

# Annual General Meeting

November 26, 2019

Dr. Mike Perry



# Forward-Looking Statements

This presentation may include forward-looking statements. You can identify these statements by the fact that they use words such as “anticipate”, “estimate”, “expect”, “project”, “intend”, “plan”, “believe”, “target”, “may”, “assume” or similar expressions.

These forward-looking statements speak only as at the date of this presentation and are based on management’s expectations and beliefs concerning future events. Forward-looking statements are necessarily subject to risks, uncertainties and other factors, many of which are outside the control of AVITA Medical that could cause actual results to differ materially from such statements.

AVITA Medical makes no undertaking to subsequently update or revise the forward-looking statements made in this release to reflect events or circumstances after the date of this release.

This presentation is intended to provide background information only and does not constitute or form part of an offer of securities or a solicitation or invitation to buy or apply for securities, nor may it or any part of it form the basis of, or be relied on in any connection with any contract or commitment whatsoever.

# AVITA Medical:

## Transforming Lives with Skin Regeneration

- **RECELL® System: FDA approved for the treatment of acute thermal burns**
  - Proprietary Spray-On Skin™ offers life changing benefits
  - Safe & effective; reduces hospital costs
- **Successful commercial launch**
- **Ongoing platform expansion: \$2 billion U.S. market opportunity**
  - Pediatrics & outpatient settings in burns
  - Soft Tissue Reconstruction
    - inclusive of Trauma
  - Regenerative dermatology: Vitiligo
- **Further potential for cell-based gene therapy and aesthetics**
- **Highly experienced team**



---

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

---

# Experienced Leadership Team



**Dr. Michael S. Perry**  
CEO

>30 years  
experience

#### Affiliations:



**David McIntyre**  
CFO

25 years  
experience

#### Affiliations:



**Tim Rooney**  
CAO

25 years  
experience

#### Affiliations:



**Erin Liberto**  
CCO

17 years  
experience

#### Affiliations:



**Andrew Quick**  
CTO

25 years  
experience

#### Affiliations:



**Donna Shiroma**  
General Counsel

20 years  
experience

#### Affiliations:



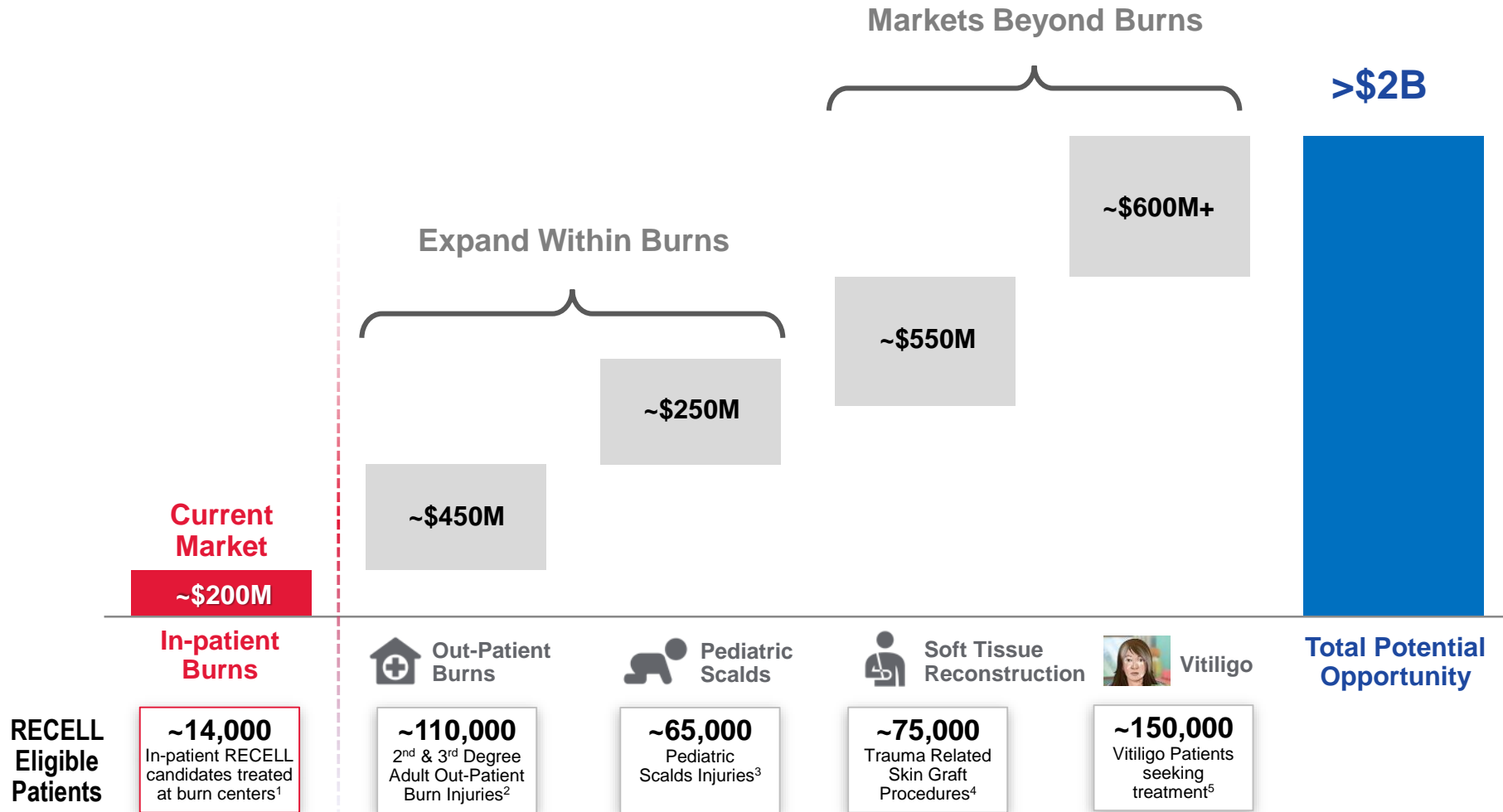
# Overview: 2019 Value-Creating Milestones

- Received FDA approval of PMA in September 2018
- RECELL is Positioned for Successful Adoption in U.S. Burns

## Key Accomplishments in 2019

- ✓ U.S. nationwide launch in January 2019
- ✓ Market & distribution collaboration in Japan (Cosmotec/M3) and PMDA submission of RECELL dossier
- ✓ Ten presentations of RECELL data at 2019 ABA meeting
- ✓ Publication of RECELL health economic model
- ✓ U.S. product sales of A\$10.8 million through September 30, 2019
- ✓ FDA approval of pivotal Soft-Tissue Repair/Trauma clinical trial
- ✓ Listing of ADRs on NASDAQ (Ticker Symbol: RCEL)

# Current RECELL Platform Addresses Opportunities Exceeding USD \$2 Billion in the United States



Please see Important Safety Information

# **RECELL<sup>®</sup> System: In-patient Burns**

## **Current Market**



# Addressing Critical Patient Need:

## 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

- Large donor area required
- Pain associated with donor site
- Extended hospitalization and costs
- Multiple complex, costly, surgical procedures
- Risk of infection

---

**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 System: FDA-Approved Skin Regeneration Platform

## Regenerative Medicine Platform Designed by Burn Surgeons

- *Autologous Cell Harvesting Device* that uses proprietary enzyme and buffer formulations to prepare *Spray-On Skin™ Cells* within 30 minutes at point of care

## Proven Safety and Effectiveness

- 8,000+ uses to date in multiple world markets with no observed safety signals
- Treatment area is 80x donor area (credit card size skin sample can treat an entire back)
- Compelling clinical results and robust health economic data

## Pre-Market Approval (PMA)

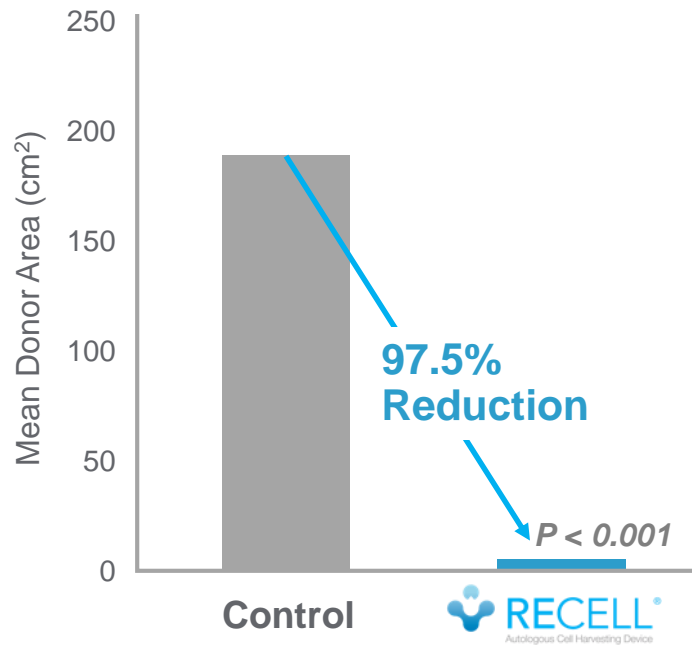
- First burn care product with PMA in over 20 years



# Positive U.S. Clinical Trials in Burns

RECELL System *Alone* versus Standard of Care in Deep-Partial Thickness Burns  
(Second-Degree)

Significant Drop in Donor Skin Requirement

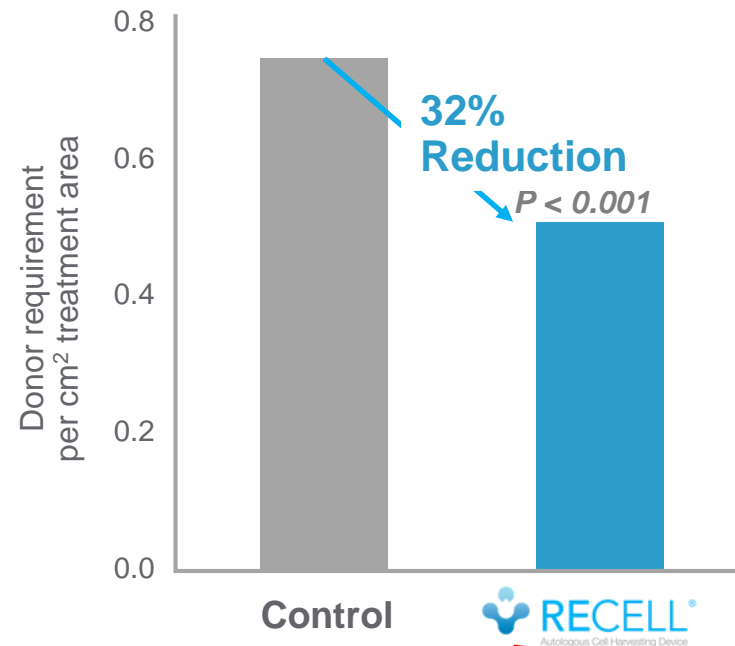


Published in JBCR  
and Presented at ABA

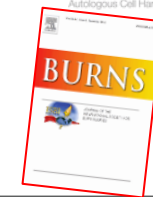


RECELL System *Combined with Widely-Spaced Skin Grafts* versus Standard of Care in Full-Thickness Burns (Third-Degree)

Less Requirement for Donor Skin



Published in Burns  
and Presented at ABA



# Life-Changing Outcomes and Economic Benefit



## Case Series Presented at 50<sup>th</sup> Annual ABA Meeting (2018)

- Compassionate Use Case (example)
- 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 is ideal for the treatment of deep partial-thickness facial burns**

---

# **RECELL U.S. Commercial Launch**

# In-Patient Burns: The Initial U.S. Target Market

**486,000**

Burn Patients  
Treated Annually  
in the U.S.<sup>1</sup>



**53,000**

In-patient Burn  
Treatments<sup>2</sup>



**75%**

In-patient Burns  
Are Treated in  
Burn Centers<sup>3</sup>



**~132**

Burn centers  
in the U.S.<sup>1</sup>



---

**\$200MM Addressable Market**

---

# Well Positioned for Success

## Key Marketing Requirements

## AVITA Addresses the Market Need

Robust Clinical Data

2 Randomized Controlled Clinical Studies  
Demonstrating Positive Safety & Efficacy



Experienced Field Team

21 Commercial Field Positions Averaging  
Over 15 Years of Industry Experience



Health Economic  
Value Proposition

Attractive Pricing & Published Health  
Economic Model Demonstrating RECELL  
Can Reduce Overall Hospital Costs



Reimbursement & Coding

CPT Codes Offer Attractive Reimbursement  
Unique ICD-10 codes in Place



KOL Engagement

>50 publications and >140 conference  
presentations





# RECELL<sup>®</sup> Launched Nationwide in January 2019

## Physician and Patient Education Materials



## Data Published in Medical Journals



## National Media Coverage



**FDA approves first spray-on skin treatment for burns**



**Avita Medical wins FDA PMA for Recell severe burn treatment device**

SEPTEMBER 21, 2018 BY PINK DENFORD — LEAVE A COMMENT



**FDA grants premarket approval to Recell for burn treatments**

September 21, 2018

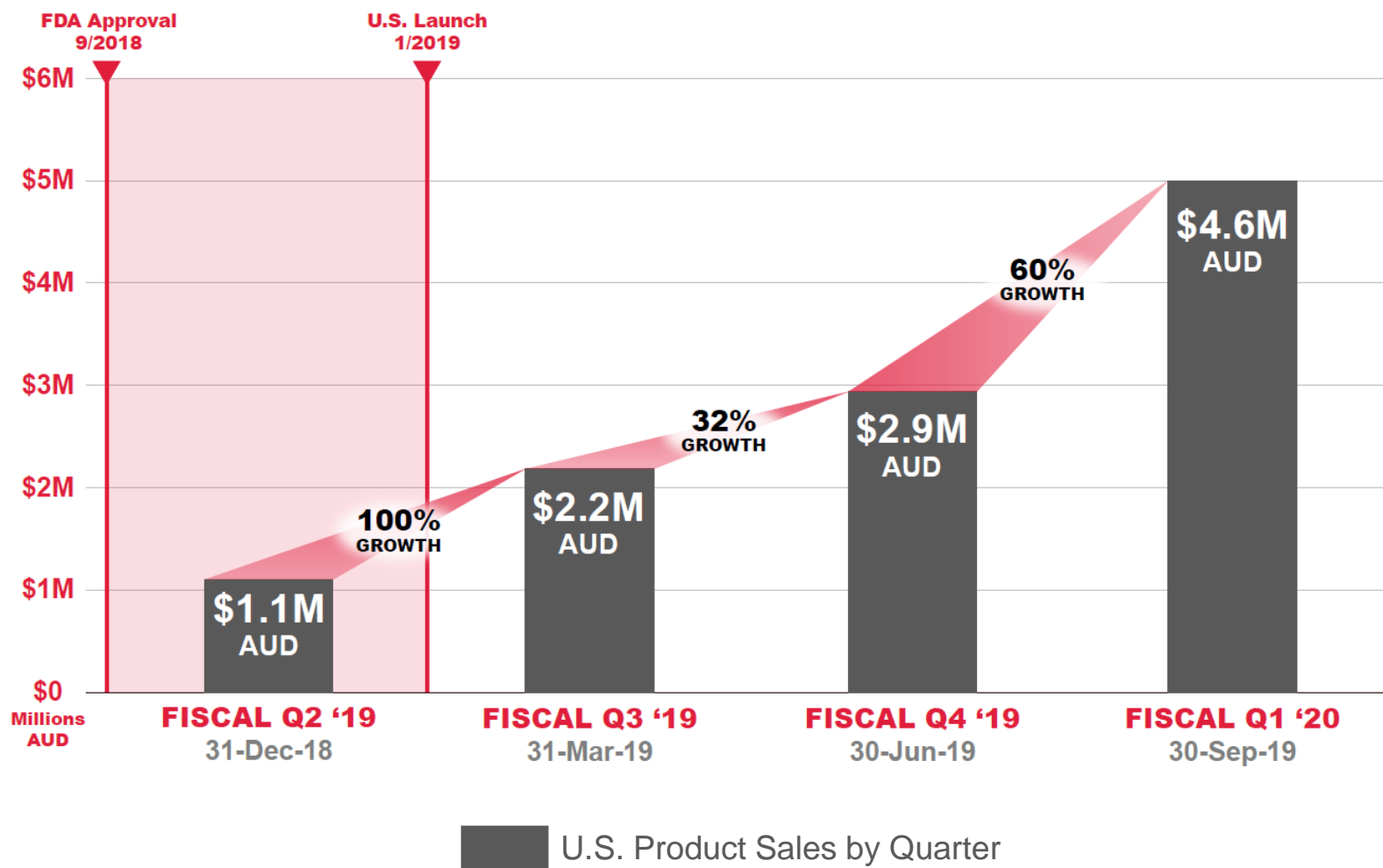
**Seeking Alpha<sup>α</sup>**

**Avita Medical launches Recell in U.S.**

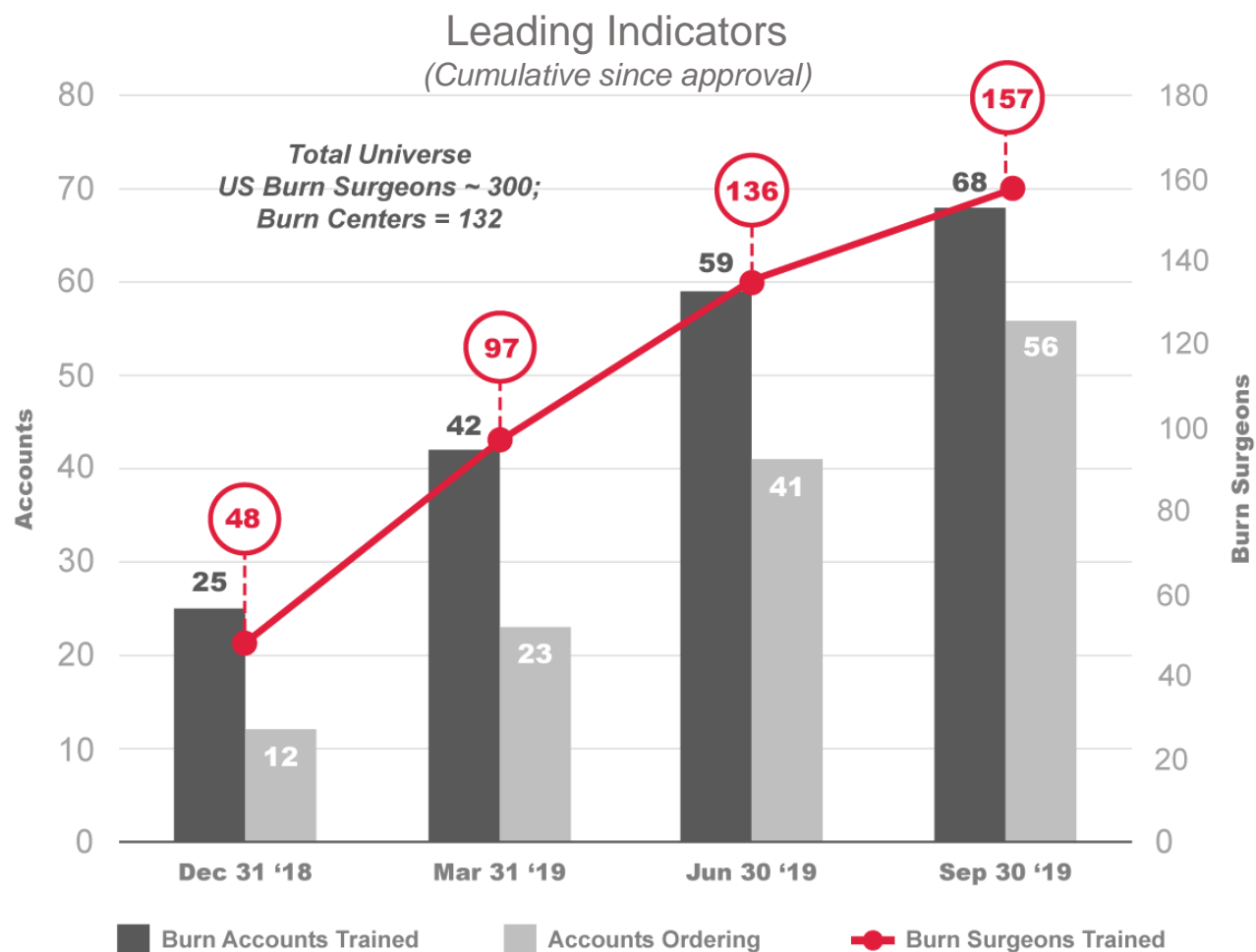
Jan. 8, 2019 6:41 AM ET | By: Douglas W. House, SA News Editor



# The U.S. Market Is **Swiftly Adopting** RECELL



# Over Half of U.S. Burn Centers and Surgeons Trained on RECELL



## Accomplishments Since Approval (through 30 Sept 2019)



**157 Doctors  
Trained**



**68 Accounts  
Trained**



**56 Accounts  
Ordering**

# **Development Pipeline & Growth Potential**

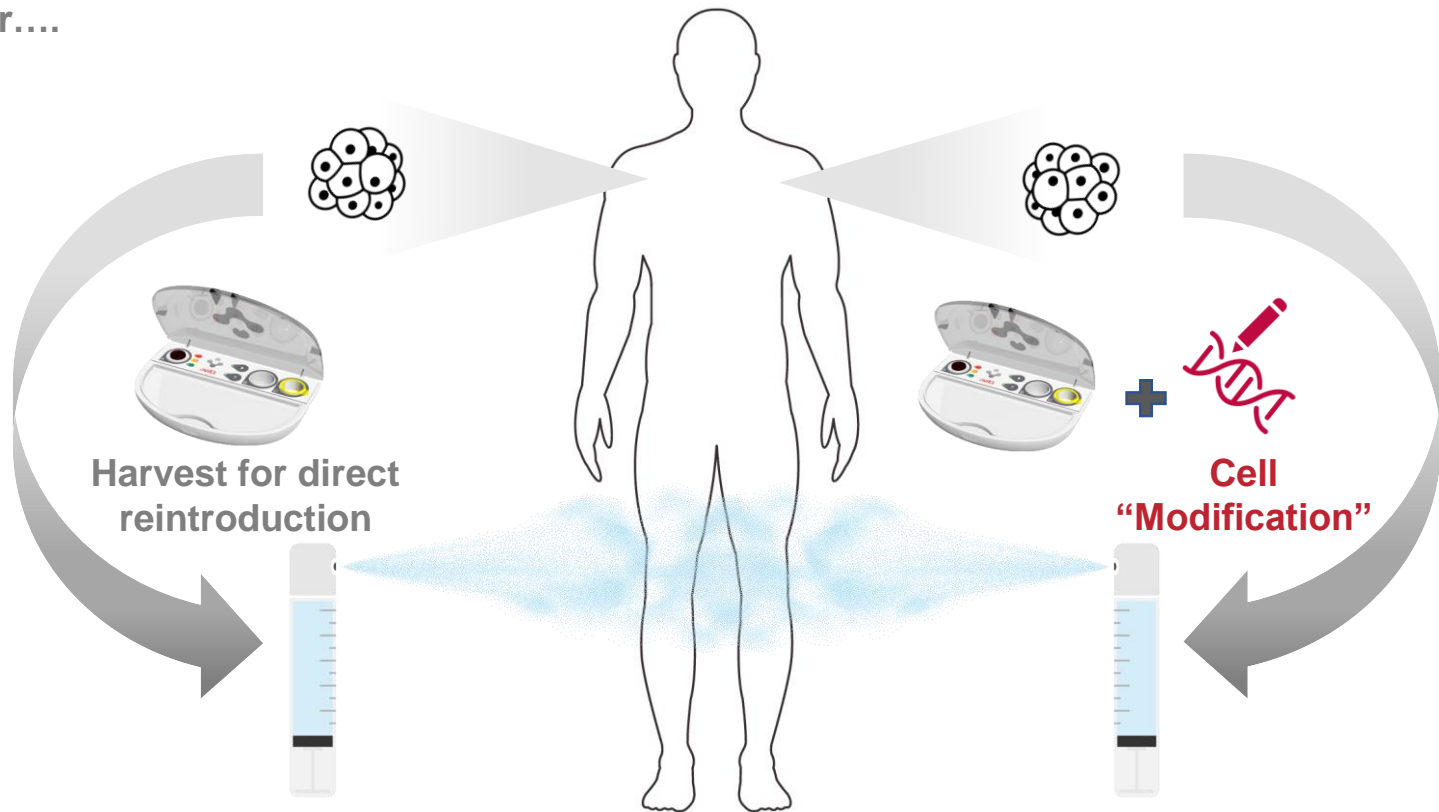
# Evolving Platform to Deliver Cells that Need to be Made “Healthy”

## CURRENT PLATFORM

From facilitating healthy dermal cell delivery from one part of the body to another....

## FUTURE PLATFORM

... to enabling delivery of dermal cells modified to become healthy



# Next Generation Products will Enhance **Ease of Use** and Support **Adoption of New Indications**



Gen 1  
Current Platform



Gen 1.5  
FDA Submission: 1Q/2Q 2021

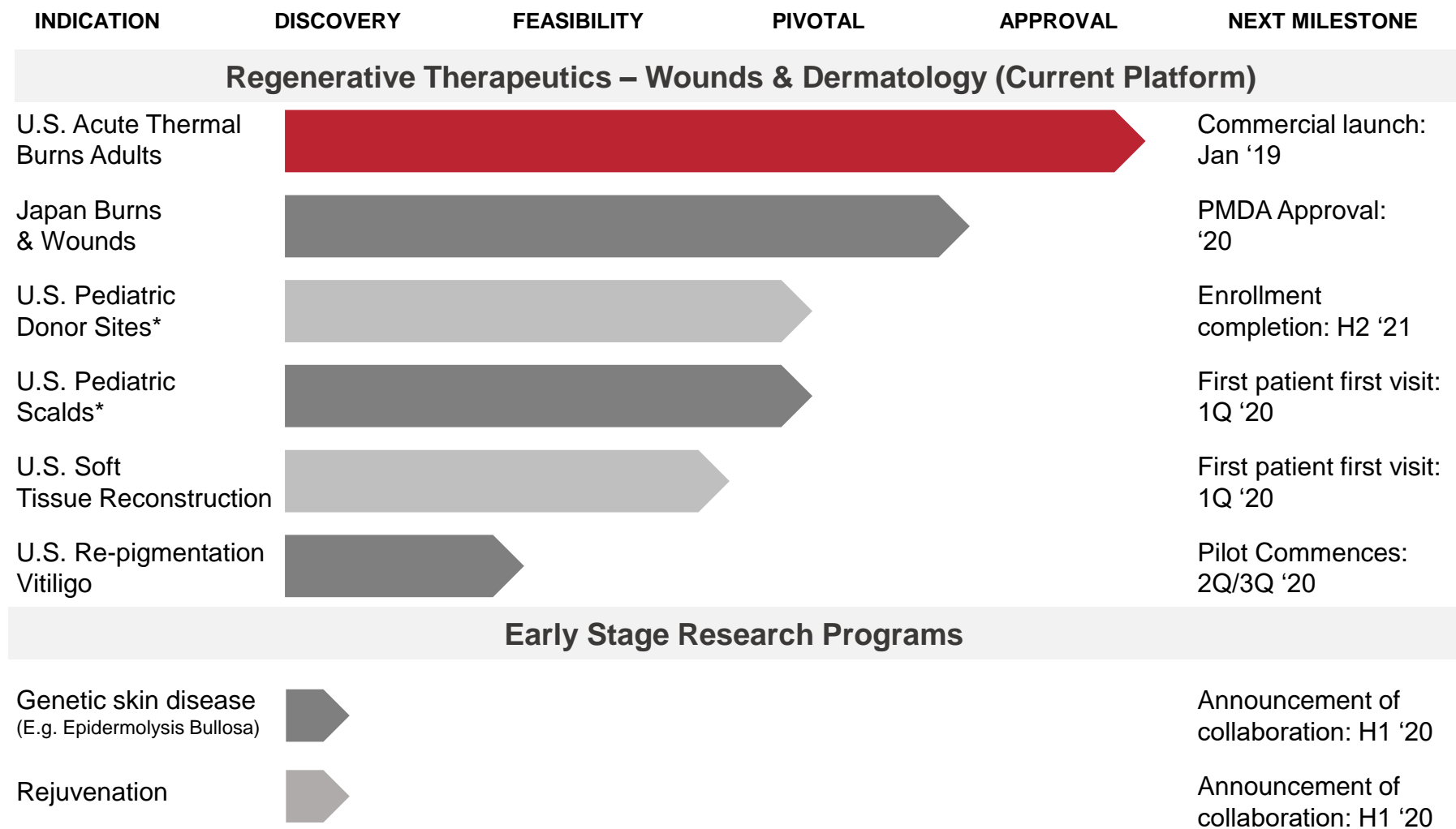


Gen 2  
Office-based procedures

Features	Benefits
System entirely sterile	Reduces staff requirements
Optimized component placement to minimize footprint	Improves efficiency with multiple devices
Fewer steps, organized to reflect workflow	Easier to use, train and acclimatize new centers

Features	Benefits
Rapid cellular disaggregation	Office-based procedures
Ergonomic Hand-held device	Easy to use in smaller wounds
Sprayer independent of the device	Target new applications in cell and gene therapy

# Focused Pipeline with Strong Growth Potential



# Exploring Cell-Based Gene Therapy for Dystrophic Epidermolysis Bullosa – A Devastating Orphan Disorder / Disease

Entering this market with high unmet need will likely open doors  
to other<sup>3</sup> genetically correctable disorders of the skin

## The Challenge

### Debilitating

Skin fragility, disability, cancer, death

### High unmet need

No FDA-approved treatment

### Rare

~3-8 per million in the US<sup>1,2</sup>

### Cost burden

Care of \$200k-\$500k/yr/patient<sup>2</sup>



## The Opportunity

### Curative

Correct COL7A1 genetic defect

### Efficient

Shorten time to treatment

### Aesthetic

Minimal scarring post-healing

### Durable

Long-term wound closure



# Early Research Programs Show Market Potential for **Application in Rejuvenation**



## **Skin Rejuvenation**

Americans spend >\$16.5B in aesthetic procedures annually<sup>1</sup>

>3M aesthetic procedures per year (US)<sup>2</sup> aimed to improve skin tightness, texture & evenness of skin tone

Consumers desire superior results over current offerings with a single outpatient treatment

---

**A 5% market capture of the skin rejuvenation market could represent > \$500MM opportunity**

---

# 2020 Catalysts

## Key Milestones through 2020

- U.S. revenue growth (RECELL in burns)
- First patient enrolled in U.S. Pediatric Scalds Clinical Study
- First patient enrolled in U.S. Soft-Tissue Repair Clinical Study
- First patient enrolled in U.S. Vitiligo Pilot Clinical Study
- PMDA Approval of RECELL in Japan
- Early Research Ongoing and Progress Reports on
  - Gene Therapy (EB)
  - Rejuvenation Field

# **Financial Overview & Milestones**

# Avita 2019 Stock Performance



## 2019 Milestones (as of Nov. 15<sup>th</sup>)

- Stock Price: 0.58 AUD
- Market Cap: 1.12B AUD
- > 7X Share Price Growth in 2019
- Added to ASX 300 and then to ASX 200
- Up-listed - OTCQX to NASDAQ (ADS)



S&P/ASX 200



ASX ticker  
symbol:  
**AVH.AX**



Nasdaq ticker  
symbol: **RCEL**

# Financial Overview

	<u>Year Ended 30 June</u>	
	2019	2018
Global Sales	\$7,705,398	\$1,198,861
BARDA Income	8,259,152	10,104,081
Other Income	456,695	68,617
Total Income	<u><u>\$16,421,245</u></u>	<u><u>\$11,371,559</u></u>
Total Net Revenue	\$14,723,422	\$10,859,913
Net Loss	(\$35,160,227)	(\$16,519,155)
Cash & Cash Equivalents	\$28,983,491	\$14,825,532

Cash as of 22 November 2019 = A\$ 134.5 Million

# 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 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, 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 [www.RECELLSYSTEM.COM](http://www.RECELLSYSTEM.COM)



# Thank you for your attention!

Questions?



**avita**<sup>medical</sup>  
*transforming lives*