

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): March 8, 2022

**Avita Medical, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-39059**  
(Commission  
File Number)

**85-1021707**  
(IRS Employer  
Identification No.)

**28159 Avenue Stanford, Suite 220, Valencia, CA 91355**  
(Address of principal executive offices, including Zip Code)

**661.367.9170**  
(Registrant's telephone number, including area code)

N/A  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	RCEL	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934. Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 8.01. Other Events.**

On March 8, 2022, AVITA Medical, Inc. (“the Company”) presented at the Cowen 42<sup>nd</sup> Annual Health Care Conference. Interested parties may access an archived webcast of the presentation through the “Investors” section of the Company website at [ir.avitamedical.com](http://ir.avitamedical.com). The replay of the webcast will be archived for 90 days. A copy of the presentation given by the Company’s CEO, Dr. Mike Perry, is attached hereto as Exhibit 99.1.

The information under this Item 8.01 and in Item 9.01 below is being furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 and shall not be deemed incorporated by reference into any filing made under the Securities Act of 1933, except as expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">AVITA Medical Cowen 42<sup>nd</sup> Annual Health Care Conference Presentation</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 9, 2022

**AVITA MEDICAL, INC.**

By: /s/ Donna Shiroma

Name: Donna Shiroma

Title: General Counsel

**avita** medical

**One Platform.  
Endless Possibilities.**

February 2022

NASDAQ: RCEL

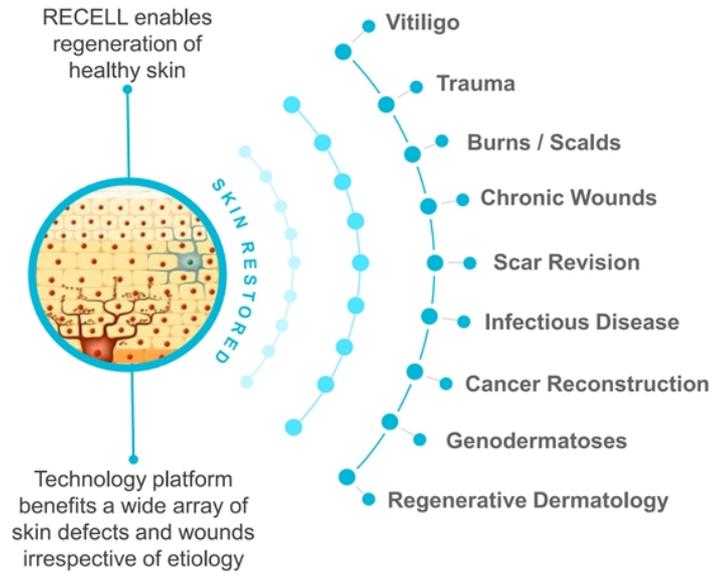
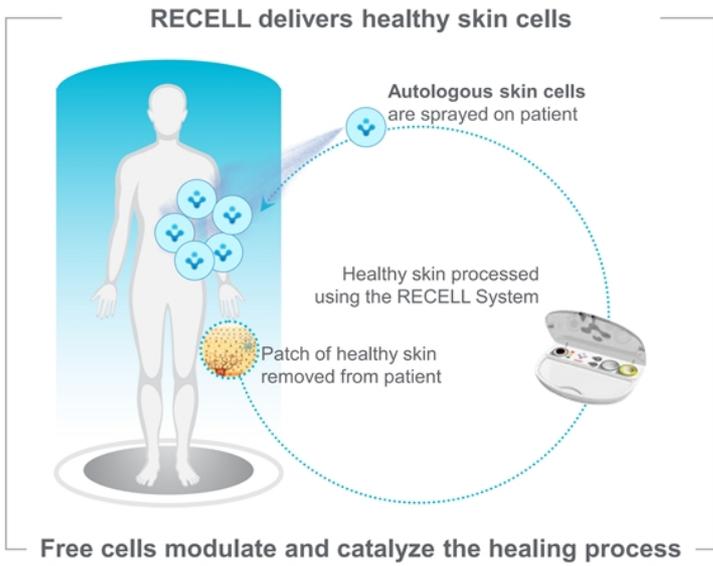
ASX: AVH



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 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).



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.

## 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 style="list-style-type: none"> <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 style="list-style-type: none"> <li>• Outpatient Launch</li> <li>• Launch of New “Ease of Use” RECELL Device</li> </ul>	H1 22
<ul style="list-style-type: none"> <li>• IND Enabling Studies (EB &amp; Rejuvenation)</li> <li>• Reimbursement &amp; Launch of Burns in Japan</li> </ul>	H2 22

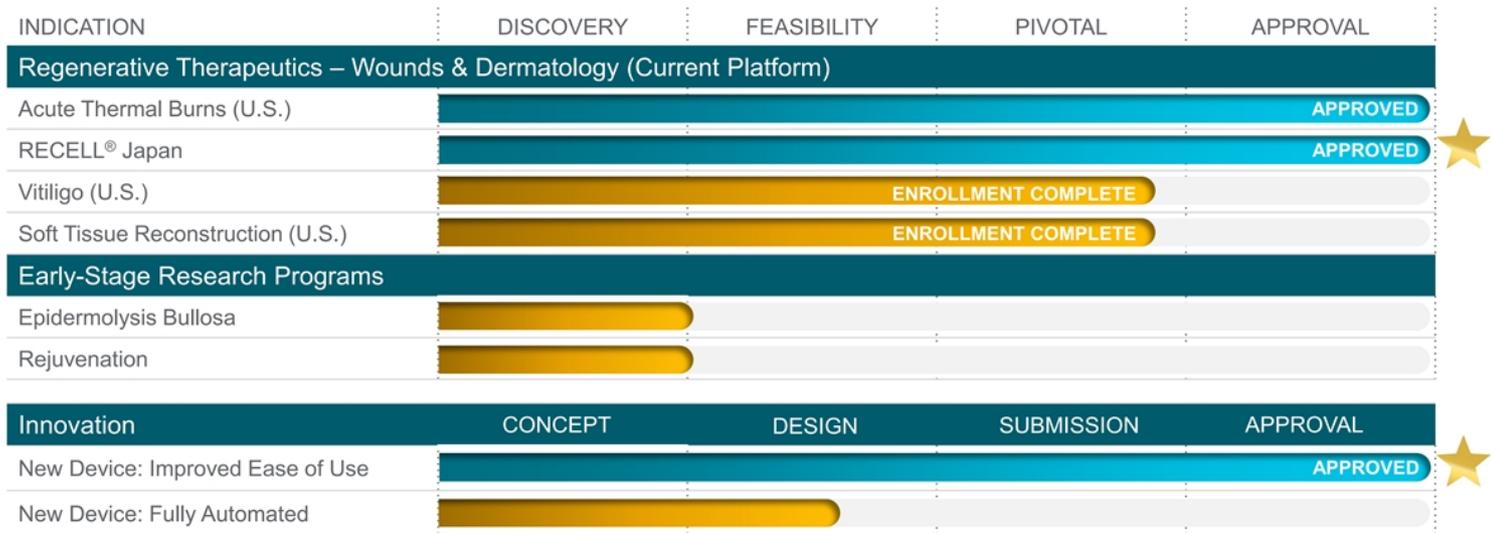
Quarters referenced in calendar year. As of January 1, 2022 Avita Medical is reporting on a calendar year basis.



## Development Pipeline and Growth Potential

avita<sup>medical</sup>

# Focused Pipeline with Strong Growth Potential

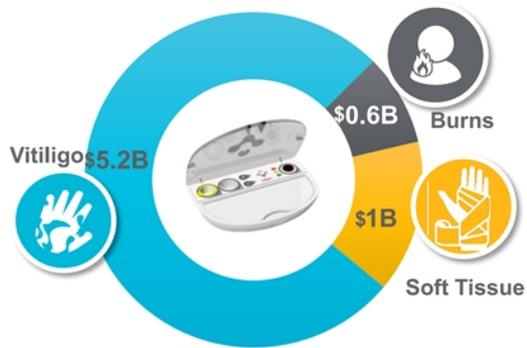


## Focused Effort on Business Development to Supplement Pipeline

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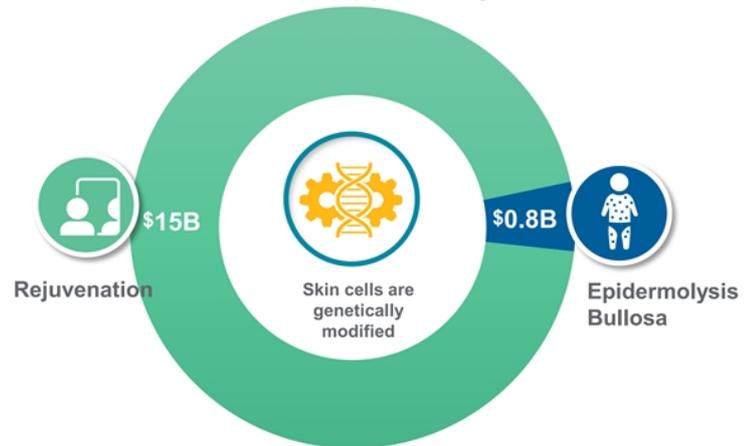
## EXISTING PLATFORM

~\$6.8B Opportunity



## NEW PLATFORMS: CELL BASED GENE THERAPY

~\$15.8B Opportunity



> \$22 Billion in Combined TOTAL ADDRESSABLE MARKET

## 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

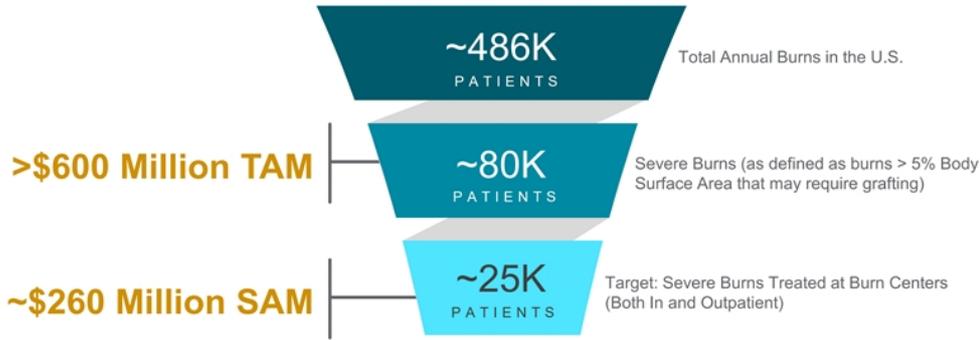
Highly De-risked Pipeline with >15,000 Patients Treated Globally

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

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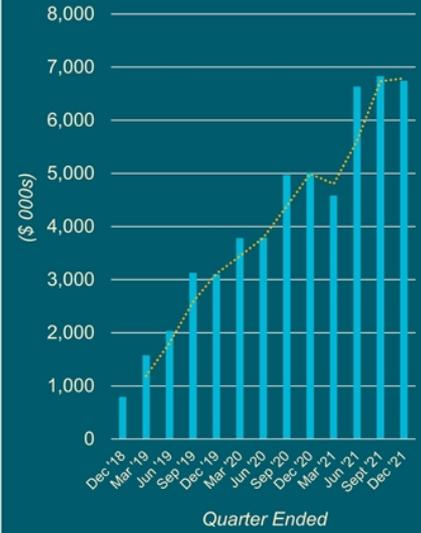
# Thermal Burns: U.S. Target Market Expanded to Include Small Burns and Outpatient

Patient Funnel and Addressable Market

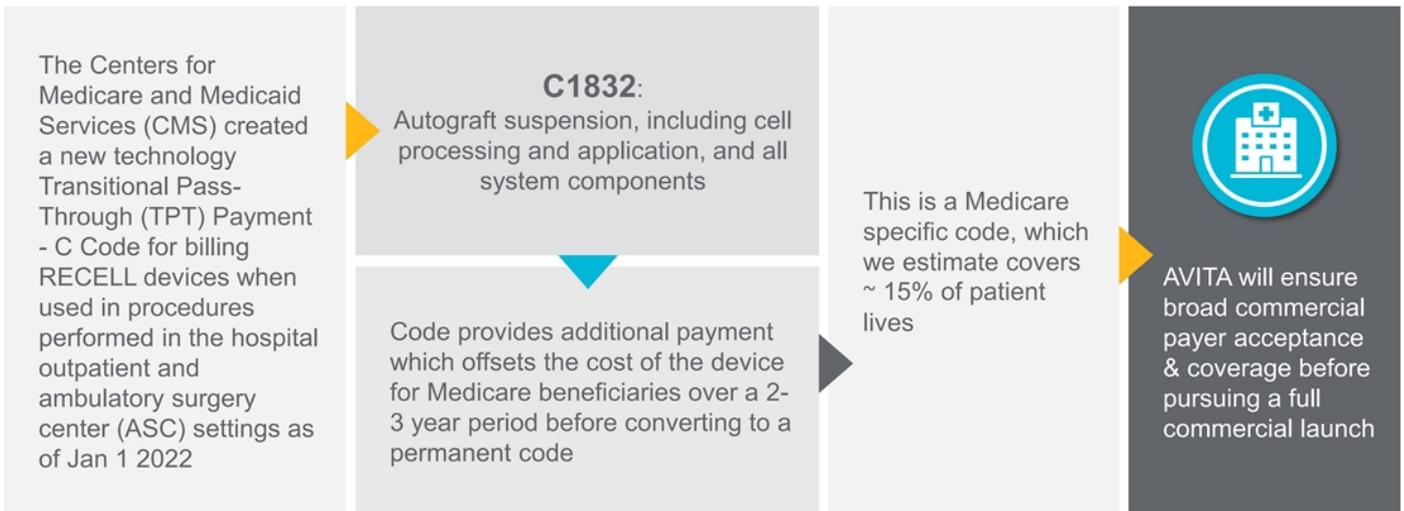


Outpatient Pass Through Code Opens Doors to Small Burns and Expands Serviceable Market Opportunity

U.S. RECELL Commercial Sales Since Approval



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



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



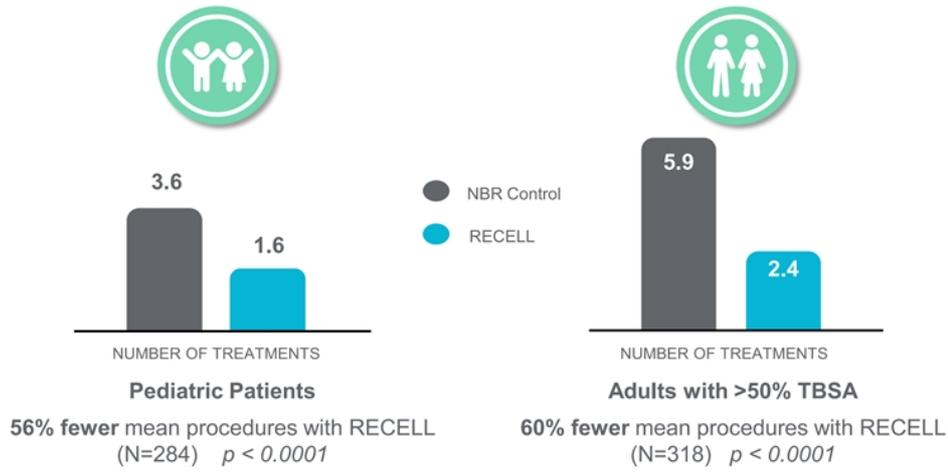
94% of users of the RECELL System believe it will reduce their workload/allow them to perform other duties\*

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

\* 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>



~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"

## BACKGROUND



AVITA Commercial Partner:  
COSMOTEC, an M3 Company

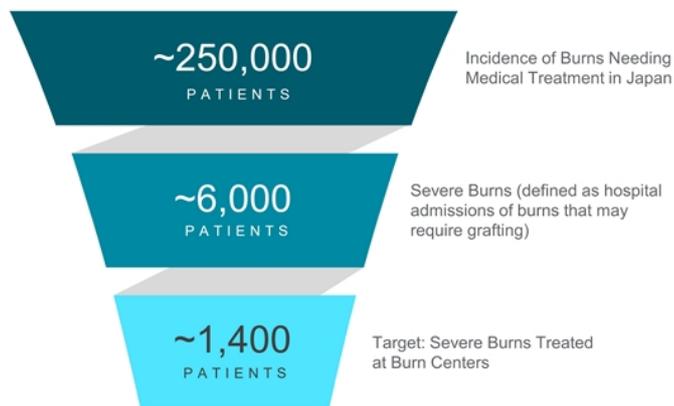


INDICATION: Burns  
Soft Tissue and Vitiligo to Follow Based on U.S. Pivotal Clinical Data



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

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\\_2/36BF2](https://injuryprevention.bmj.com/content/26/Suppl_2/36BF2) and Cosmotec estimates

## SIGNIFICANT UNMET NEED

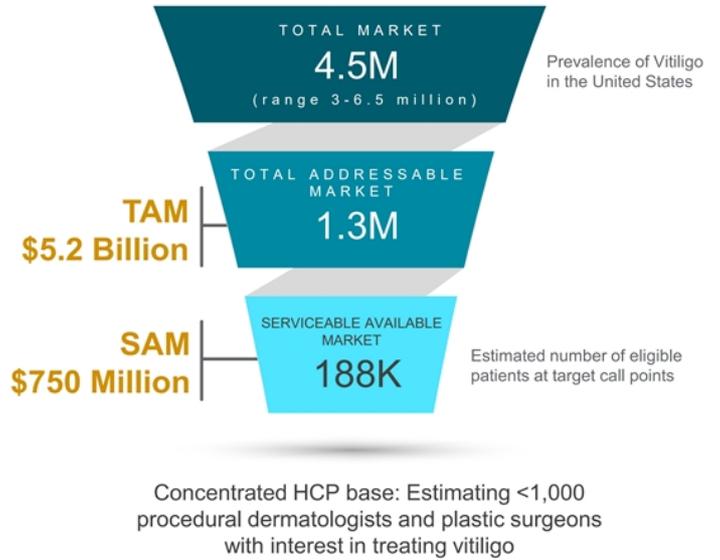


Up to 2% of the population affected

**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

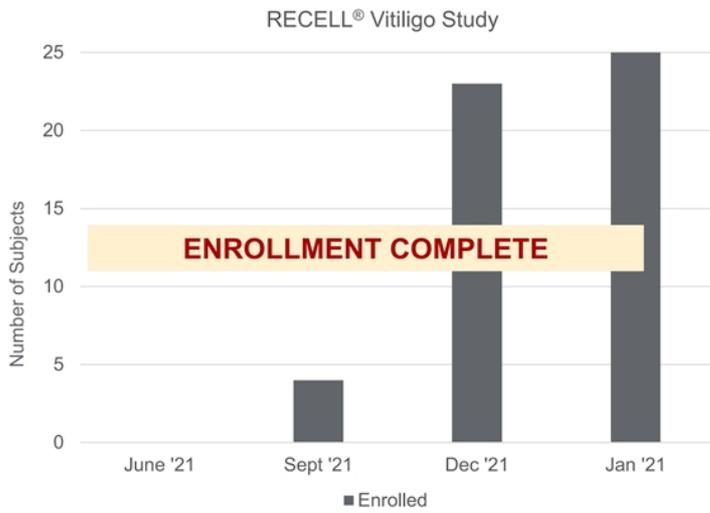
## OPPORTUNITY ESTIMATION



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.

# Vitiligo Study Enrollment Complete

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



Patient from a Prior Study at 6 MONTHS  
RECELL-treated area was 100% re-pigmented

**POTENTIAL RECELL BENEFITS**

**For Stable Vitiligo:**  
Segmental & Non-Segmental

**Durable:** One-time treatment

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

In the United States, RECELL is not approved for treatment of vitiligo.



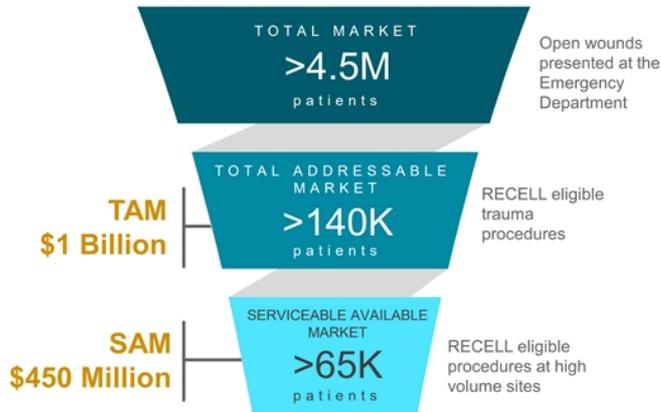
- 23 year old female with vitiligo.
- Donor skin was harvested from adjacent unaffected areas.
- Depigmented epidermis was removed using dermabrasion.
- The cellular suspension was then sprayed on both the recipient and donor areas (expansion ratio ranged from 1:20-1:40).

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

Yu et al. Repigmentation of nipple-areola complex after RECELL® treatment on breast vitiligo. Journal of Cosmetic Dermatology, 2021  
In the United States, RECELL is not approved for use with patients suffering vitiligo.

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

## OPPORTUNITY ESTIMATION



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



POST DEBRIDEMENT OF INJURY



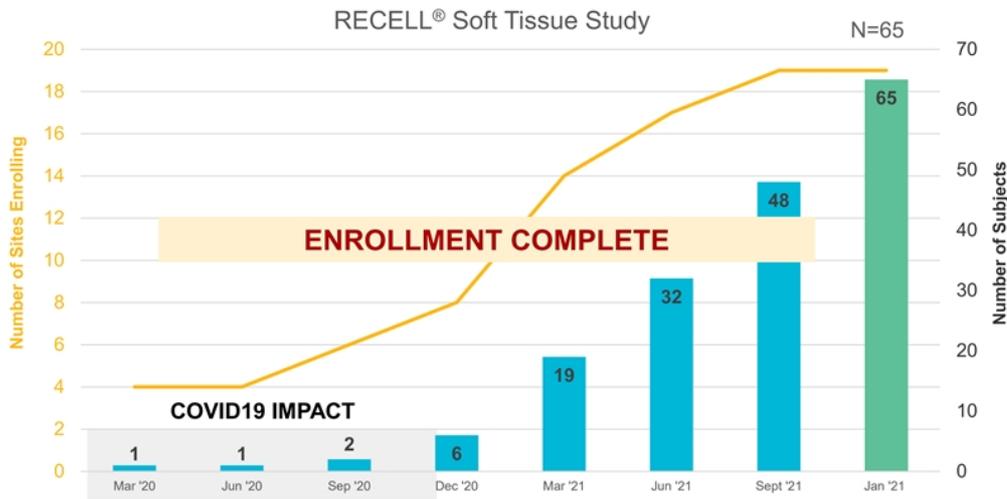
6 MONTH POST-RECELL TREATMENT

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. 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.

# 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

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 treated for necrotizing fasciitis



TREATMENT DAY



1 YEAR POST-RECELL TREATMENT

Photos courtesy of Kevin Foster, Valleywise Health Medical Center

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**

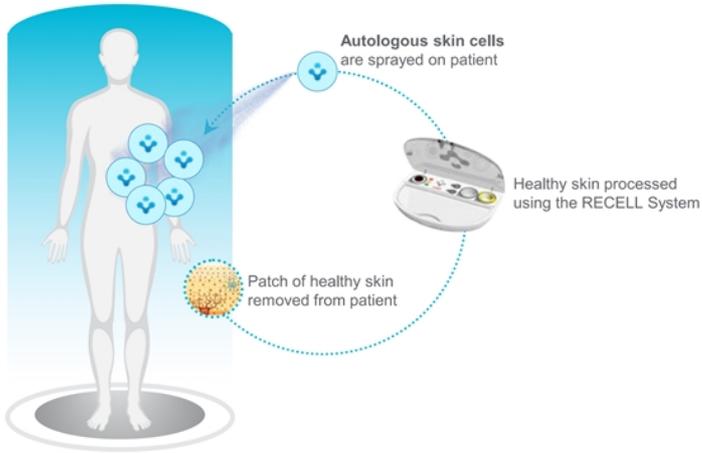
Reduction of donor site morbidity & donor site requirements are top unmet needs

Large opportunity that leverages existing burns infrastructure

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.

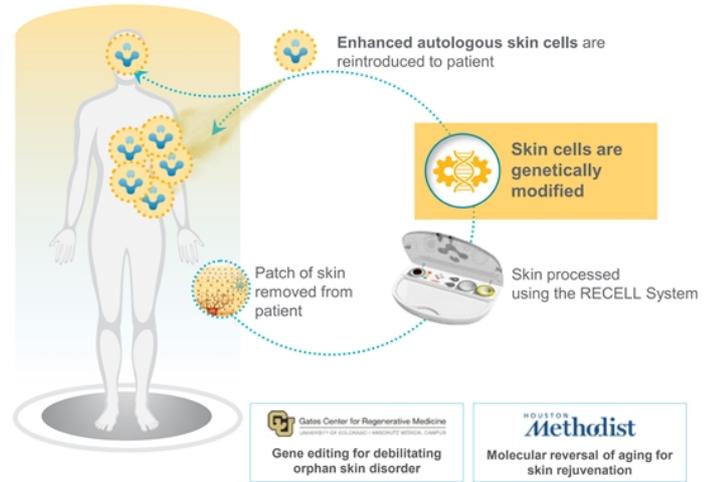
## CURRENT PLATFORM

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)



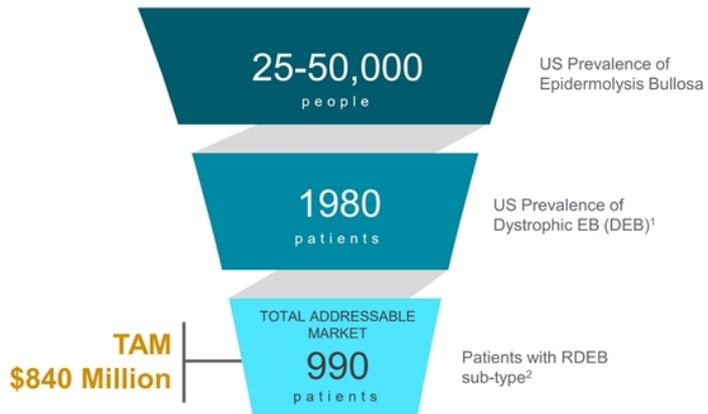
Program Objective:

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

# 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



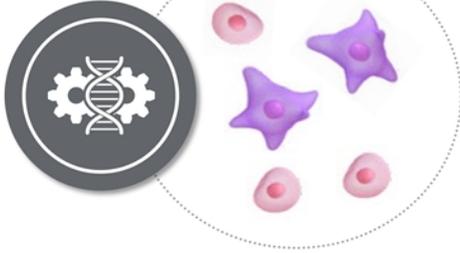
*Ex vivo* gene editing of skin cells has a safety advantage over *in vivo* gene therapeutics

**~\$840M target US market opportunity, assuming \$850,000<sup>4</sup> per patient / treatment**

1. Has et al, "Consensus reclassification of inherited epidermolysis bullosa and other disorders with skin fragility." Br J of Dermatology, 2020. Range 1,100-2,500. 2. DEB prevalence estimated as 6/million. RDEB estimated to be approximately half of DEB prevalence = 3/million. Range: 1.35- 8/million. Fine et al, "Epidemiology of Inherited Epidermolysis Bullosa..." JAMA, 2016. 3. Luxturna (gene therapy for a rare, inherited retinal disease that can lead to blindness) was priced at \$850,000 for a population between 1000-2000 patients in US. Zolgensma for spinal muscular atrophy is priced at \$2.1 million

Successful reverse-differentiation (induced pluripotency) and gene correction of Recessive Dystrophic Epidermolysis Bullosa (RDEB) Skin Cells

Correction of RDEB Single-Site Mutation



## In Vivo Evaluation of Gene-corrected Skin Cells

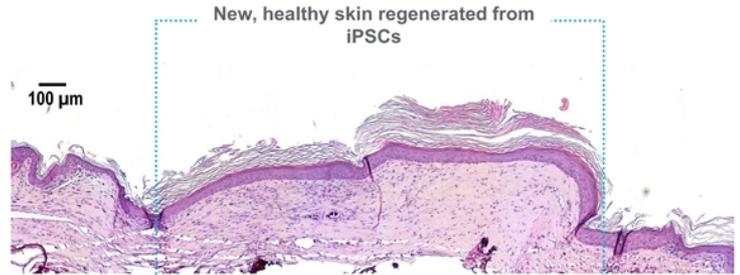
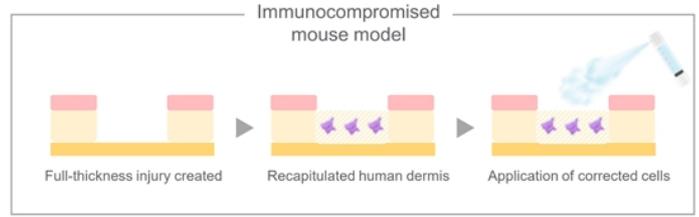


Image courtesy of Gates Center for Regenerative Medicine, University of Colorado

## 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)

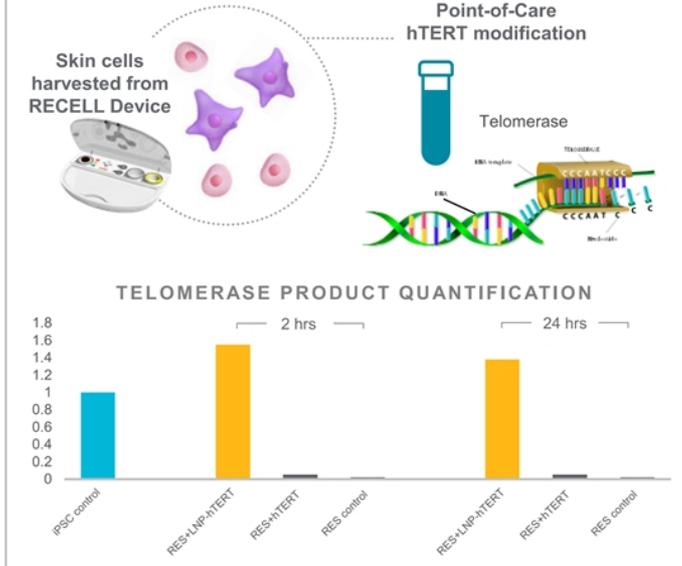


**EFFICIENT:** Suspension-based approach eliminates growth & transport of fragile skin sheets

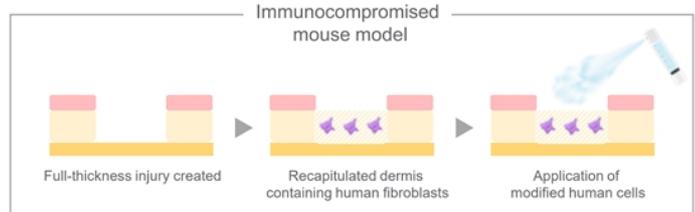


**CONVENIENT:** Suspension-based product simplifies application onto patient wounds (vs surgical anchoring of epidermal sheets which can result in issues with “take rates”)

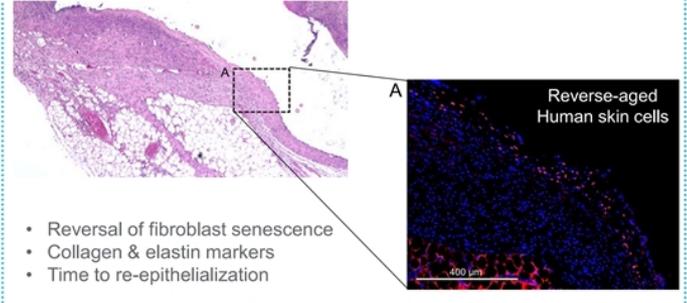
## Successful delivery of mRNA-hTERT & expression in Skin Cells Derived from RECELL



## In Vivo Evaluation of mRNA-hTERT Modified Skin Cells



## On-going Characterization



Data and image courtesy of Houston Methodist Research Institute, Houston, TX

# 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

(USD in \$000s)	12 Months Ended June 30				(Unaudited) 12 Months Ended December 31	(Unaudited) 12 Months Ended December 31
	2018	2019	2020	2021	2020	2021
Commercial Sales	929	5,474	14,263	21,483	17,918	25,091
BARDA Sales	-	-	-	7,749	-	7,934
<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>
Gross Profit	383	4,203	11,290	23,283	14,660	26,921
BARDA Income	7,734	5,921	3,926	2,055	2,534	1,590
Cash, cash equivalents and Marketable Securities	10,986	20,174	73,639	110,746	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:  
**RCEL**

ASX ticker  
symbol:  
**AVH**

1. RCEL as 2/25/2022

## 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**

# 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:

Affiliations:

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<ul style="list-style-type: none"> <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 style="list-style-type: none"> <li>• Outpatient Launch</li> <li>• Launch of New 'Ease of Use' RECELL Device</li> </ul>	H1 22
<ul style="list-style-type: none"> <li>• IND Enabling Studies (EB &amp; Rejuvenation)</li> <li>• Reimbursement &amp; Launch of Burns in Japan</li> </ul>	H2 22

Quarters referenced in calendar year. As of January 1, 2022 Avita Medical is reporting on a calendar year basis.

- 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.

- **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>



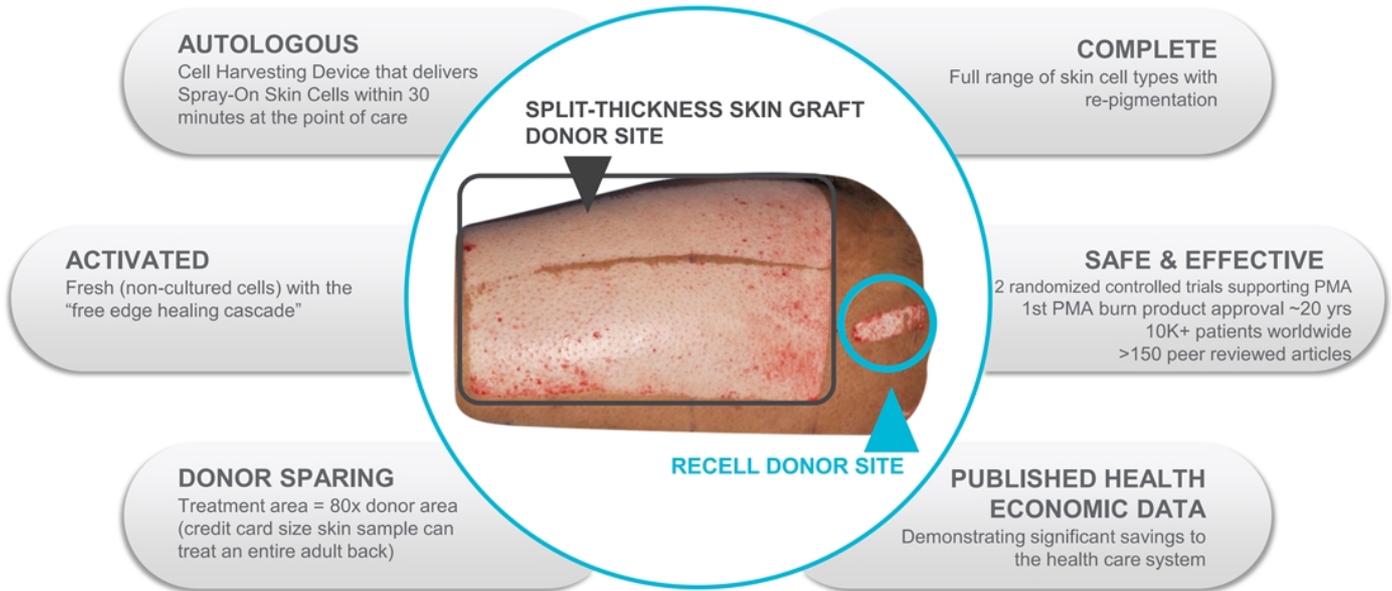
Zed, treated with the RECELL® System

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.



# RECELL Spray-On Skin™

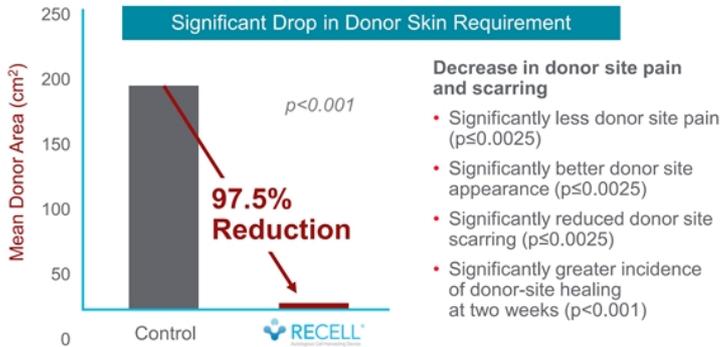
## Treats 80cm<sup>2</sup> of Skin from a 1cm<sup>2</sup> Biopsy



Dual multi-center, randomized, controlled premarket approval studies

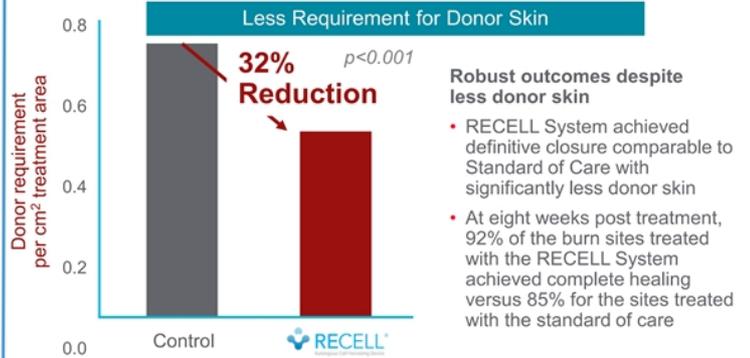
## Pivotal Trial #1 (101 Patients) RECELL (alone) versus SoC (STSG) in Second-Degree Burns

Published in JBCR and Presented at ABA



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

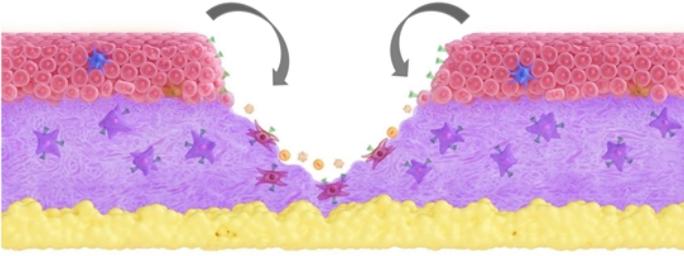
Published in Burns and Presented at ABA



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

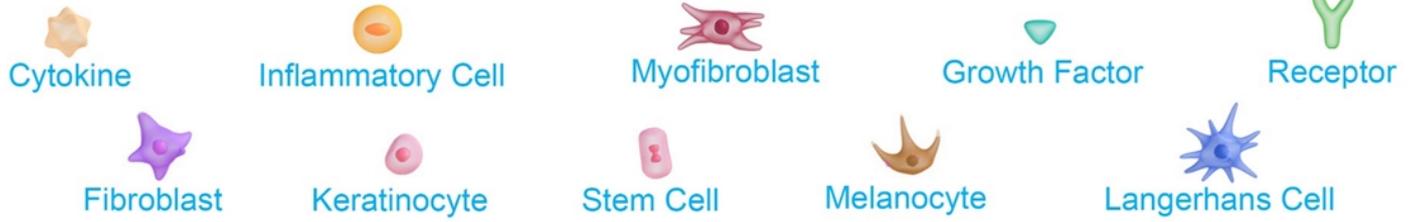
## Healing Process *without* RECELL

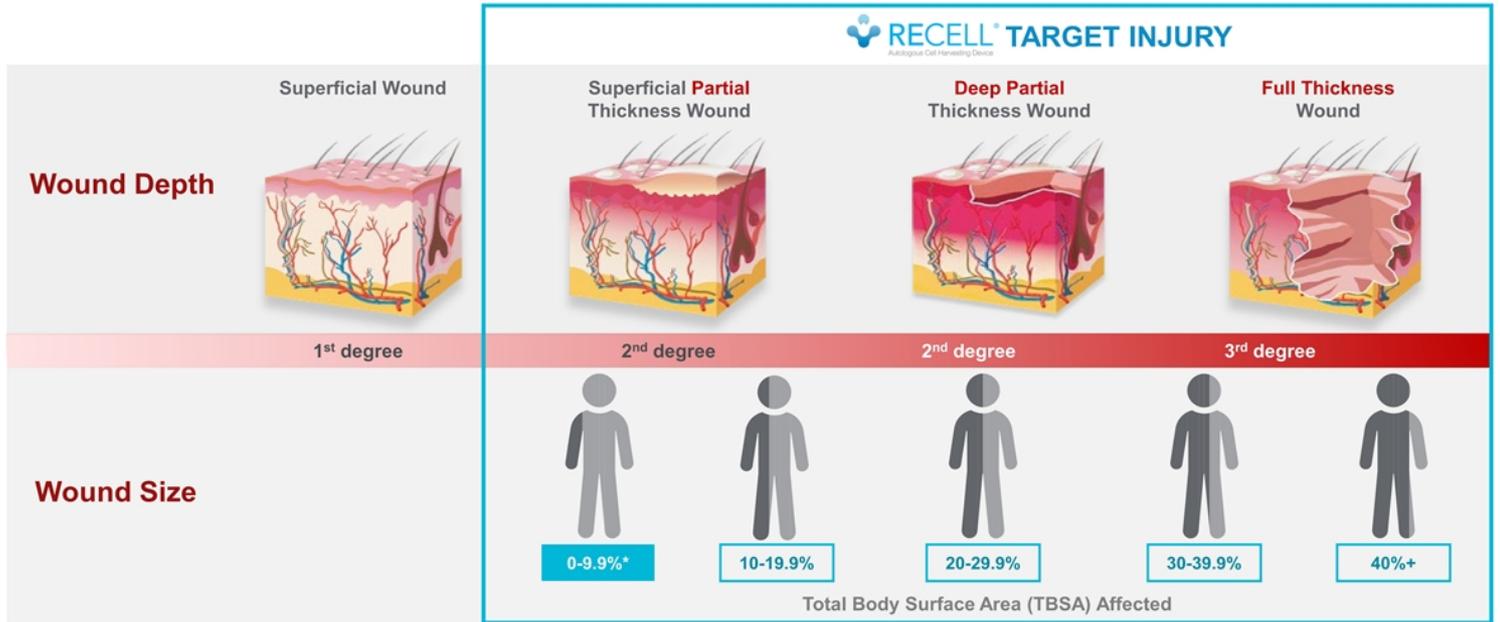
Free edge limits signaling to wound boundary (i.e. outside → in)



## Healing Process *with* RECELL

Spray-On Skin Cells signal from within the wound (i.e. inside → out)





**Adoption Trajectory**

Small / Partial Thickness ← Results / Experience ← Large / Full Thickness

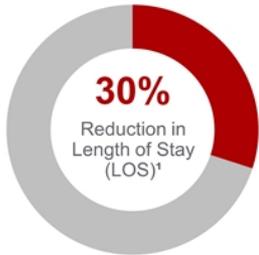
For more information on RECELL's indication for use, please go to [www.recellsystem.com](http://www.recellsystem.com).

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

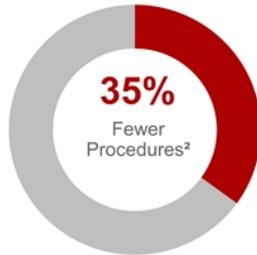
RECELL saves the hospital money in in-patient scenarios where the burn is 10% Total Body Surface Area (TBSA) or greater

## 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

1. 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>

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