



# One Platform. Endless Possibilities.

Investor Webinar Briefing  
September 20, 2022 (U.S.) /  
September 21, 2022 (AU)

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 AVITA Medical as well as the aforementioned 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, 2022, and our most recent Transition Report on Form 10-KT period from July 1, 2021 to December 31, 2021. 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® 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).

## AVITA MEDICAL OVERVIEW



Regenerative medicine company leading the development and commercialization of first-in-class devices and autologous cellular therapies for skin restoration



Patented RECELL® technology, a new treatment paradigm for burn injuries



Leveraging proven RECELL® platform to advance new indications in acute traumatic wounds and vitiligo, as well a pipeline of cell and gene therapies

# Why AVITA Medical?



## Strong IP Estate

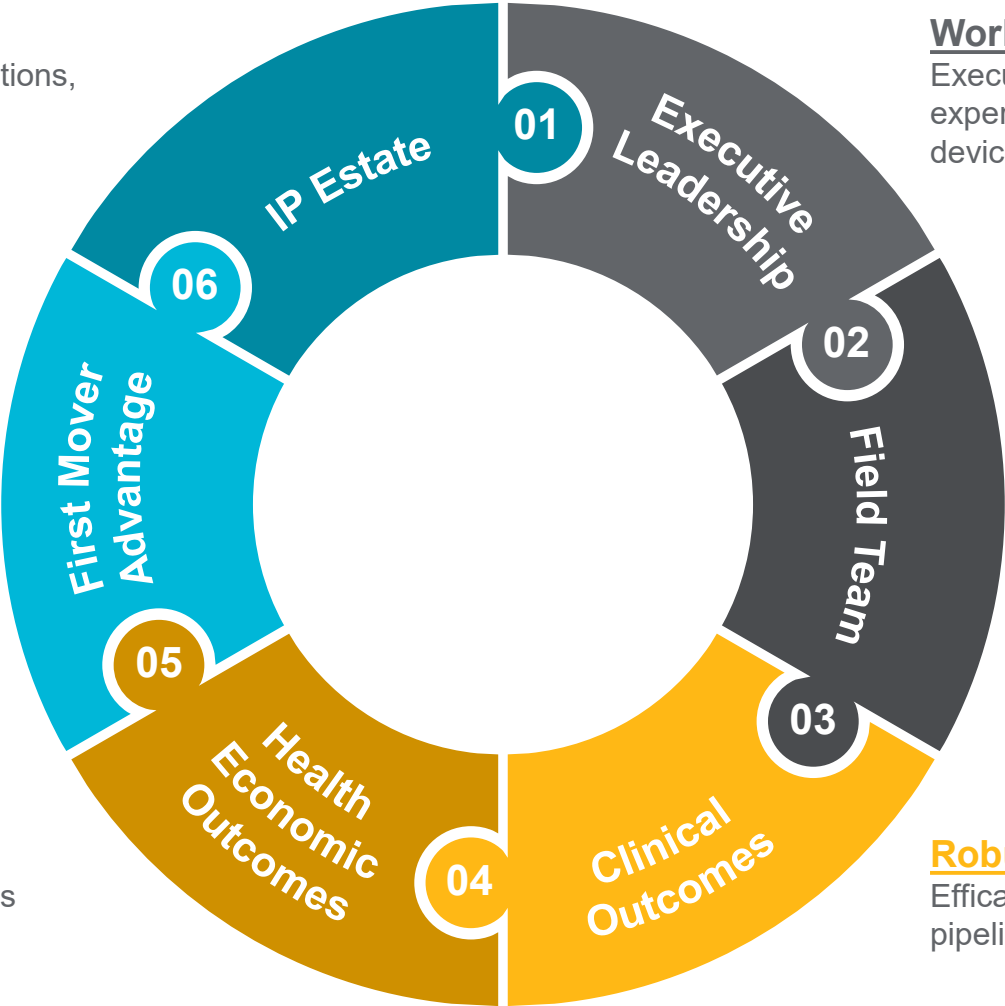
Total of 19 granted patents, 25 pending applications, and automated devices in development with associated established IP protection

## First PMA in Burns in 20+ Years

PMA-approved Class III\* device for burn care sets precedent and creates a significant barrier to entry

## Proven Health Economic Outcomes

Published health economic model demonstrates significant savings to patients and the health care system



## World-Class Executive Team

Executive management team has 150+ years of experience with proven track records across medical device, biotech, and pharmaceutical companies

## Best-in-Class Field Team

Highly experienced team averaging over 15 years of Burn Care Experience

## Robust Clinical Outcomes

Efficacy of platform is well studied; de-risked pipeline with >15,000 patients treated globally

\* FDA's designation of RECELL as a Class III device established precedent for future similar devices to require pivotal clinical data and PMA submissions for FDA approval. This is the highest level of rigor for a U.S. device approval.

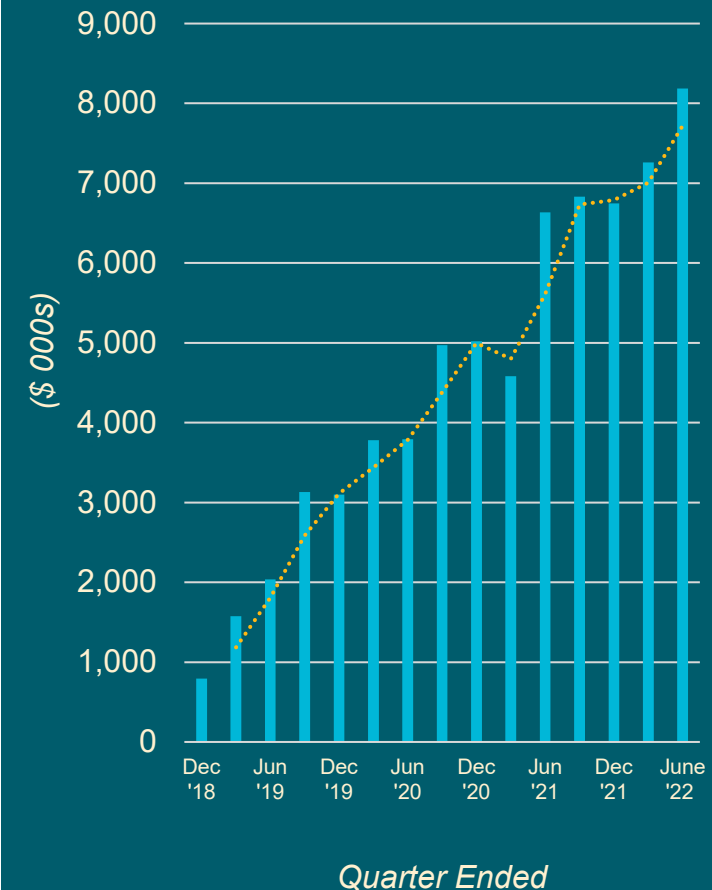
# Year in Review: Continued Growth and Expansion

## Recent Accomplishments

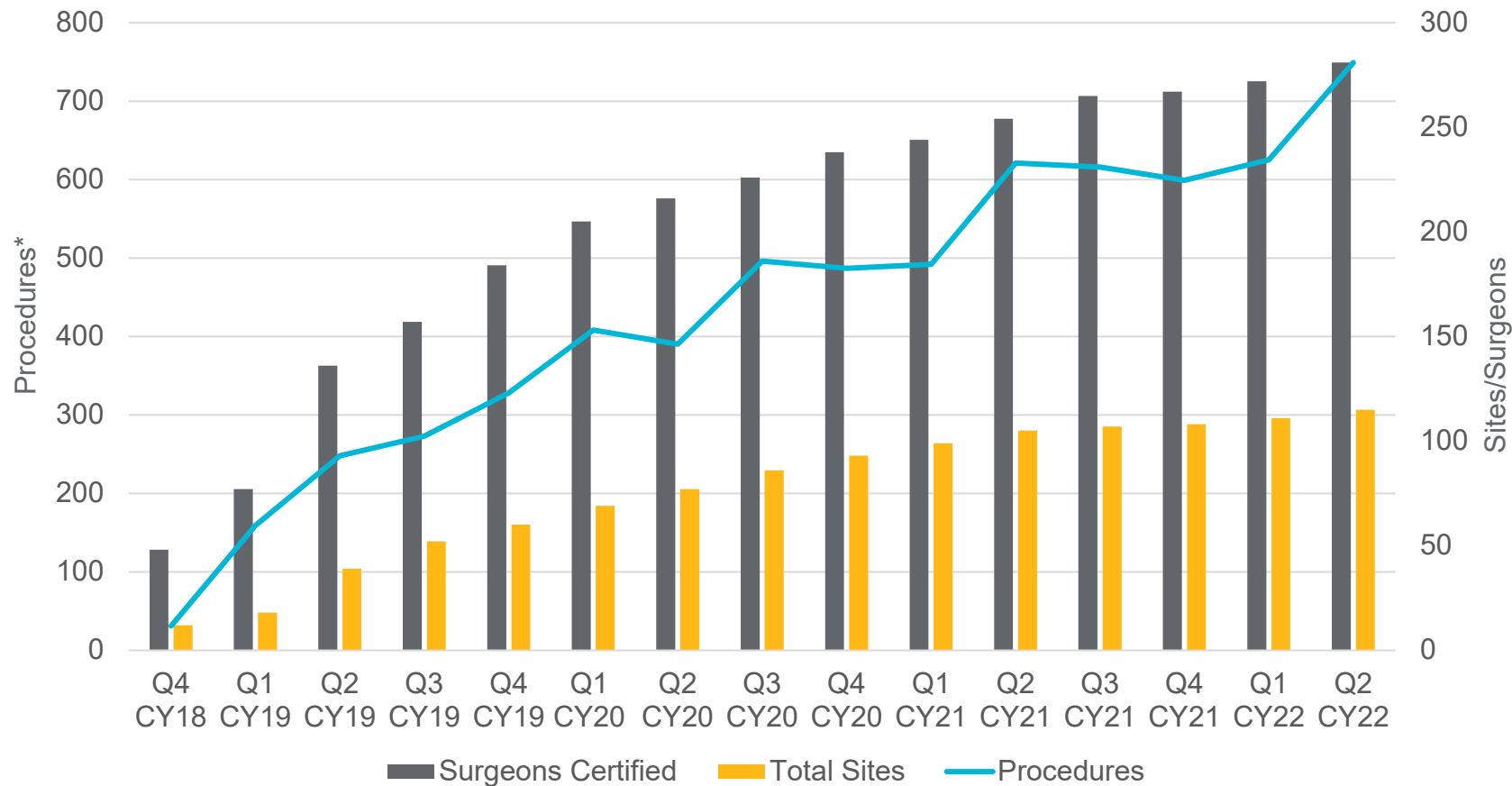


- Commercial Revenue Growth:
  - Year-to-date 2022: +39% year-over-year
  - Second Quarter 2022: +23% same quarter prior year
- New “Ease of Use” RECELL Device:
  - FDA approval and launch
- Japan:
  - PMDA approval of Burns and cases completed
  - Favorable reimbursement and commercial launch in Burns
- Pivotal Trials Topline Results :
  - Acute traumatic wounds: statistically superior donor sparing and comparable healing rates
  - Vitiligo: achieved primary effectiveness endpoint of super-superior response rate

## Strong U.S. RECELL Commercial Growth



# Strong Adoption of RECELL Reflected in Key Leading Indicators



## Accomplishments Since Approval

93% Burn Surgeons Certified

84% Burn Sites Activated

~6,500 Procedures\*

> \$71 Million in U.S. RECELL Revenue Since Approval

\*Data is compiled based on information voluntarily provided by our customers and is subject to change.

# New Ease of Use Device FDA Approved & Launched

## New Device



Reduced  
number of steps

Simplified  
Process

Improved  
Usability



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

Steps Reduced By 33%

# Approval of Burns and Favorable Reimbursement in Japan

## BACKGROUND



COMMERCIAL PARTNER: COSMOTEC, an M3 Company



INDICATION: Burns  
Additional Indication(s) to Follow Based on U.S. Pivotal Clinical Data

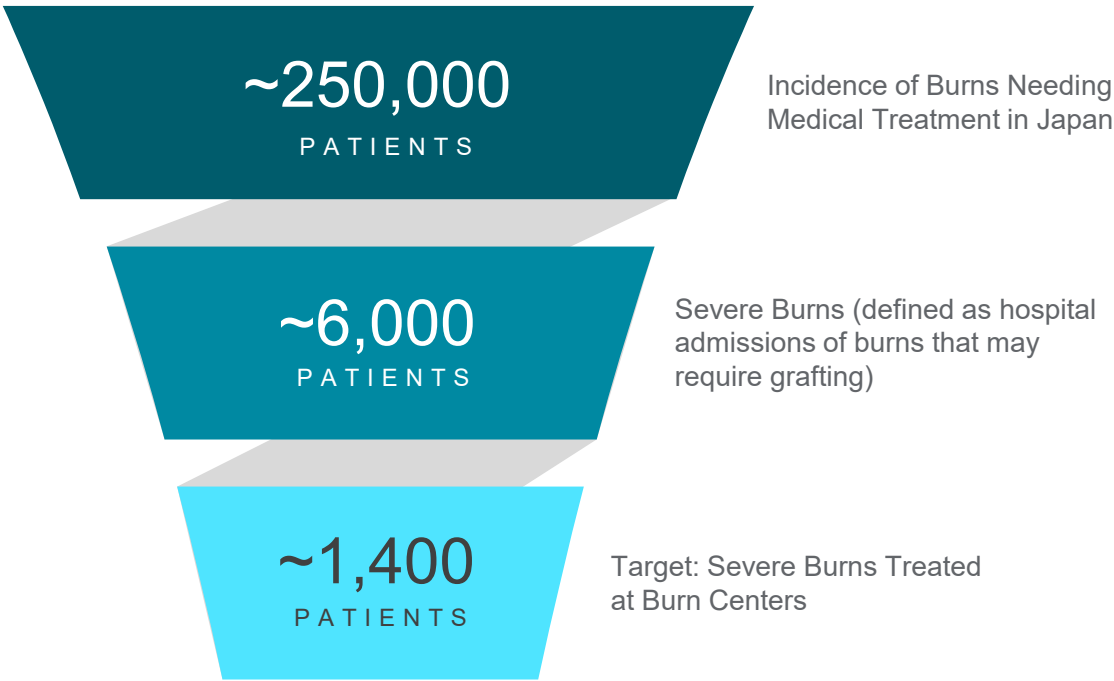


PMDA APPROVAL: Q1 2022



LAUNCHED: Q3 2022  
Ministry of Health, Labour, and Welfare (MHLW) granted favorable reimbursement pricing in September 2022

## PATIENT FUNNEL - BURNS ADDRESSABLE MARKET \*



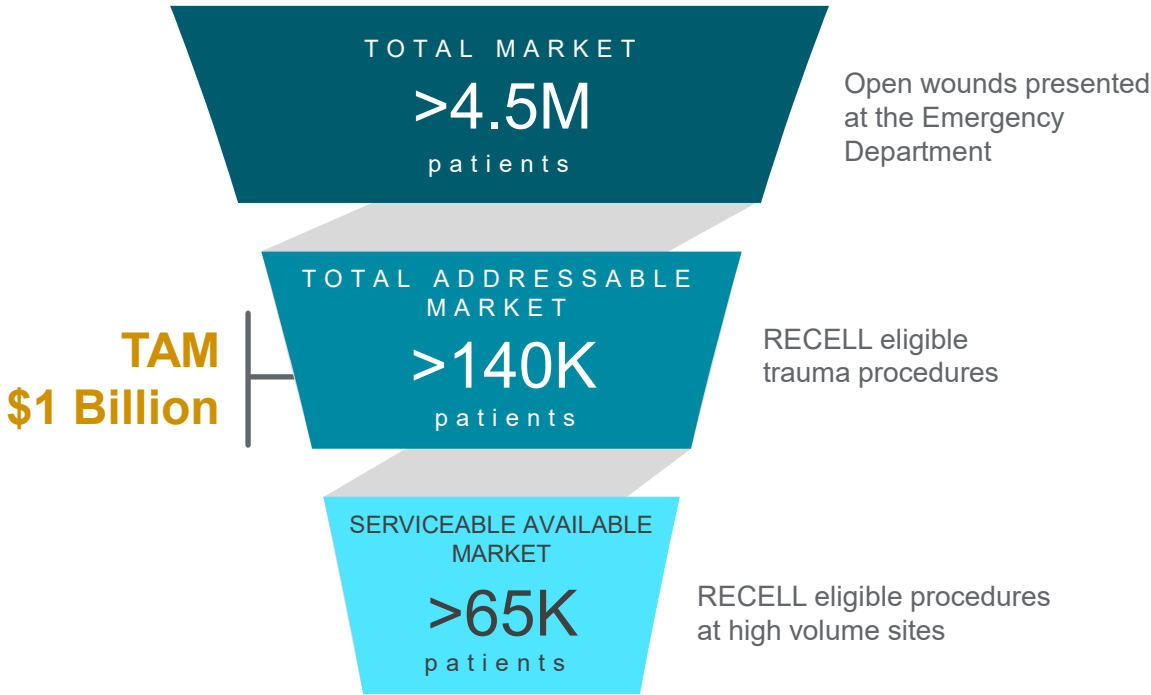
Commercial Launch Underway

\* Furue M, Yamazaki S, Jimbow K, Tsuchida T, Amagai M, Tanaka T et al. Prevalence of dermatological disorders in Japan: a nationwide, cross-sectional, seasonal, multi-center, hospital-based study. J Dermatol. 2011 April; 38(4):310-20, Japan Health System Review, 2018. Additional estimates based on data from 2016 JSBI National Burns Repository, [https://injuryprevention.bmj.com/content/26/Suppl\\_2/i36#F2](https://injuryprevention.bmj.com/content/26/Suppl_2/i36#F2) and Cosmotec estimates



# Acute Traumatic Wound Opportunity

## OPPORTUNITY ESTIMATION



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



POST DEBRIDEMENT OF INJURY



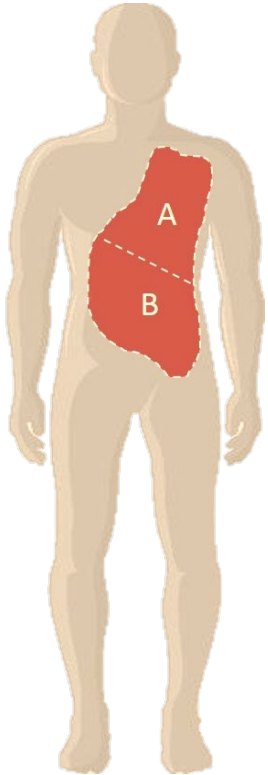
6 MONTH POST-RECELL TREATMENT

Soft Tissue Repair Expands Burns Business to Encompass All Acute Wounds

In the U.S., RECELL is approved for acute thermal burns. 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.

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

# Acute Traumatic Wounds Indication on Track for FDA Submission



Within-subject comparisons  
(treatment site healing and donor sparing)

## Effectiveness Data

As seen with burns treatment with RECELL, the study confirms use of less donor skin relative to the standard of care control (conventional skin grafting)

## Safety Data

Preliminary review of adverse events shows consistency with prior RECELL experience

FDA Submission Expected in H2 2022 with Approval in H2 2023

Patient treated for necrotizing fasciitis



TREATMENT DAY



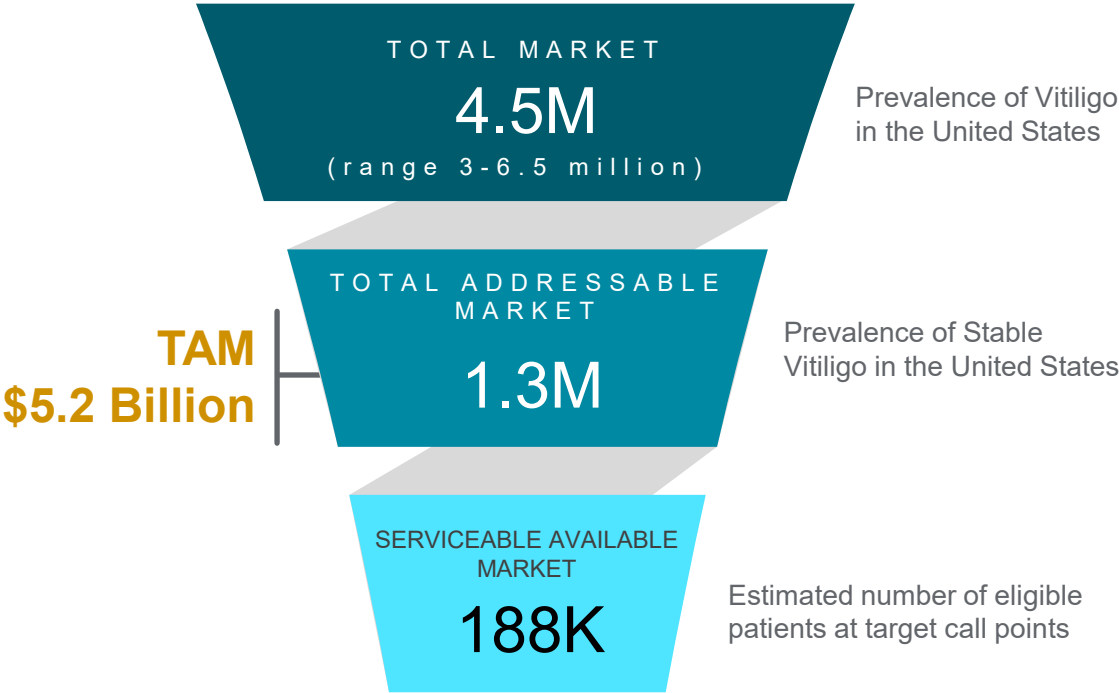
1 YEAR POST-RECELL TREATMENT

In the U.S., RECELL is approved for acute thermal burns. Use of RECELL in other indications is either (1) limited by United States law to investigational use; or (2) otherwise prohibited.

Photos courtesy of Kevin Foster, Valleywise Health Medical Center. Patient treated under Compassionate Use Program IDE13053

# Vitiligo Opportunity

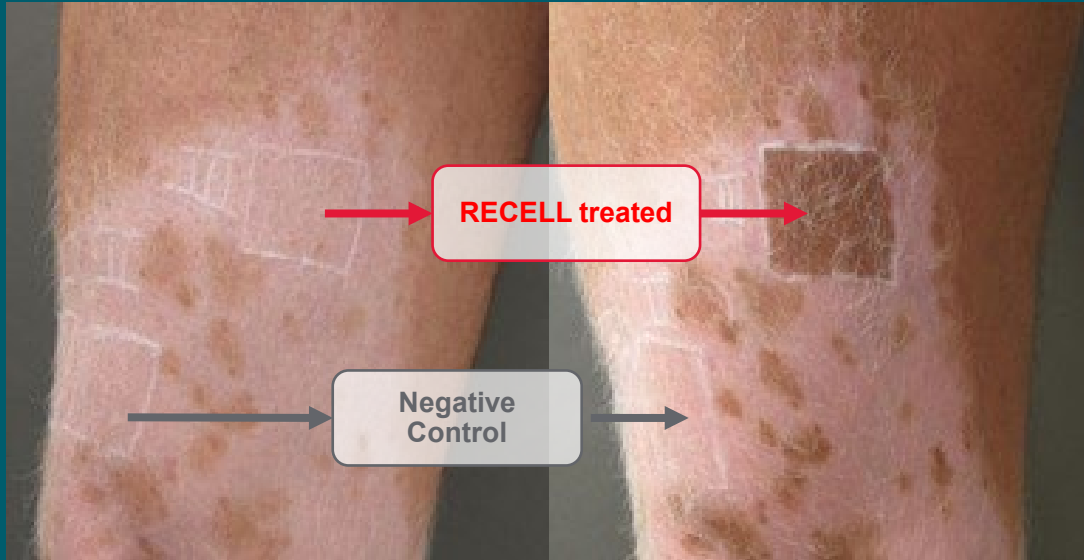
## OPPORTUNITY ESTIMATION



Targeting <1,000 procedural dermatologists and plastic surgeons who, along with patients, have extremely low satisfaction with existing products

Advances in Vitiligo: An Update on Medical and Surgical Treatments. A. Dillon, et al. J Clin Aesth Derm. 2017. Willingness-to-Pay and Quality of Life in Patients with Vitiligo. Radtke, et al. BJD. 2009.  
In the U.S., RECELL is approved for acute thermal burns. Use of RECELL in other indications is either (1) limited by United States law to investigational use; or (2) otherwise prohibited.

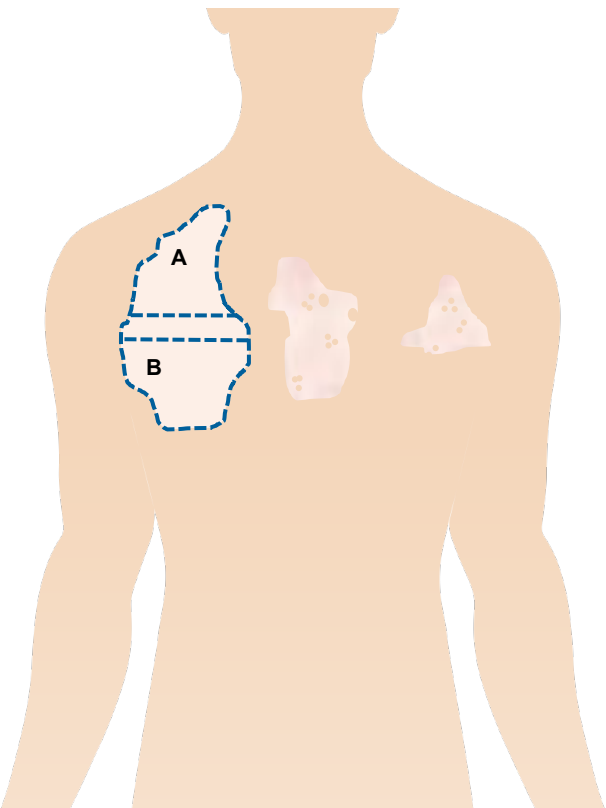
Patient from a prior study at 6 months  
RECELL-treated area was 100% re-pigmented



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.

\*NB-UVB protocol per Vitiligo Working Group recommendations JAAD 2017.  
In the United States, RECELL is not approved for treatment of vitiligo.

# Vitiligo Indication on Track for FDA Submission



Within-subject comparison

## Effectiveness Data

Study achieved its primary effectiveness endpoint of super-superiority

## Safety Data

Preliminary review of adverse events shows consistency with prior RECELL experience

## Primary Endpoint

Proportion of study sites achieving  $\geq 80\%$  repigmentation for RECELL-treated sites vs Control at Week 24

## Treatment

Laser ablation  
+  RECELL<sup>®</sup> (1:20)  
Autologous Cell Harvesting Device  
+ NB-UVB

## Control

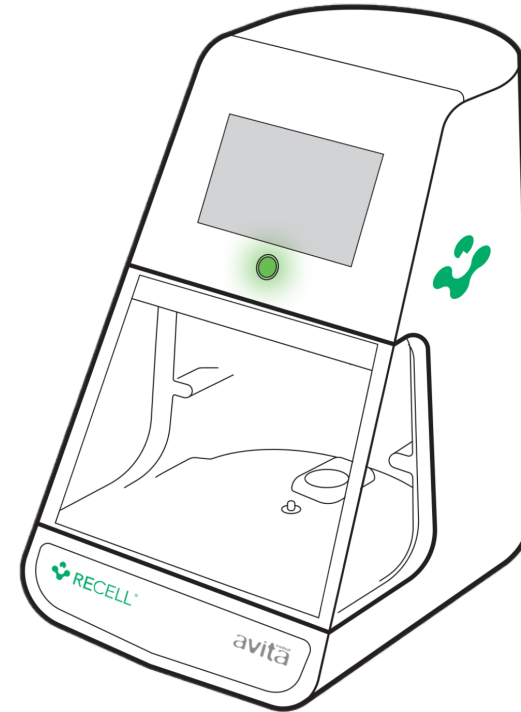
NB-UVB alone

Primary Endpoint Met; FDA Submission End of 2022

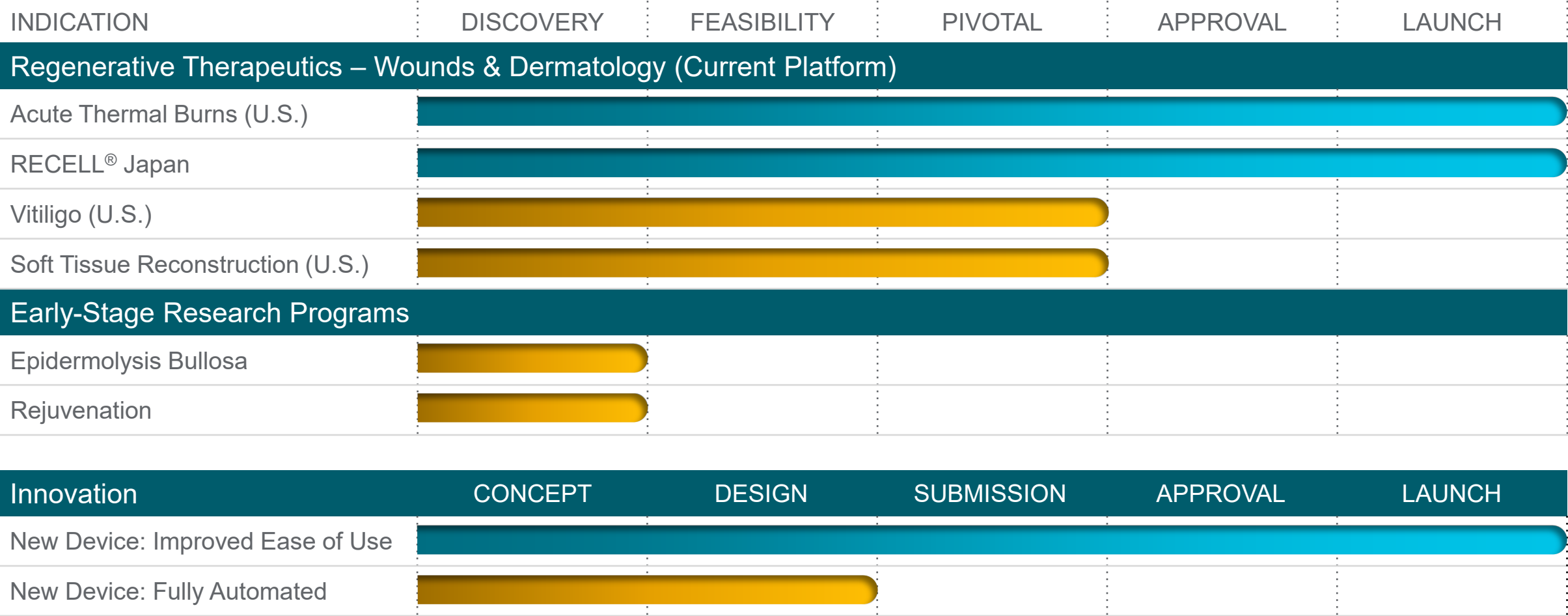
# New RECELL Device: Automated

## KEY UPDATES

- New RECELL Automated Device in development for Vitiligo:
  - FDA Submission expected in H2 2023
  - FDA Approval expected in H2 2024
- Protected by issued patents in the U.S. and certain other countries for automated device which provides a further barrier to entry for potential competitors



# Summary: Focused Pipeline with Strong Growth Potential



In the U.S., RECELL is approved for acute thermal burns. Use of RECELL in other indications is either (1) limited by United States law to investigational use; or (2) otherwise prohibited.

## Platform Expansion and Automation



### **Vitiligo:**

- FDA Submission H2 2022
- FDA Approval H2 2023

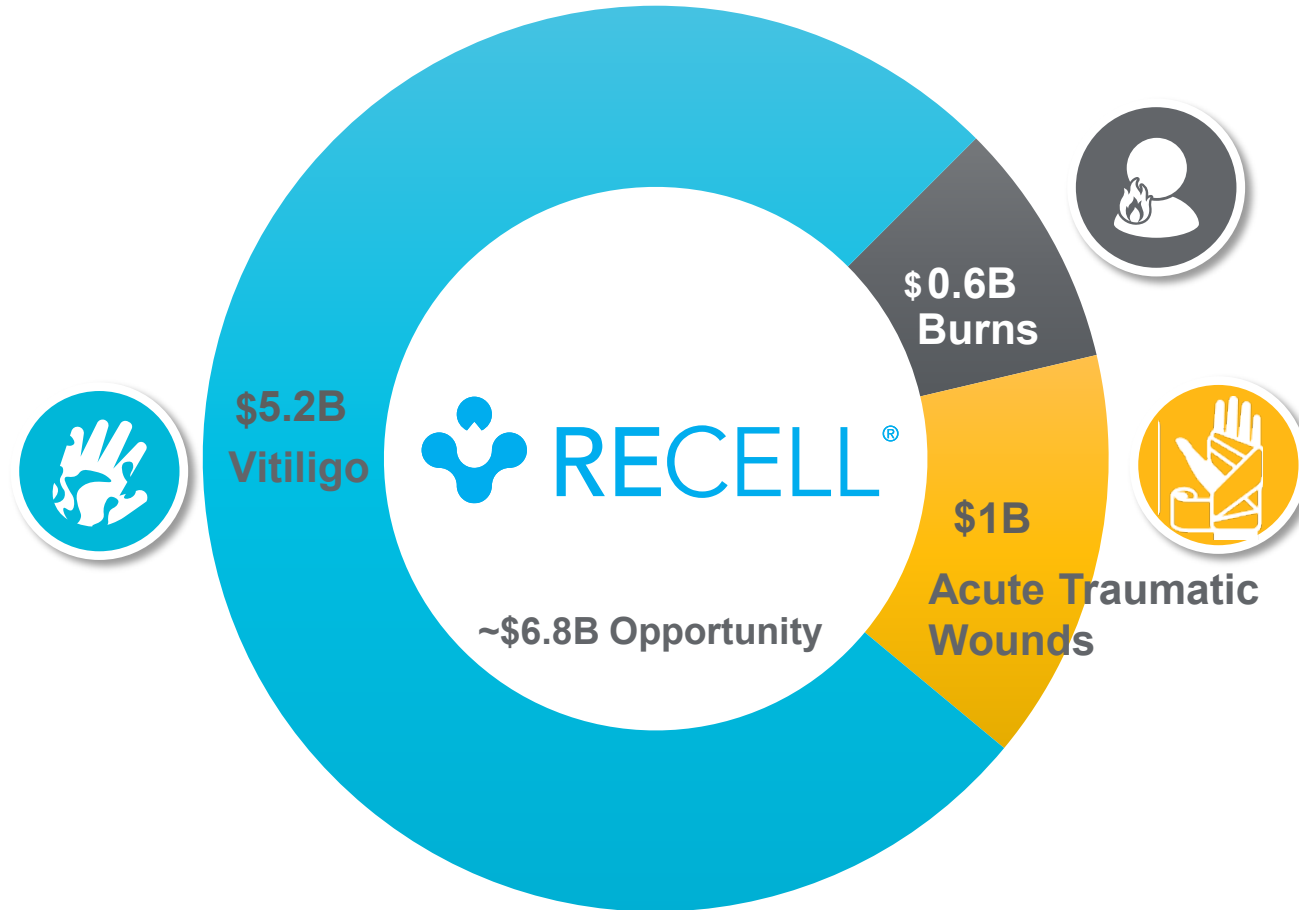
### **Acute Traumatic Wounds:**

- FDA Submission H2 2022
- FDA Approval H2 2023

### **Automated Vitiligo Device:**

- FDA Submission H2 2023
- FDA Approval H2 2024

# Current Platform Has Significant Market Opportunity



~ \$7 Billion in Combined TOTAL ADDRESSABLE MARKET





Corporate

avita<sup>medical</sup>

# Financial Overview

	12 Months Ended June 30				Unaudited 12 Months Ended December 31		Unaudited 3 Months Ended June 30	
(USD in \$000s)	2018	2019	2020	2021	2020	2021	2021	2022
Commercial Sales	929	5,474	14,263	21,483	17,918	25,091	6,699	8,242
BARDA Sales	-	-	-	7,749	-	7,934	3,605	93
<b>Total Revenue</b>	<b>929</b>	<b>5,474</b>	<b>14,263</b>	<b>29,232</b>	<b>17,918</b>	<b>33,025</b>	<b>10,304</b>	<b>8,335</b>
Gross Profit	383	4,203	11,290	23,283	14,660	26,921	8,251	6,949
BARDA Income	7,734	5,921	3,926	2,055	2,534	1,590	440	551
Cash, Cash Equivalents & Marketable Securities	10,986	20,174	73,639	110,746	59,765	104,852	110,746	91,098

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

NASDAQ ticker  
symbol:  
**RCEL**

ASX ticker  
symbol:  
**AVH**

# 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:

ImmuneCyte  
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



# 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.
- Clinical Studies to Support Any Regulatory Applications for Additional Commercial Applications: The Company cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. As a result, we may not achieve the expected clinical milestones necessary for approval by the FDA, or other regulators, for the use of RECELL® System for additional applications in the United States or other countries. A failure or delay in a clinical study or regulatory application can occur at any stage. Delays can be costly and could negatively affect our ability to complete clinical trials for our product candidates. If we are not able to successfully complete clinical trials, we will not be able to obtain regulatory approval for the use of our product for additional applications, all of which could have a material adverse effect on our business, financial condition and results of operations.

# 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

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