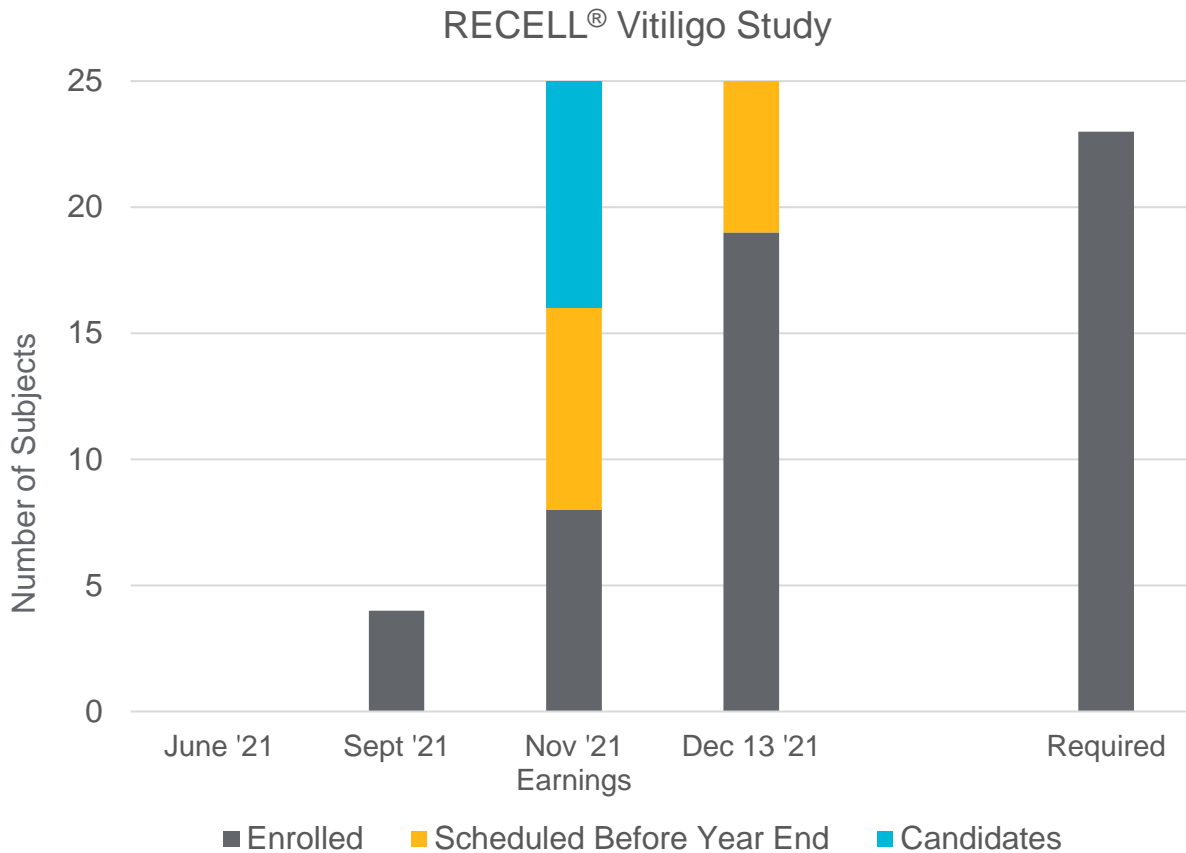
- 2-3 treatments / week for a few months to over a year
- Typically combined with a topical drug
- Not Durable

### Melanocyte-Keratinocyte Transplantation

- For repigmentation of stable lesions
- Requires substantial laboratory equipment
- Performed rarely and only at 3 highly specialized academic centers in the United States

# Vitiligo Study is Close to Completion

Blinded, Randomized, Study Evaluating RECELL for Repigmentation of Stable Vitiligo in 23 Patients



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

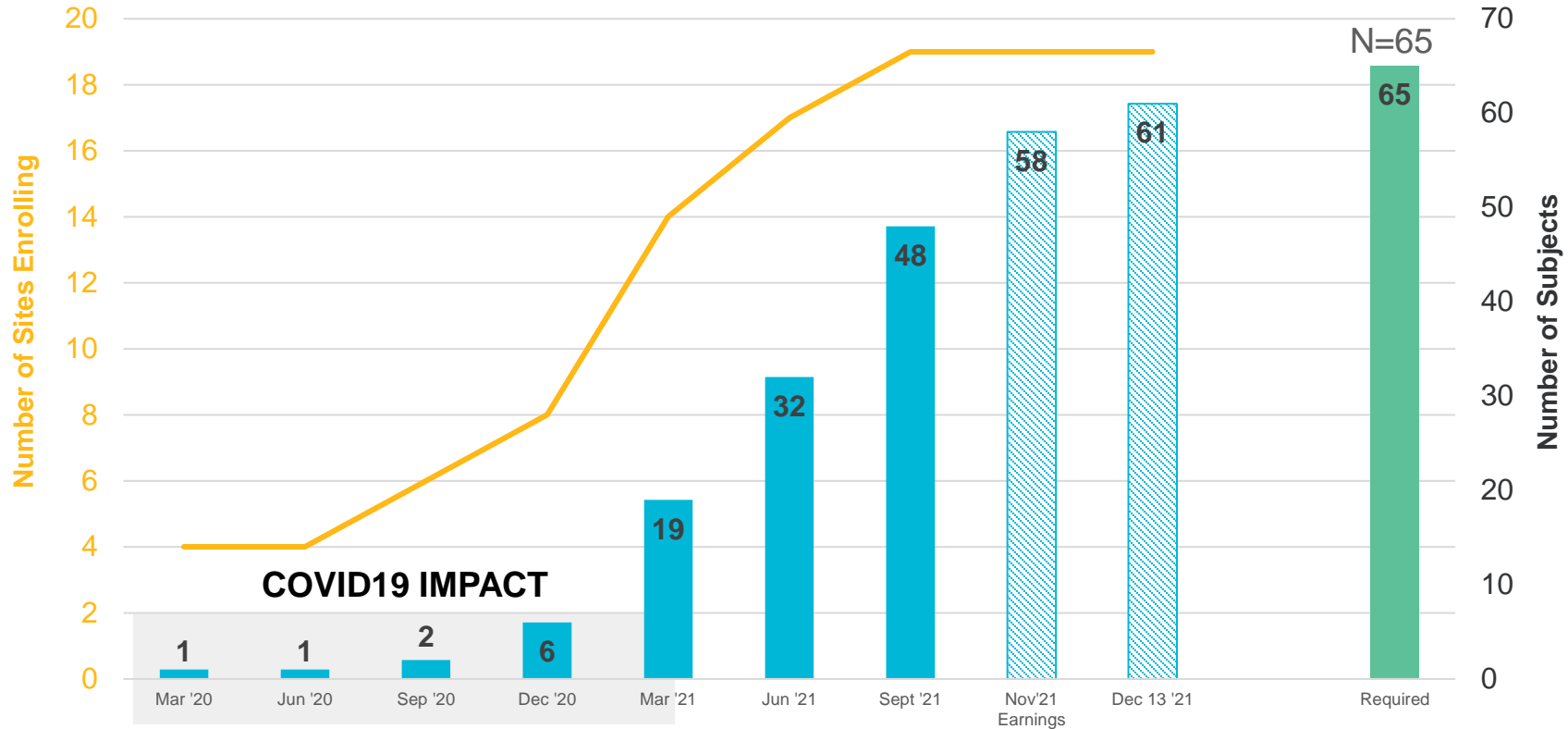
FDA Submission Expected in H2 '22 with Approval in H2 '23



# Early Completion of Soft Tissue Reconstruction Trial

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

RECELL® Soft Tissue Study



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

Patient treated for necrotizing fasciitis



TREATMENT DAY



1 YEAR POST-RECELL TREATMENT

# Soft Tissue Synergies with Current Commercial Burn Focus

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

~50% of Burn Centers are also Level 1 / Level 2 Trauma Centers



### Reimbursement in Place

Able to leverage existing CPT & Outpatient C Code

### Same Treatment Protocol to Burns

Consistent treatment protocol across acute injuries

### Same Unmet Needs as Burns

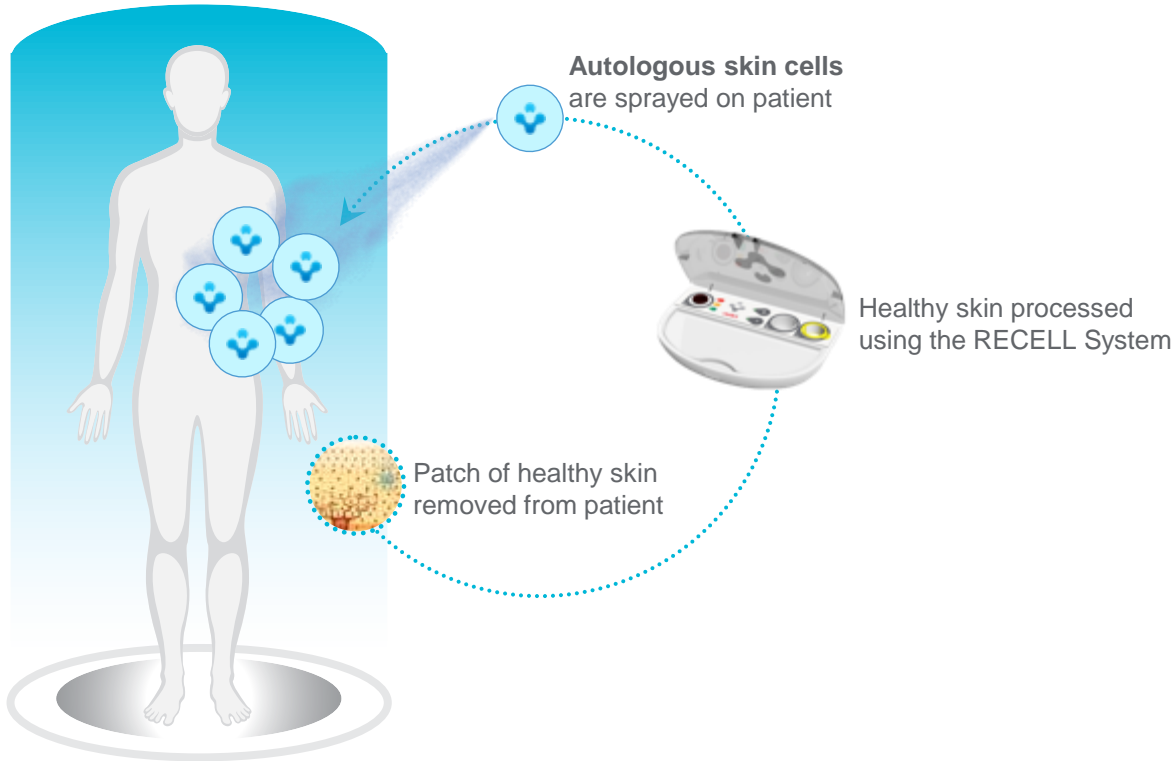
Reduction of donor site morbidity & donor site requirements are top unmet needs

Large opportunity that leverages existing burns infrastructure

# RECELL in Genetic Skin Defects and Rejuvenation

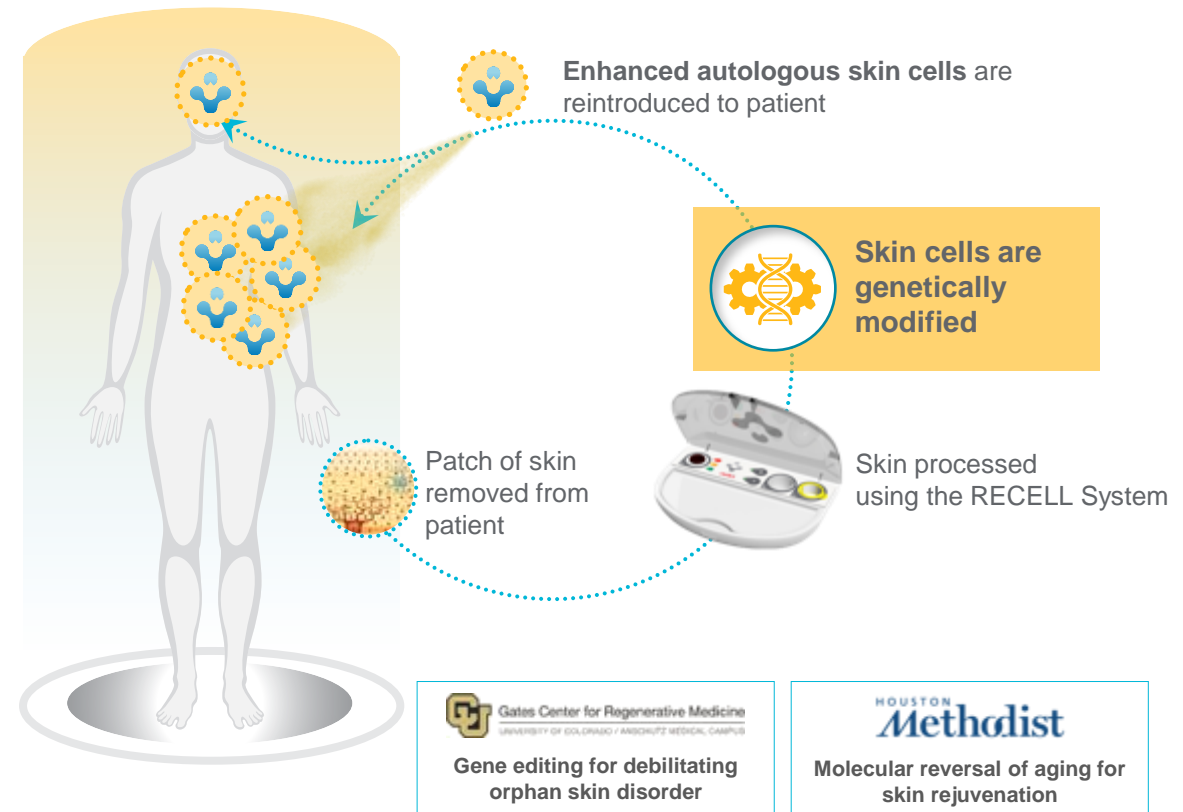
## CURRENT PLATFORM

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



## FOUR KEY STEPS

Proof of Concept



FDA Interaction



IND-enabling Studies



First-in-human (IND)



Study Objectives:

Develop a 'Spray-on' suspension delivery system of modified cells and establish proof-of-concept

Target IND-enablement by establishing preclinical evidence of safety and dosing

## THE CHALLENGE



### DEBILITATING

Skin fragility,  
disability, cancer

### HIGH UNMET NEED

No FDA-approved  
treatment, only  
palliative measures

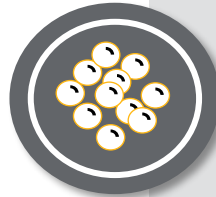
### COST BURDEN

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”)

# Exploring Novel RNA-Based Approach for Rejuvenation



HOUSTON  
**Methodist**  
LEADING MEDICINE



avita<sup>medical</sup>

- **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

\*1. 2020 Plastic Surgery Statistics Report, 2. 2020 Plastic Surgery Statistics Report (Defined as Facelifts, Ablative Laser, Dermabrasion, Non-Surgical Skin Tightening)  
In the U.S., RECELL is approved for acute thermal burns in patients > 18 years. Use of RECELL in other indications is either (1) limited by United States law to investigational use; or (2) otherwise prohibited.



Corporate

avita<sup>medical</sup>

# 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
<b>Total Revenue</b>	<b>929</b>	<b>5,474</b>	<b>14,263</b>	<b>29,232</b>
Gross Profit	383	4,203	11,290	23,283
BARDA Income	7,734	5,921	3,926	2,055
Cash	10,986	20,174	73,639	110,746

\$12.45  
Share Price<sup>1</sup>

\$310 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:  
**RCEL**

ASX ticker  
symbol:  
**AVH**



# A Global Total of 56 Granted Patents & 26 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

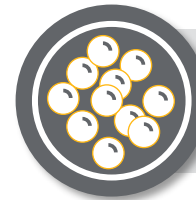
## EXPANDING PORTFOLIO TO SUPPORT CURRENT AND FUTURE INDICATIONS



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 suspension-based delivery of genetically modified cells, with applications to genetic skin disorders

**Robust and Expanding Patent Estate:  
Expiration from 2022 to 2040**

## Projected Key Milestones



<ul style="list-style-type: none"> <li>• Vitiligo Pivotal Trial Last Patient Enrolled / Vitiligo Commercial launch</li> <li>• Last patient enrolled in Soft Tissue Trial / Soft Tissue Commercial Launch</li> </ul>	<p>Q4 21 / H2 23 Q1 22 / H2 23</p>
<ul style="list-style-type: none"> <li>• Outpatient Launch</li> <li>• PMDA Approval of Burns in Japan</li> <li>• FDA Approval of New 'Ease of Use' RECELL Device</li> </ul>	<p>H1 22</p>
<ul style="list-style-type: none"> <li>• EB: Initial proof of concept for delivery of genetically modified skin cells in suspension</li> <li>• Telomerase/Rejuvenation: Initial proof of concept on impact of telomerase on human skin in a mouse model</li> </ul>	<p>Q4 21</p>

- 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 cm<sup>2</sup>, 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

avita<sup>medical</sup>



Zed, treated with the RECELL<sup>®</sup> System