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): January 10, 2022

Avita Medical, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-39059	85-1021707
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

28159 Avenue Stanford, Suite 220, Valencia, CA 91355	661.367.9170
(Address of principal executive offices, including Zip Code)	(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 2.02. Results of Operations and Financial Condition.

On January 10, 2022, Avita Medical, Inc. (the "Company"), announced preliminary unaudited results for the quarter ended December 31, 2021 and certain other business updates. A copy of a press release announcing same is furnished herewith as Exhibit 99.1 to this report.

Item 7.01. Regulation FD Disclosure.

On January 11, 2022, the Company participated in the 40th Annual J.P. Morgan Healthcare Conference. During the presentation, representatives of the Company presented slides, attached hereto as Exhibit 99.2.

The information under these Items 2.02, 7.01, and in Item 9.01 below are 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.

Exhibit No.	Description
99.1	**AVITA Medical Announces Preliminary Unaudited Results for the Quarter Ended December 31, 2021**
99.2	**JP Morgan Healthcare Conference Presentation**
EXHIBIT 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: January 11, 2022

AVITA MEDICAL, INC.

By: /s/ Donna Shiroma
Name: Donna Shiroma
Title: General Counsel

AVITA Medical Announces Preliminary Unaudited Results for the Quarter ended December 31, 2021

VALENCIA, Calif, January 10, 2022 and MELBOURNE, Australia, January 11, 2022 — AVITA Medical, Inc. (NASDAQ: RCEL, ASX:AVH) (the "**Company**"), a regenerative medicine company that is developing and commercializing a technology platform that enables point-of-care autologous skin restoration for multiple unmet needs, today announced preliminary unaudited estimates of its top line results for the three months ended December 31, 2021.

Preliminary Results for the Quarter ended December 31 and Recent Updates:

- Total revenue increased 35% to $6.9 million in the quarter ended December 31, 2021, compared to $5.1 million over the same quarter in the prior year
- As of December 31, 2021, the Company had approximately $55.5 million in cash and cash equivalents and $49.3 million in short-term and long-term marketable securities, and no debt
- Effective December 2021, the Company changed its fiscal year-end to December 31
- Completed enrollment in two clinical trials with the goal of submitting premarket approval (PMA) supplements in 2022
    - In December 2021, completed enrollment of pivotal clinical trial evaluating the safety and effectiveness of the RECELL® System for the repigmentation of stable vitiligo lesions
    - In January 2022, completed enrollment of pivotal study of RECELL System for soft tissue reconstruction (trauma)
- Successfully established proof of concept with preclinical data in two key areas of cell-based gene therapy – skin rejuvenation and epidermolysis bullosa.

"Our recent successes in getting two pivotal clinical trials fully enrolled, and also demonstrating proof of concept in two other potential indications, underscore our commitment to further growing the market opportunities for the RECELL system," said Dr. Mike Perry, AVITA Medical Chief Executive Officer. "Looking ahead, we will be preparing our vitiligo and soft tissue dossiers to submit PMA supplement applications to the FDA in late 2022 for commercial launches for those indications in 2023."

Authorized for release by the Chief Financial Officer of AVITA Medical, Inc.

# # #

ABOUT AVITA Medical, Inc.

AVITA Medical, Inc. is a regenerative medicine company with a technology platform positioned to address unmet medical needs in burns, chronic wounds, and aesthetics indications. AVITA Medical Inc. patented and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient's own skin. The medical devices work by preparing a RES® REGENERATIVE EPIDERMAL SUSPENSION, an autologous suspension comprised of the patient's skin cells necessary to regenerate natural healthy epidermis. This autologous suspension is then sprayed onto the areas of the patient requiring treatment.

AVITA Medicals' first U.S. product, the RECELL® System, was approved by the U.S. Food and Drug Administration (FDA) in September 2018. The RECELL® System is approved for 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. The RECELL® System is used to prepare

Spray-On Skin™ Cells using a small amount of a patient's own skin, providing a new way to treat severe burns, while significantly reducing the amount of donor skin required. The RECELL® System is designed to be used at the point of care alone or in combination with autografts depending on the depth of the burn injury. Compelling data from randomized, controlled clinical trials conducted at major U.S. burn centers and real-world use in more than 8,000 patients globally, reinforce that the RECELL® System is a significant advancement over the current standard of care for burn patients and offers benefits in clinical outcomes and cost savings. Healthcare professionals should read the INSTRUCTIONS FOR USE—RECELL® Autologous Cell Harvesting Device (https://recellsystem.com/) for a full description of indications for use and important safety information including contraindications, warnings, and precautions.

In international markets, our products are marketed under the RECELL® System brand to promote skin healing in a wide range of applications including burns, chronic wounds, and aesthetics. The RECELL® System is TGA-registered in Australia and received CE-mark approval in Europe.
To learn more, visit www.avitamedical.com.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This press release includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as "anticipate," "expect," "intend," "could," "may," "will," "believe," "estimate," "look forward," "forecast," "goal," "target," "project," "continue," "outlook," "guidance," "future," other words of similar meaning and the use of future dates. Forward-looking statements in this press release include, but are not limited to, statements concerning, among other things, our ongoing clinical trials and product development activities, regulatory approval of our products, the potential for future growth in our business, and our ability to achieve our key strategic, operational, and financial goals. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Each forward- looking statement contained in this press release is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, the timing of regulatory approvals of our products; physician acceptance, endorsement, and use of our products; failure to achieve the anticipated benefits from approval of our products; the effect of regulatory actions; product liability claims; risks associated with international operations and expansion; and other business effects, including the effects of industry, economic or political conditions including, but not limited to the ongoing COVID-19 pandemic which are outside of the company's control. Investors should not place considerable reliance on the forward-looking statements contained in this press release. Investors are encouraged to read our publicly available filings for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this release, and we undertake no obligation to update or revise any of these statements.

FOR FURTHER INFORMATION:

U.S. Media
Sam Brown, Inc.
Christy Curran
Phone +1 615 414 8668

christycurran@sambrown.com

O.U.S Media
Monsoon Communications
Rudi Michelson
Phone +61 (0)3 9620 3333
Mobile +61 (0)411 402 737

rudim@monsoon.com.au

Investors
ICR Westwicke
Caroline Corner
Phone +1 415 202 5678
caroline.corner@westwicke.com

# # #

PR20220110

Exhibit 99.

One Platform.
Endless Possibilities.

January 2022

NASDAQ: RCEL ASX: AVH

Legal Disclaimers

Certain statements in this presentation and the accompanying oral commentary are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this presentation, including statements regarding our future financial condition, technology platform, development strategy, prospective products, pipeline and milestones, regulatory objectives, expected payments from and outcomes of collaborations, and likelihood of success, are forward-looking statements. Such statements are predictions only and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, among others, the costs, timing and results of clinical trials and other development activities; the uncertainties inherent in the initiation and enrollment of clinical trials; the uncertainties associated with the COVID-19 pandemic; the unpredictability of the timing and results of regulatory submissions and reviews; market acceptance for approved products and innovative therapeutic treatments; competition; the possible impairment of, inability to obtain and costs of obtaining intellectual property rights; and possible safety or efficacy concerns, general business, financial and accounting risks and litigation. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. More information concerning AVITA Medical as well as the aforementioned risks and uncertainties is available in our public filings with the U.S. Securities and Exchange Commission, including our most recent Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 and our most recent Annual Report on Form 10-K for the year ended June 30, 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).

Value Creation

Recent Key Accomplishments

- 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
- Quarter Ending December ’21, Total Revenue Growth of +35% vs Same Quarter Prior Year
- FDA Approval of Pediatric Label Expansion
- New Ease of Use RECELL Device under FDA Review

Projected Key Milestones

• Vitiligo FDA Submission / Vitiligo Commercial launch • Soft Tissue FDA Submission / Soft Tissue Commercial Launch	H2 22 / H2 23
• Outpatient Launch • PMDA Approval of Burns in Japan • FDA Approval of New ‘Ease of Use’ RECELL Device	H1 22
• IND Enabling Studies (EB & Rejuvenation)	H2 22

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

AVITA Leadership Team

Dr. Michael S. Perry
CEO
>30 years experience

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

Michael Holder
CFO
>30 years experience

Affiliations:
ImmuneCyte
PREMIER
CAROLINA LONGEVITY INSTITUTE

Erin Liberto
CCO
>20 years experience

Affiliations:
Allergan
Johnson & Johnson

Andrew Quick
CTO
>25 years experience

Affiliations:
Boston Scientific
AB
sonova
SonaMed Corp

Kathy McGee
COO
>25 years experience

Affiliations:
Shire
at advanced tissue
SmithNephew

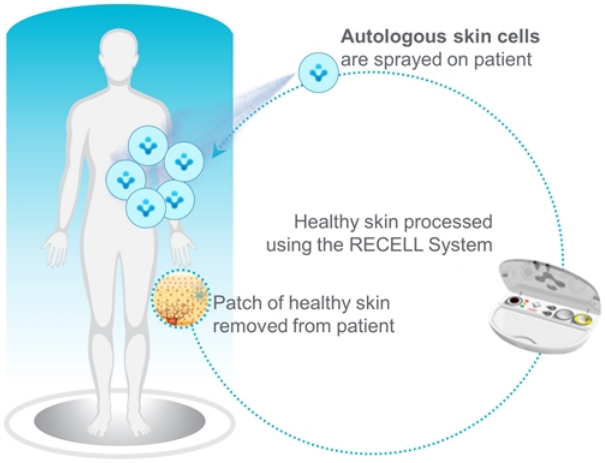
Donna Shiroma
General Counsel
>20 years experience

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

One Platform. Endless Possibilities.

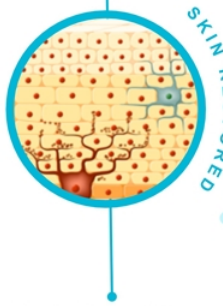
RECELL®
Autologous Cell Harvesting Device

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

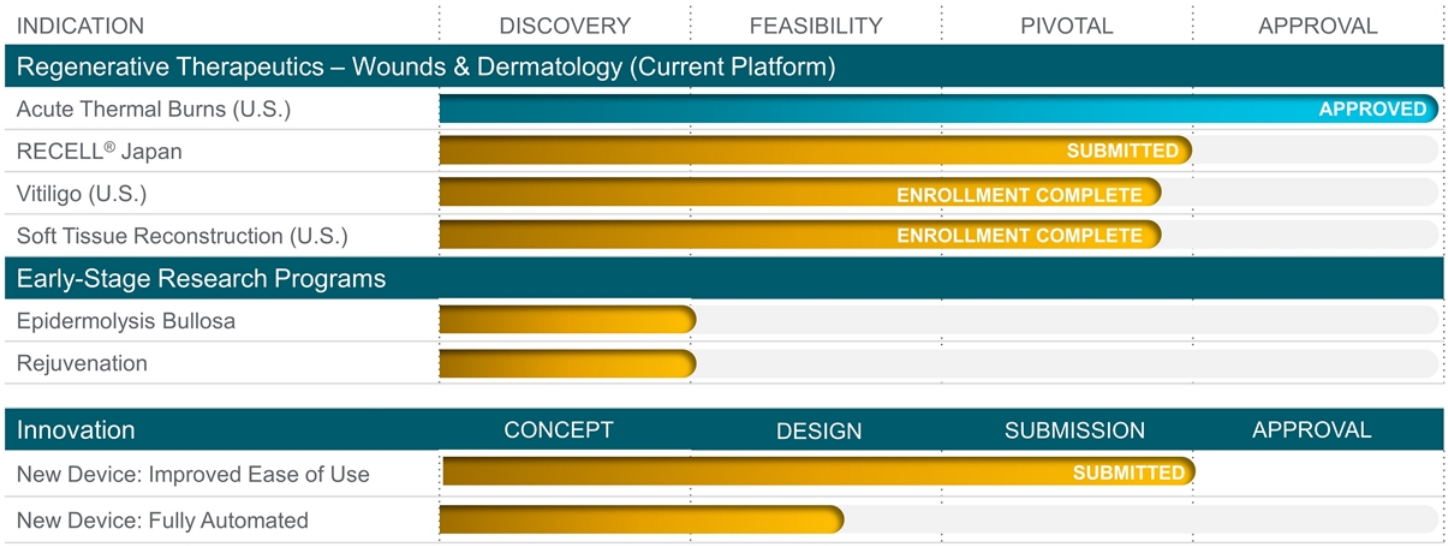
- Vitiligo
- Trauma
- Burns / Scalds
- Chronic Wounds
- Scar Revision
- Infectious Disease
- Cancer Reconstruction
- Genodermatoses
- Regenerative Dermatology

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.

Development Pipeline and Growth Potential

avita medical

Focused Pipeline with Strong Growth Potential



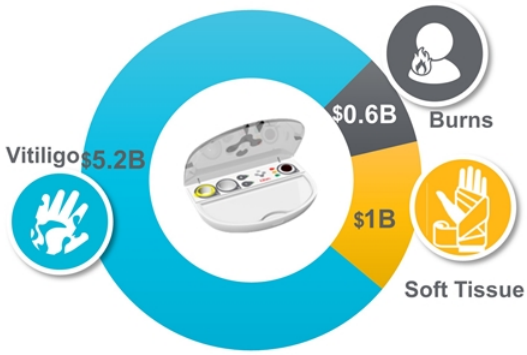
Focused Effort on Business Development to Supplement Pipeline

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.

Market Opportunity of Pipeline Exceeds $22 Billion

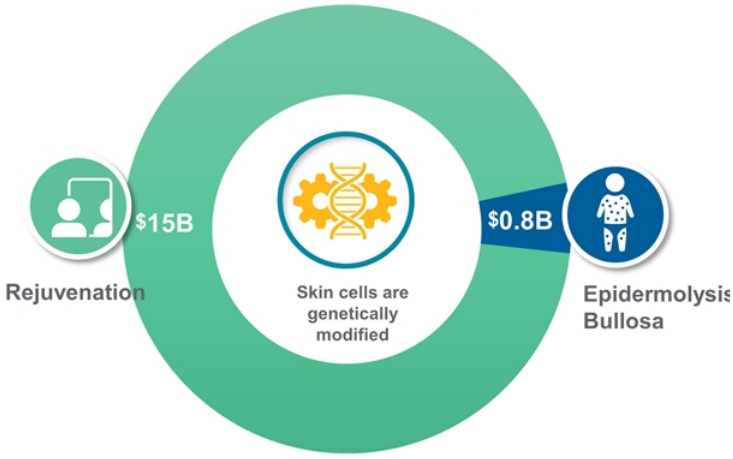
EXISTING PLATFORM

~$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
ACUTE WOUNDS *(Including Thermal Burns)*	1,772	206
DEFECTS/ VITILIGO	453	57
CHRONIC WOUNDS	143	17

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

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

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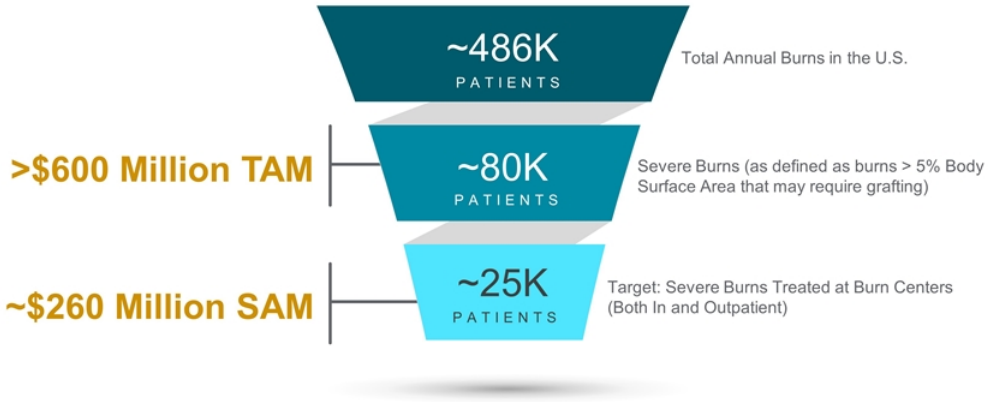
Thermal Burns: U.S. Target Market Expanded to Include Small Burns and Outpatient

Patient Funnel and Addressable Market



Outpatient Pass Thru 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 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

New Device

Reduced number of steps

Simplified Process

Improved Usability

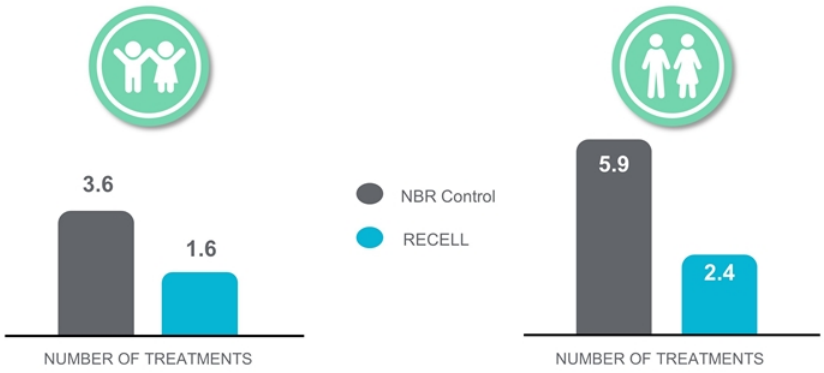
94% of users of the RECELL System believe it will **reduce their workload/allow them to perform other duties***

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

* Market Research March 2020 HCPs N=15

FDA Approval in Pediatric Full-Thickness & Larger Burns

FEWER PROCEDURES REQUIRED FOR DEFINITIVE CLOSURE VS CONVENTIONAL AUTOGRAFT[1]

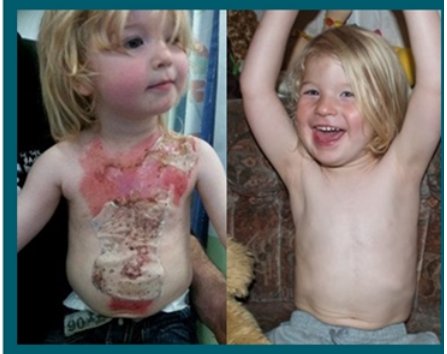


Pediatric Patients

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

Adults with >50% TBSA

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



~25% of all burns occur in children

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

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

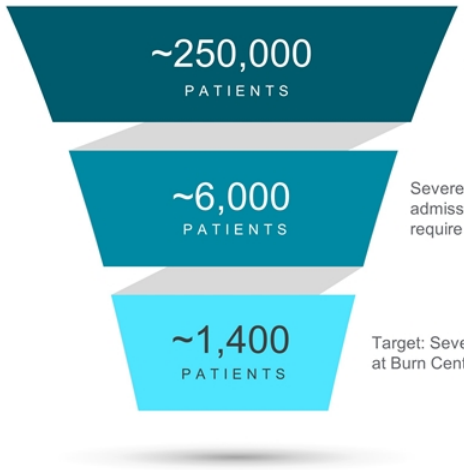
INDICATION: Burns

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

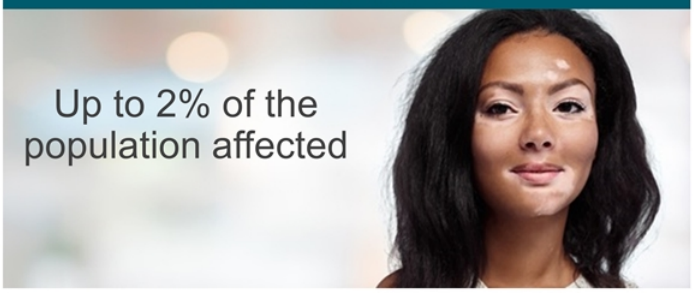


Reimbursement Anticipated in June 2022 with Commercial Launch Following Thereafter

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 and Cosmotec estimates

Vitiligo: Hight Unmet Need, No FDA-Approved Products

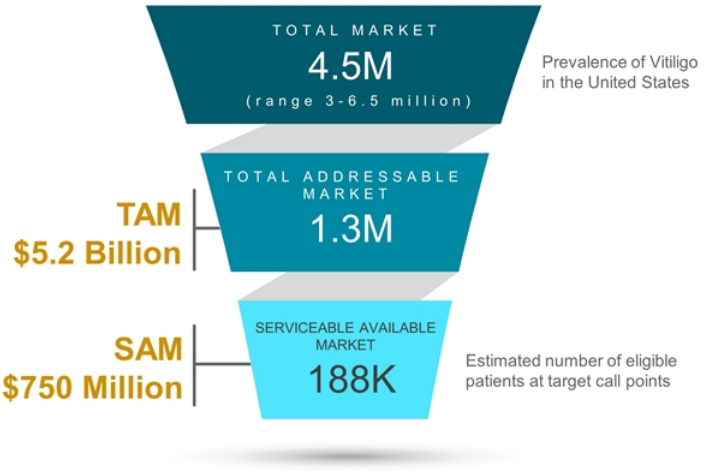
SIGNIFICANT UNMENT NEED



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

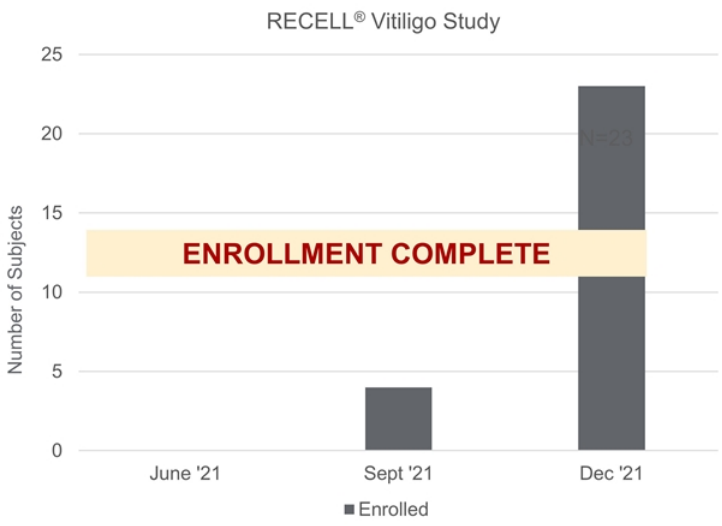


Concentrated HCP base: Estimating <1,000 procedural dermatologists and plastic surgeons with interest in treating vitiligo

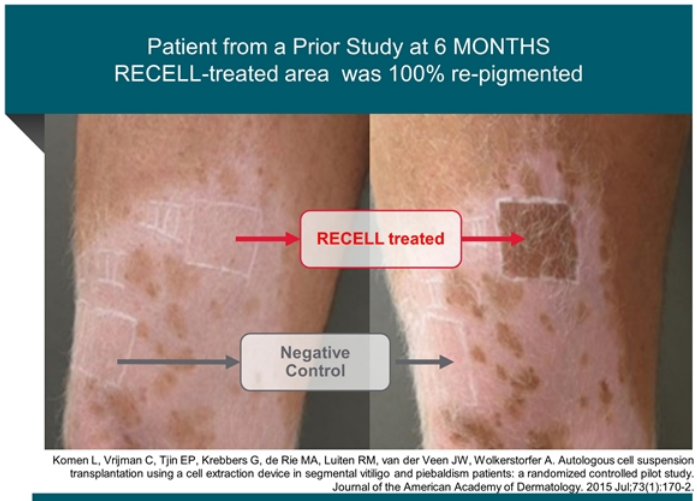
Advances in Vitiligo: An Update on Medical and Surgical Treatments. A. Dillon, et al. J Clin Aesth Derm. 2017. Willingness-to-Pay and Quality of Life in Patients with Vitiligo. Radtke, et al. BJD. 2009.
In the U.S., RECELL is approved for acute thermal burns. Use of RECELL in other indications is either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

Vitiligo Study Completed in Two Quarters

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



FDA Submission Expected in H2 ’22 with Approval in H2 ‘23



Komen L, Vrijman C, Tjin EP, Krebbers G, de Rie MA, Luiten RM, van der Veen JW, Wolkerstorfer A. Autologous cell suspension transplantation using a cell extraction device in segmental vitiligo and piebaldism patients: a randomized controlled pilot study. Journal of the American Academy of Dermatology. 2015 Jul;73(1):170-2.

POTENTIAL RECELL BENEFITS

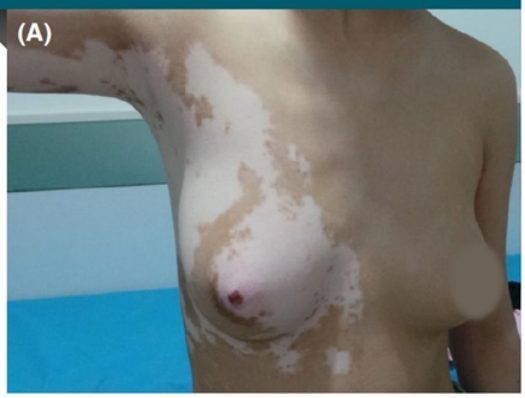
For Stable Vitiligo: Segmental & Non-Segmental

Durable: One-time treatment

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

RECELL Case: Repigmentation of the Nipple-Areola Complex

Before RECELL®



12 months After RECELL®

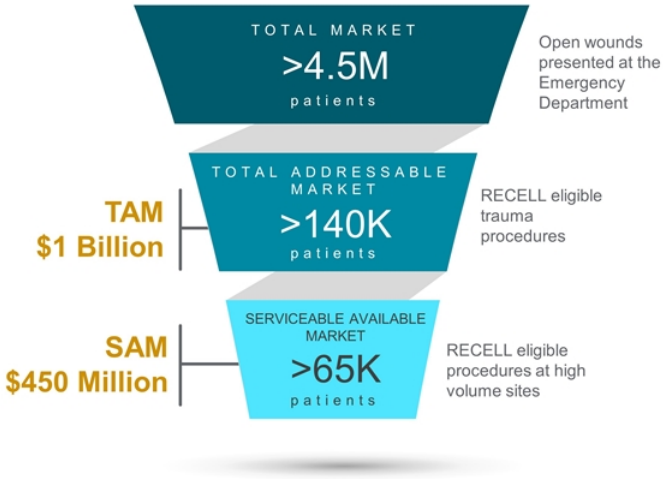
- 23 year old female with vitiligo.
- Donor skin was harvested from adjacent unaffected areas.
- Depigmented epidermis was removed using dermabrasion.
- The cellular suspension was then sprayed on both the recipient and donor areas (expansion ratio ranged from 1:20-1:40).

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

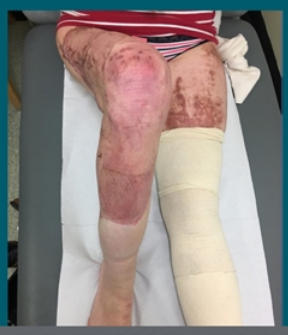


In the U.S., RECELL is approved for acute thermal burns. Use of RECELL in other indications is either (1) limited by United States law to investigational use; or (2) otherwise prohibited. In the United States, RECELL is not approved for use in pediatrics. Use of RECELL in this case was performed internationally where the indication is approved.

avita

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

POST DEBRIDEMENT OF INJURY

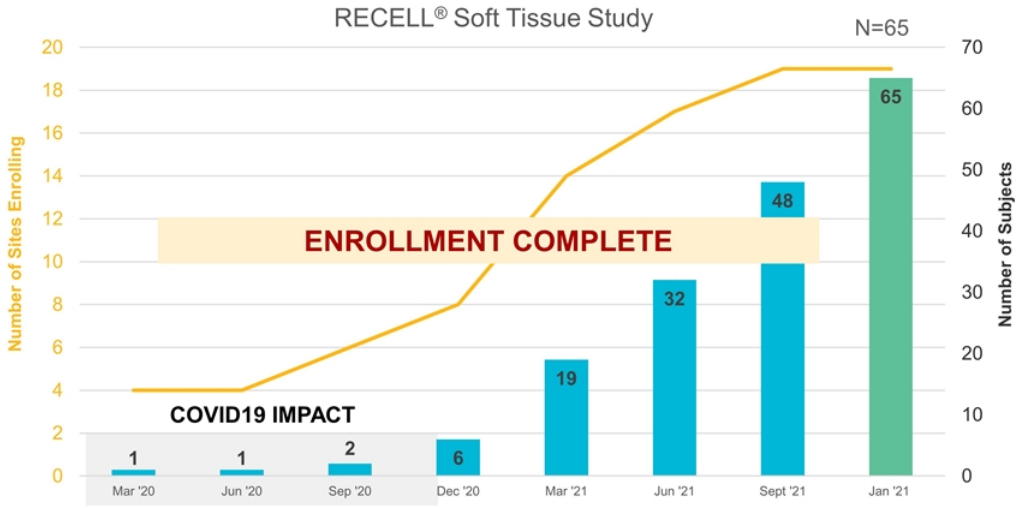


6 MONTH POST-RECELL TREATMENT

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

Early Completion of Soft Tissue Reconstruction Trial

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



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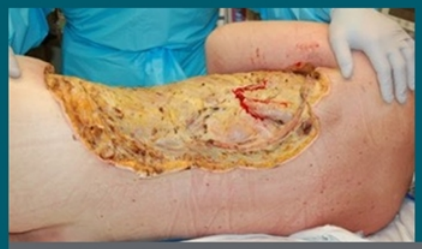
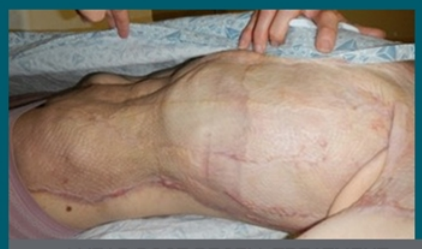
avita

Patient treated for necrotizing fasciitis



TREATMENT DAY



1 YEAR POST-RECELL TREATMENT

Photos courtesy of Kevin Foster, Valleywise Health Medical Center

Soft Tissue Synergies with Current Commercial Burn Focus

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

~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

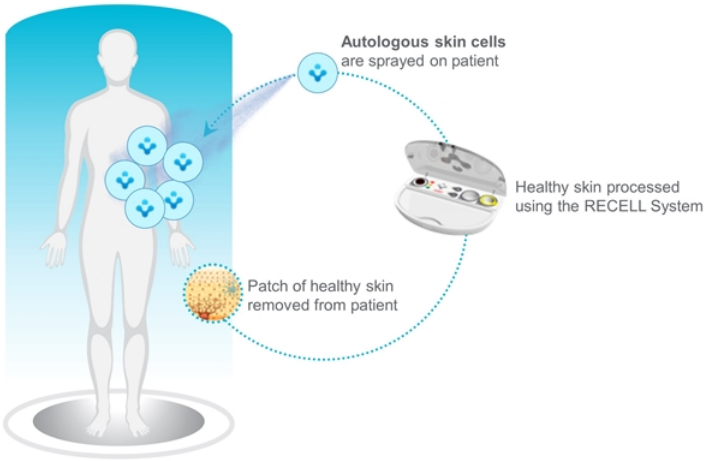
Large opportunity that leverages existing burns infrastructure

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.

RECELL in Genetic Skin Defects and Rejuvenation

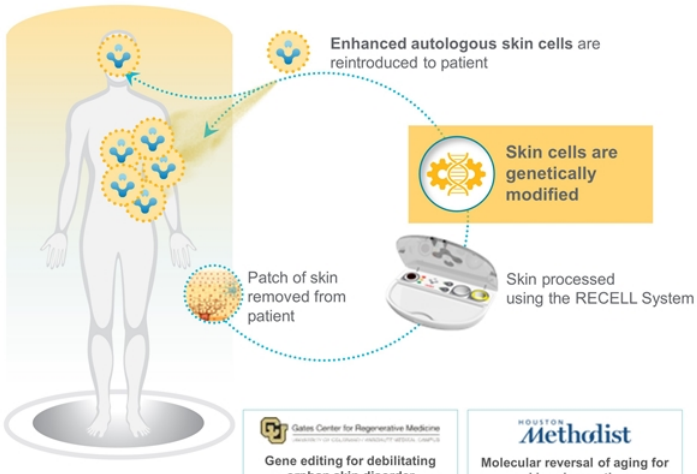
CURRENT PLATFORM

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



Gates Center for Regenerative Medicine

Gene editing for debilitating orphan skin disorder

HOUSTON Methodist

Molecular reversal of aging for skin rejuvenation

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.

Cell Based Gene Therapy Development Activity

FOUR KEY STEPS

- **Proof of Concept**
- **FDA Interaction**
- **IND-enabling Studies**
- **First-in-human (IND)**

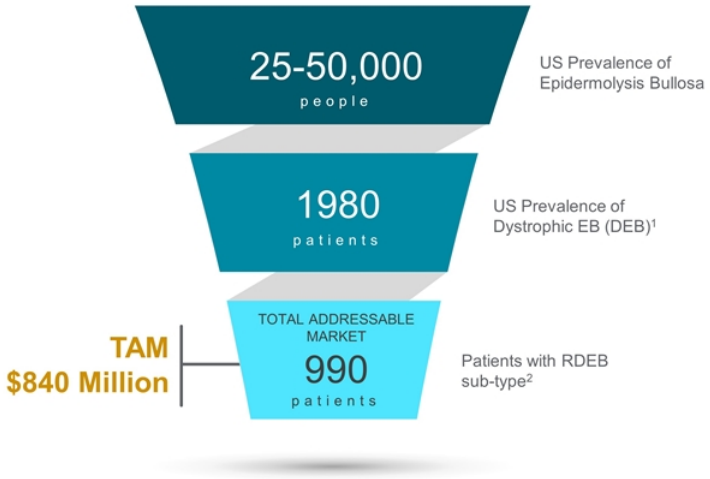
Study Objectives:

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

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

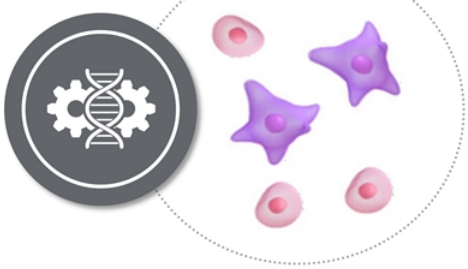
~$840M target US market opportunity, assuming $850,000[4] per patient / treatment

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

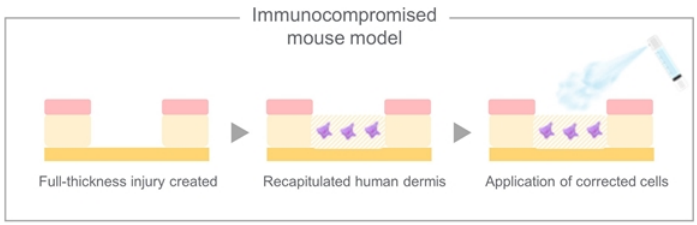
Skin Regeneration from Corrected Autologous Skin Cell Suspension

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



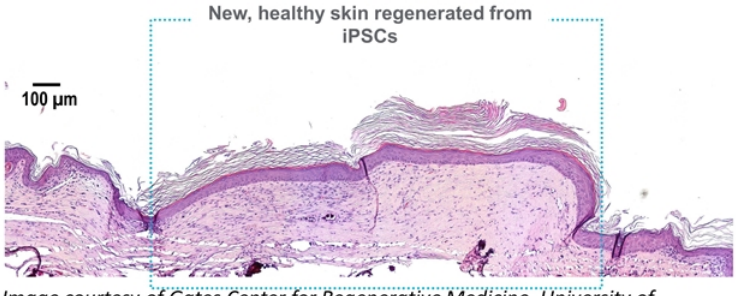
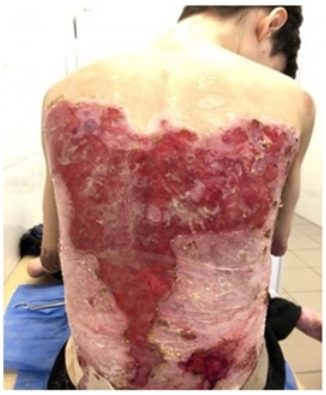


Image courtesy of Gates Center for Regenerative Medicine, University of Colorado

Exploring Cell-Based Gene Therapy for Epidermolysis Bullosa

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)

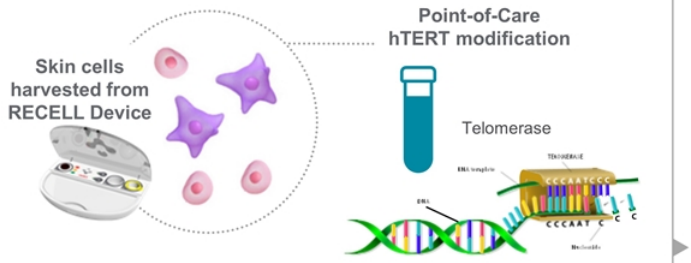
EFFICIENT: Suspension-based approach eliminates growth & transport of fragile skin sheets

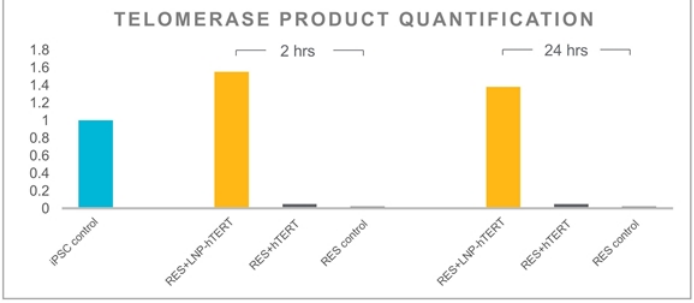
CONVENIENT: Suspension-based product simplifies application onto patient wounds (vs surgical anchoring of epidermal sheets which can result in issues with “take rates”

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.

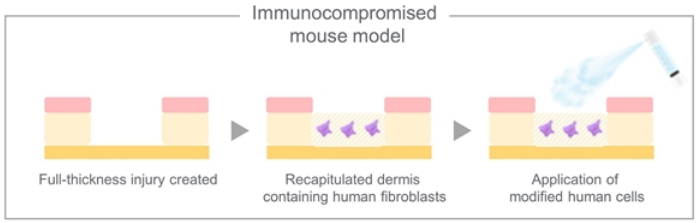
Reverse Aging of Skin Cells Derived using the RECELL Device

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

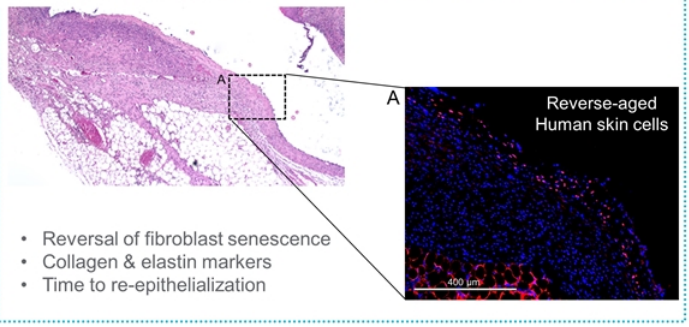




In Vivo Evaluation of mRNA-hTERT Modified Skin Cells



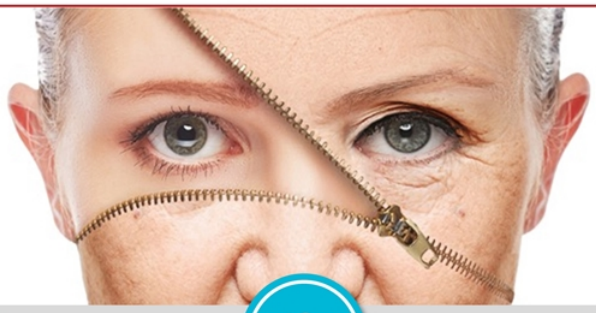
On-going Characterization



- Reversal of fibroblast senescence
- Collagen & elastin markers
- Time to re-epithelialization

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

Exploring Novel RNA-Based Approach for Rejuvenation



HOUSTON Methodist LEADING MEDICINE

avita medical

- **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

avita medical

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 [1]

~1M

PATIENTS/Yr

Target: People Who Undergo Aggressive Facial Lifting & Tightening Procedures[2]

$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 medical

Financial Overview

12 Months Ended June 30

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

$11.13
Share Price[1]

$277 Million
Market Capitalization[1]

$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 1/5/2022

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

Note: AVITA Medical owns granted patents in Austria, Australia, Belgium, Brazil, France, Germany, Hong Kong, Italy, Japan, Netherlands, Portugal, Spain, Sweden, Turkey, United Kingdom and USA. AVITA Medical owns pending patent applications in Brazil, Canada, China, Europe, Hong Kong and USA. Patent count as of 6/30/2021

Value Creation

Recent Key Accomplishments

- 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
- Quarter Ending December ’21, Total Revenue Growth of +35% vs Same Quarter Prior Year
- FDA Approval of Pediatric Label Expansion
- New Ease of Use RECELL Device under FDA Review

Projected Key Milestones

• Vitiligo FDA Submission / Vitiligo Commercial launch • Soft Tissue FDA Submission / Soft Tissue Commercial Launch	H2 22 / H2 23
• Outpatient Launch • PMDA Approval of Burns in Japan • FDA Approval of New ‘Ease of Use’ RECELL Device	H1 22
• IND Enabling Studies (EB & Rejuvenation)	H2 22

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

Risk Factors and Disclosures

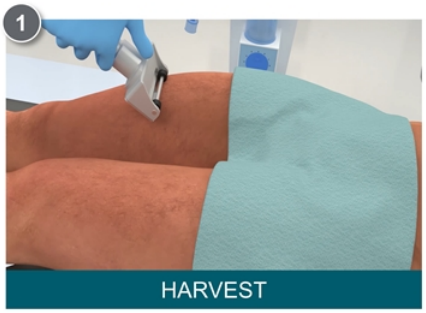
- There are numerous risk factors involved with the Company's business. Some of these risks can be mitigated by the use of safeguards and appropriate systems and controls, but some are outside the control of the Company and cannot be mitigated. Accordingly, an investment in the Company carries no guarantee with respect to the payment of dividends, return of capital or price at which securities will trade. The following is a summary of the more material matters to be considered. However, this summary is not exhaustive. Potential investor should consult their professional advisors before deciding whether to invest.
- Technological Change: Technological change presents the Company with significant opportunities for growth. However, the risk remains that any competitor may introduce new technology enabling it to gain a significant competitive advantage over the Company.
- Reliance on key personnel: The Company's success depends to a significant extent upon its key management personnel, as well as other management and technical personnel including sub-contractors. The loss of the services of any such personnel could have an adverse effect on the Company.
- Competition: The Company competes with other companies in the United States as well as in Australia and internationally. Some of these companies have greater financial and other resources than the Company and, as a result, may be in a better position to compete for future business opportunities. There can be no assurance that the Company can compete effectively with these companies.
- Patent Protection: The patent protection that the Company may obtain varies from product to product and country to country and may not be sufficient, including to maintain product exclusivity. Patent rights are also limited in time and do not always provide effective protection for products and services: competitors may successfully avoid patents through design innovation, the Company may not hold sufficient evidence of infringement to bring suit, or the infringement claim may not result in a decision that the rights are valid, enforceable or infringed. Legislation or regulatory actions subsequent to the filing date of a patent application may affect what an applicant is entitled to claim in a pending application and may also affect whether a granted patent can be enforced in certain circumstances. Laws relating to biotechnology remain the subject of ongoing political controversy in some countries. The risk of changed laws affecting patent rights is generally considered greater for the biotechnology field than in other longer established fields.
- Change in government policy and legislation: Any material adverse changes in relevant government policies or legislation of Australia / United States may affect the viability and profitability of the Company, and consequent returns to investors. The activities of the Company are subject to various federal, state and local laws governing prospecting, development, production, taxes, labor standards and occupational health and safety, and other matters.

Important Safety Information

- INDICATIONS FOR USE: The RECELL® Autologous Cell Harvesting Device is indicated for the treatment of acute thermal burn wounds. The RECELL device is used by an appropriately-licensed healthcare professional at the patient's point of care to prepare autologous RES® Regenerative Epidermal Suspension for direct application to acute partial-thickness thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients. .
- CONTRAINDICATIONS: RECELL is contraindicated for: the treatment of wounds clinically diagnosed as infected or with necrotic tissue, the treatment of patients with a known hypersensitivity to trypsin or compound sodium lactate (Hartmann's) solution, patients having a known hypersensitivity to anesthetics, adrenaline/epinephrine, povidone-iodine, or chlorhexidine solutions.
- WARNINGS: Autologous use only. Wound beds treated with a cytotoxic agent (e.g., silver sulfadiazine) should be rinsed prior to application of the cell suspension. RECELL is provided sterile and is intended for single-use. Do not use if packaging is damaged or expired. Choose a donor site with no evidence of cellulitis or infection and process skin immediately. A skin sample should require between 15 and 30 minutes contact with Enzyme. Contact in excess of 60 minutes is not recommended. RECELL Enzyme is animal derived and freedom from infectious agents cannot be guaranteed.
- PRECAUTIONS: RECELL is not intended for use without meshed autograft for treatment of full-thickness burn wounds. The safety and effectiveness of RECELL without meshed autograft have not been established for treatment of partial-thickness burn wounds: on the hands and articulating joints, >320 cm2, in patients with wounds totaling >20% total body surface area (TBSA). The safety and effectiveness of RECELL with autografting have not been established for treatment of full-thickness burn wounds: on the hands and articulated joints, and in patients younger than 28 days of age (neonates).
- SPECIAL PATIENT POPULATIONS: The safety and effectiveness of RECELL have not been established for treatment of acute thermal partial-thickness burn wounds in pediatric patients younger than 18 years of age.


Revolutionary treatment using a **patient's own skin** for life-changing outcomes
avita medical
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 Process For Autologous Cell Harvesting and Application



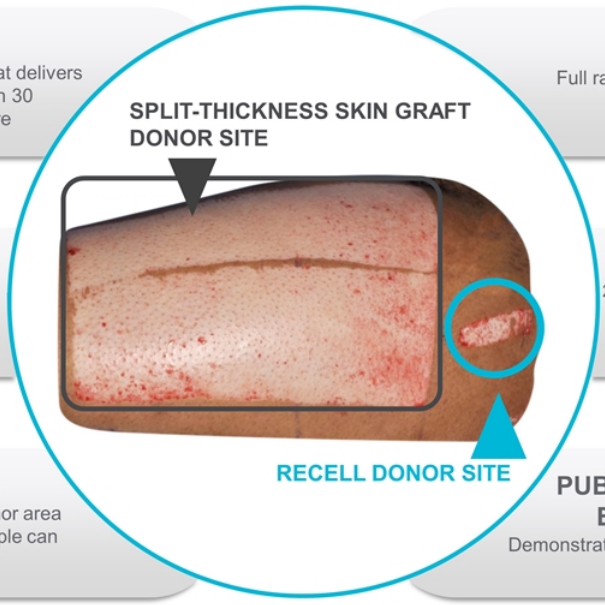
RECELL Spray-On Skin™
Treats 80cm² of Skin from a 1cm² Biopsy

AUTOLOGOUS
Cell Harvesting Device that delivers Spray-On Skin Cells within 30 minutes at the point of care

COMPLETE
Full range of skin cell types with re-pigmentation

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

SAFE & EFFECTIVE
2 randomized controlled trials supporting PMA
1st PMA burn product approval ~20 yrs
10K+ patients worldwide
>150 peer reviewed articles



DONOR SPARING
Treatment area = 80x donor area (credit card size skin sample can treat an entire adult back)

PUBLISHED HEALTH ECONOMIC DATA
Demonstrating significant savings to the health care system

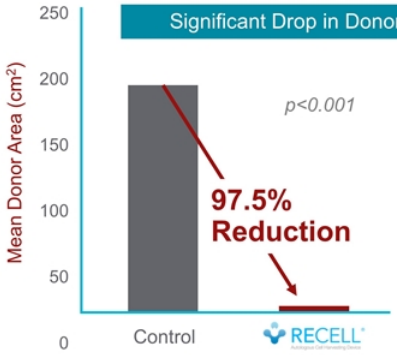
1st Premarket Approval Treatment in Burns in 20 Years

Dual multi-center, randomized, controlled premarket approval studies

Pivotal Trial #1 (101 Patients)

RECELL (alone) versus SoC (STSG) in Second-Degree Burns

Published in JBCR and Presented at ABA



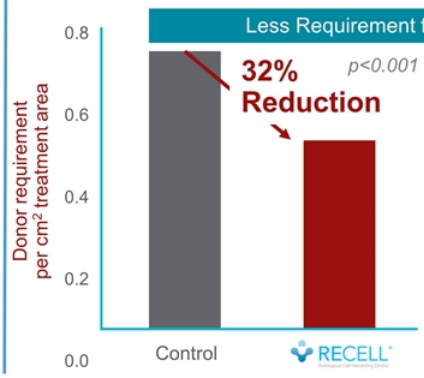
Decrease in donor site pain and scarring

- Significantly less donor site pain (p≤0.0025)
- Significantly better donor site appearance (p≤0.0025)
- Significantly reduced donor site scarring (p≤0.0025)
- Significantly greater incidence of donor-site healing at two weeks (p<0.001)

Pivotal Trial #2 (31 Patients)

RECELL (with widely expanded graft) versus STSG in Third-Degree Burns

Published in Burns and Presented at ABA



Robust outcomes despite less donor skin

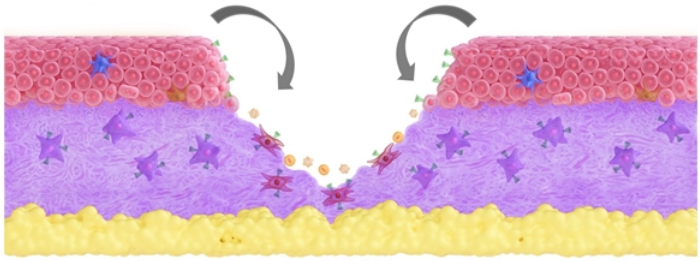
- RECELL System achieved definitive closure comparable to Standard of Care with significantly less donor skin
- At eight weeks post treatment, 92% of the burn sites treated with the RECELL System achieved complete healing versus 85% for the sites treated with the standard of care

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

RECELL "Free Edge" Advantage

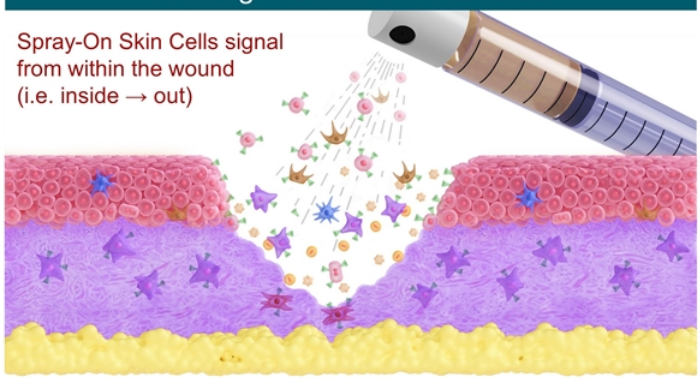
Healing Process without RECELL

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



Healing Process with RECELL

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



Cytokine

Inflammatory Cell

Myofibroblast

Growth Factor

Receptor

Fibroblast

Keratinocyte

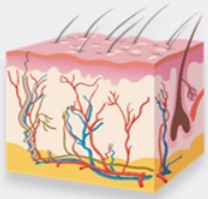
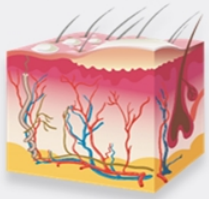
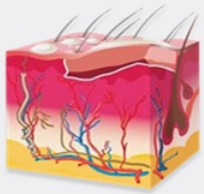
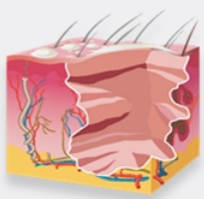
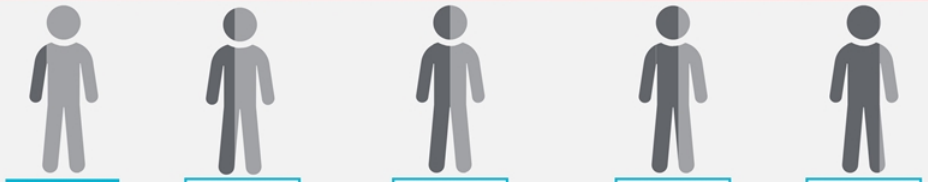
Stem Cell

Melanocyte

Langerhans Cell

Skin Injury Framework

RECELL® TARGET INJURY
Autologous Cell Harvesting Device

	Superficial Wound	Superficial **Partial** Thickness Wound	**Deep Partial** Thickness Wound	**Full Thickness** Wound
Wound Depth				
	1st degree	2nd degree	2nd degree	3rd degree
Wound Size				
	0-9.9%*	10-19.9%	20-29.9%	30-39.9%	40%+
		Total Body Surface Area (TBSA) Affected			
Adoption Trajectory	Small / Partial Thickness ← Results / Experience ← Large / Full Thickness				

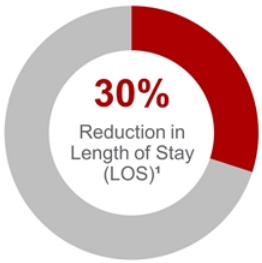
For more information on RECELL's indication for use, please go to www.recellsystem.com.

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

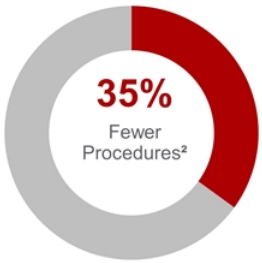
Transforming Care

Can reduce costs and accelerate recovery by decreasing the number of painful procedures and length of stay in hospital



30% Reduction in Length of Stay (LOS)[1]

Fewer procedures and faster healing times get patients home more quickly



35% Fewer Procedures[2]

Reduced donor site size and greater meshing ratio enables permanent closure with fewer invasive autograft procedures

30% Cost Savings[2]

Shorter and fewer procedures, decreased length of stay, and reduced resource use translates into burn center savings

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., Bilir, P. et al. Adv Ther (2019). https://doi.org/10.1007/s12325-019-00961-2

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