One Platform.
Endless Possibilities.

November 2021

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 COVD-19 pandemic; the unpredictability of the timing and results of regulatory submissions and reviews; market acceptance for approved products and innovative therapeutic treatments; competition; the possible impairment of, inability to obtain and costs of obtaining intellectual property rights; and possible safety or efficacy concerns, general business, financial and accounting risks and litigation. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. More information concerning us and such risks and uncertainties is available in our public filings with the U.S. Securities and Exchange Commission, including our most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 and our most recent Annual Report on Form 10-K for the year ended June 30, 2020. We are providing this information as of its date and do not undertake any obligation to update or revise it, whether as a result of new information, future events or circumstances or otherwise, except as required by law. Additional information may be available in press releases or other public announcements and public filings made after the date of this presentation.

AVITA Medical’s products are Rx only. Please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events.

In the United States, RECELL® is approved for use in patients suffering acute thermal burns. Use of RECELL in other patient populations is either prohibited by United States law or may be made available pursuant to a relevant investigational device exemption granted by the FDA (and likewise limited by United States law to investigational use only).

AVITA 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
advanced tissue
Smith+Nephew

Donna Shiroma
General Counsel
>20 years experience

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

Value Creation

Recent Key Accomplishments

- Soft Tissue Pivotal Trial: 89% Enrolled
- Vitiligo Pivotal Trial: Enrollment 70% Completed or Scheduled
- Transitional Pass-Through Payment Application Approved by CMS for Reimbursement in Outpatients
- Fiscal Q2'22 RECELL® revenue growth of +39% vs same quarter in prior year
- Cumulative U.S. commercial sales since September 2018 FDA approval exceeding $46M
- FDA Approval of Pediatric label expansion
- New Ease of Use RECELL Device Submitted to FDA for Review

Projected Key Milestones

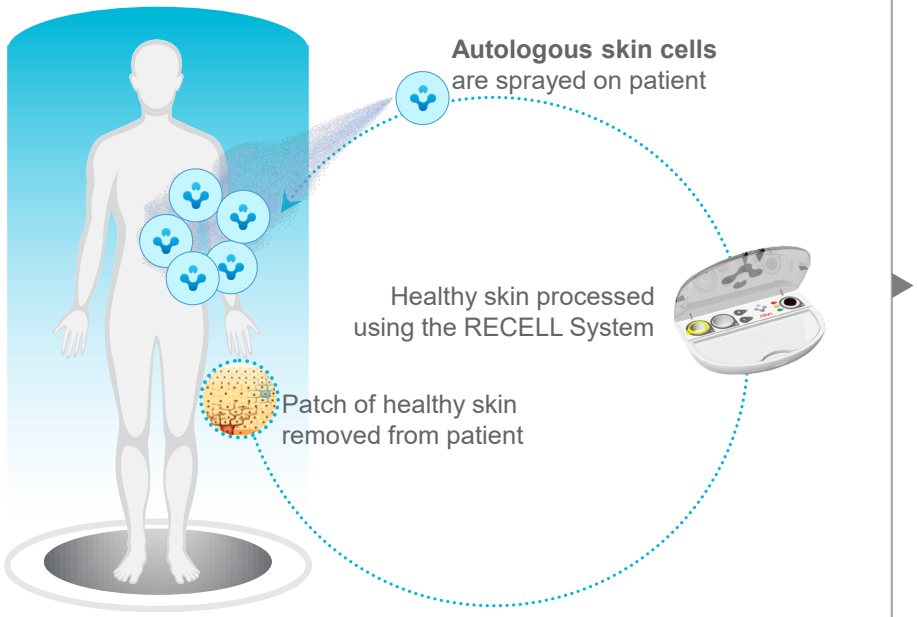
• Vitiligo Pivotal Trial Last Patient Enrolled / Vitiligo Commercial launch • Last patient enrolled in Soft Tissue Trial / Soft Tissue Commercial Launch	Q4 21 / H2 23 Q1 22 / H2 23
• Outpatient Launch • PMDA Approval of Burns in Japan • FDA Approval of New 'Ease of Use' RECELL Device	H1 22
• EB: Initial proof of concept for delivery of genetically modified skin cells in suspension • Telomerase/Rejuvenation: Initial proof of concept on impact of telomerase on human skin in a mouse model	Q4 21

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

One Platform. Endless Possibilities.

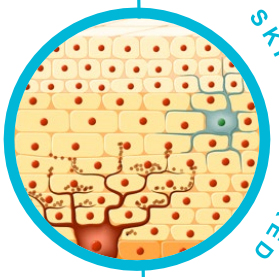
RECELL®
Autologous Cell Harvesting Device

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**

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Development Pipeline and Growth Potential

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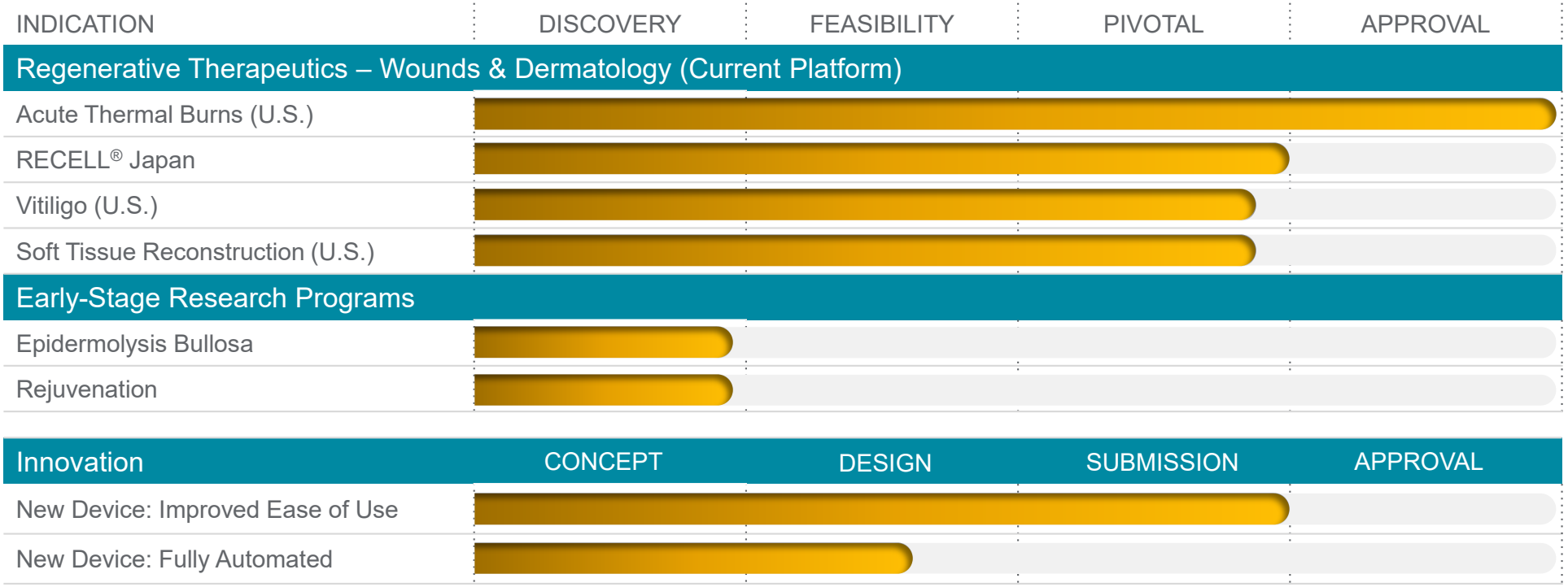
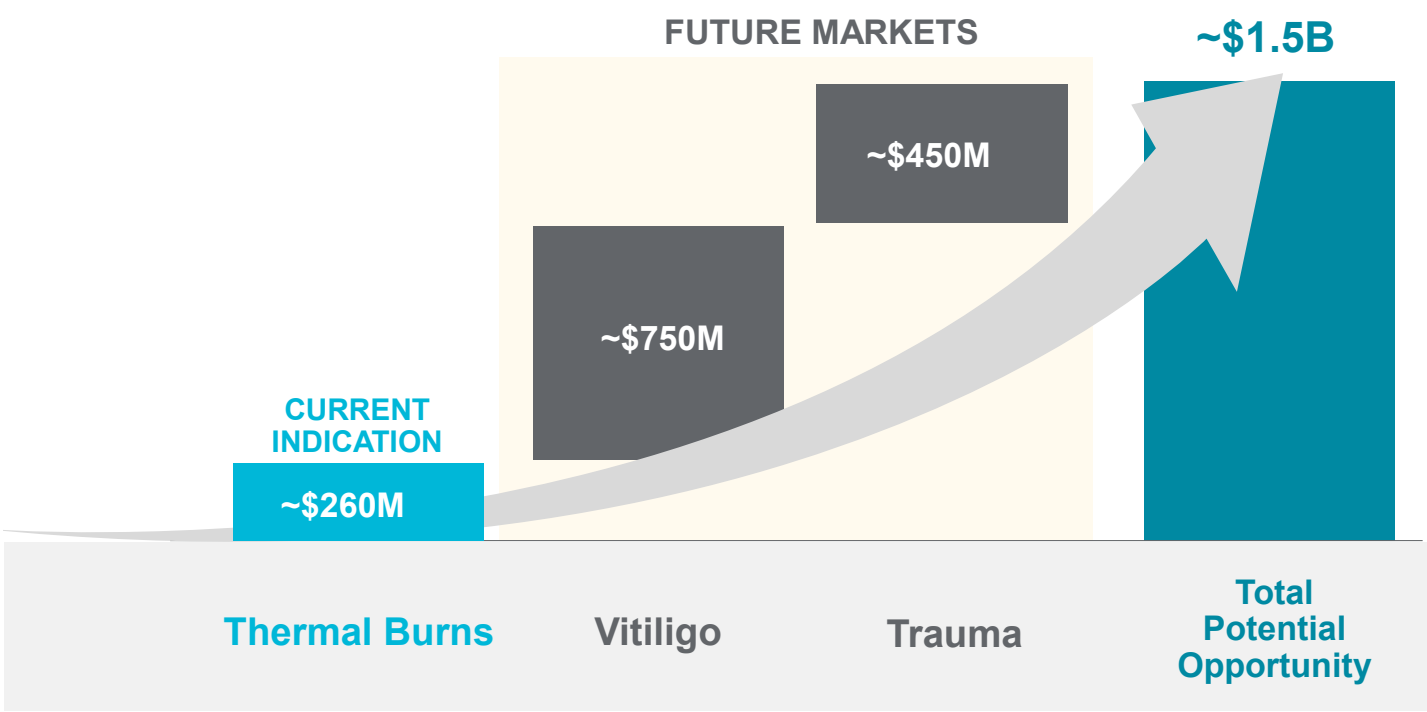
Focused Pipeline with Strong Growth Potential



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.

Current Platform Enables Access to a Large Serviceable Addressable Market (SAM)



Efficacy Well Demonstrated

	Patients (in studies)	Publications & Presentations
BURNS	1,690	181
DEFECTS/ VITILIGO	453	57
ACUTE WOUNDS	82	25

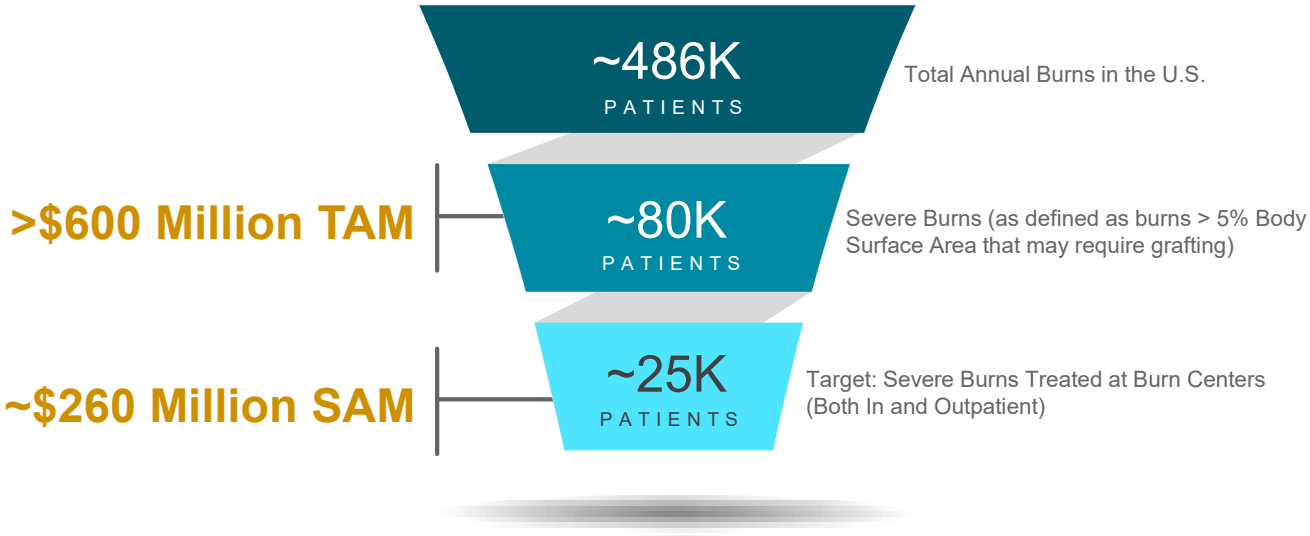
Highly De-risked Pipeline with > 14,000 Patients Treated Globally

A common goal: Full skin restoration (Re-epithelialization and re-pigmentation)

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.

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

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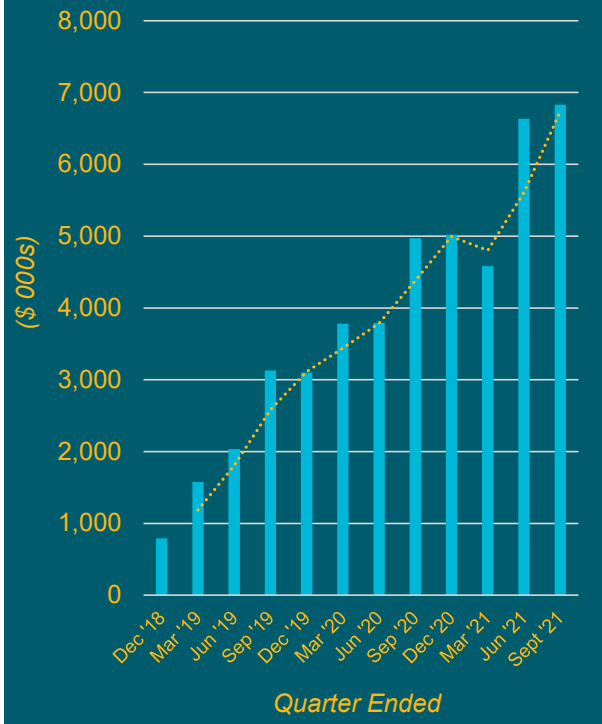
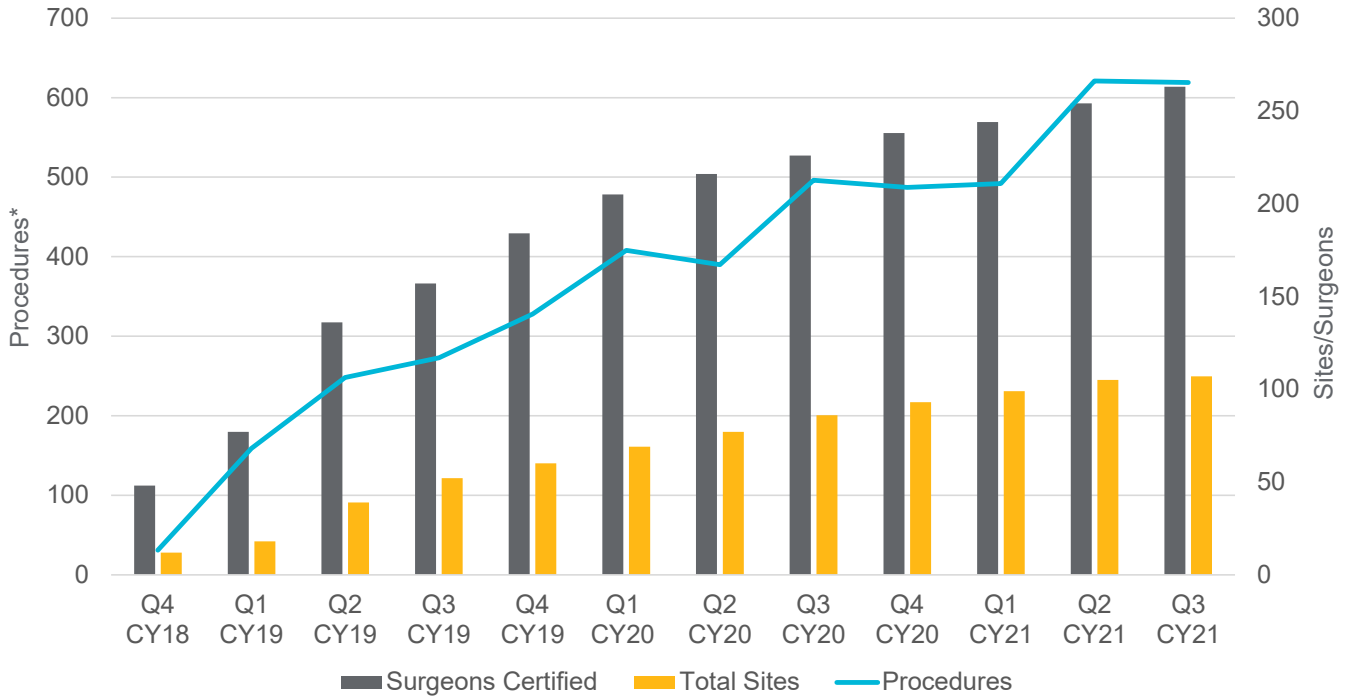
U.S. RECELL Commercial Sales Since Approval



Strong Adoption of the RECELL System



Accomplishments Since Approval

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

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

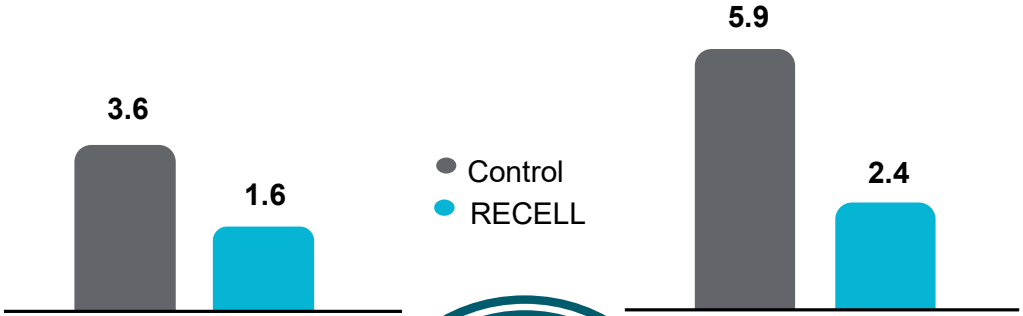
*Data is compiled based on information voluntarily provided by our customers and is subject to change.

Now Approved in Pediatric Full-Thickness Burns & Larger TBSAs

Fewer procedures required for definitive closure vs conventional autograft[1]

Pediatric Patients

56% fewer mean procedures with RECELL (N=284)



~25% of all burns occur in children

Adults with >50% TBSA

60% fewer mean procedures with RECELL (N=354)

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

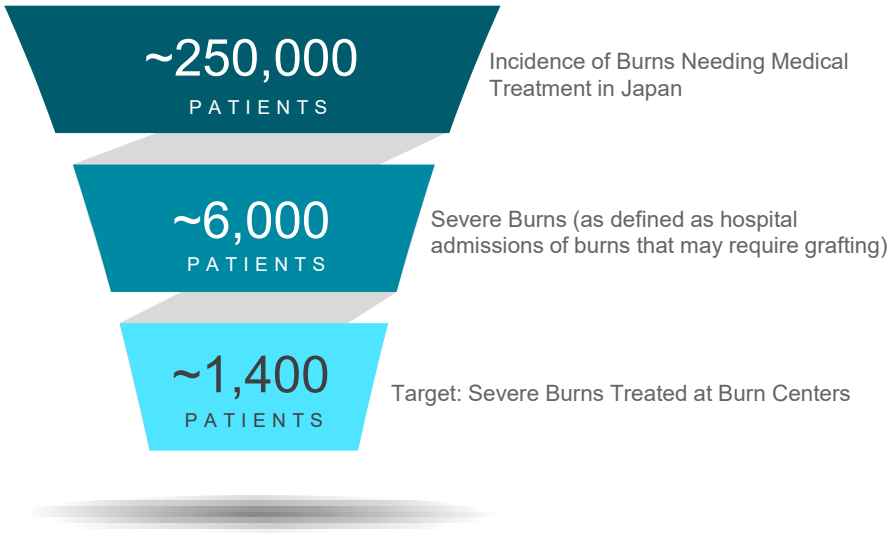
1. Instructions for Use. RECELL® Autologous Cell Harvesting Device
* N = 41, "will significantly or somewhat impact RECELL usage"

Japan Is an Attractive Opportunity for AVITA Medical

Background

- March 3, 2019, AVITA Medical and COSMOTEC Company, Ltd, an M3 Group company, announced agreement to market and distribute the RECELL System.
- Based on feedback from the Japanese Health Authority (PMDA), the indication being pursued has been narrowed to focus on Burns given its robust randomized clinical data from the United States as well as local data in Japan.
- RECELL System approval anticipated in Japan in H1 of CY 2022 followed by a reimbursement review with the Japanese Ministry of Health and Labour in June 2022. Commercial Launch will commence upon securing reimbursement.

Patient Funnel and Addressable Market

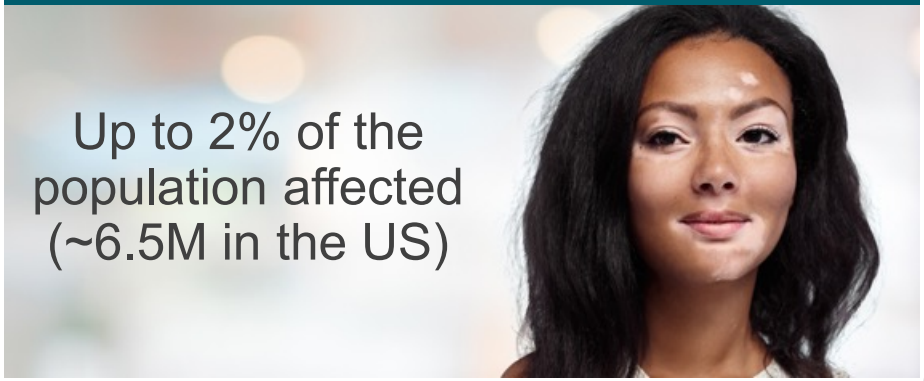


Approval Anticipated in H1 2022 with Commercial Launch mid-2022

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 Costmotec estimates

Vitiligo: 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

LIMITED TREATMENT OPTIONS

Phototherapy

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

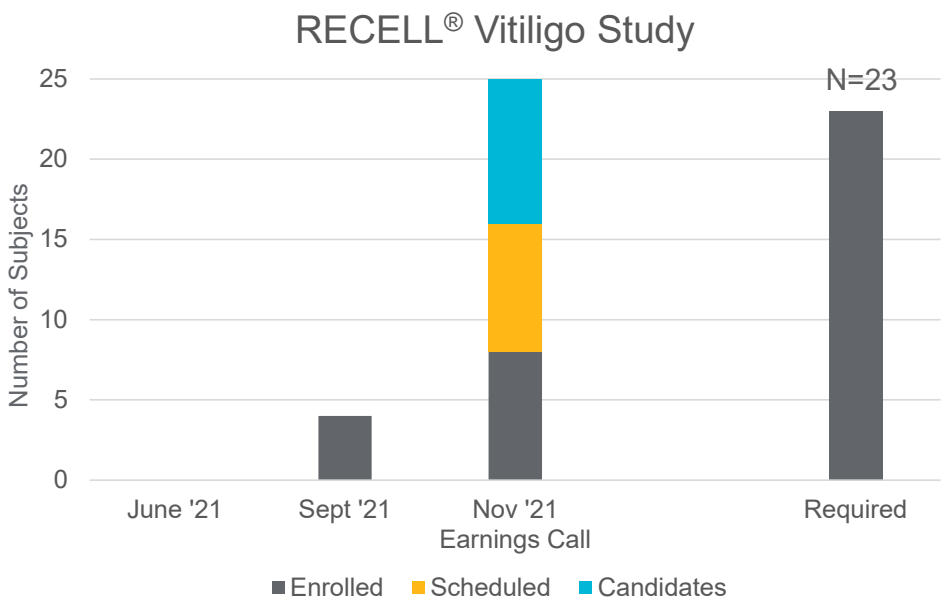
Melanocyte-Keratinocyte Transplantation

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

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.

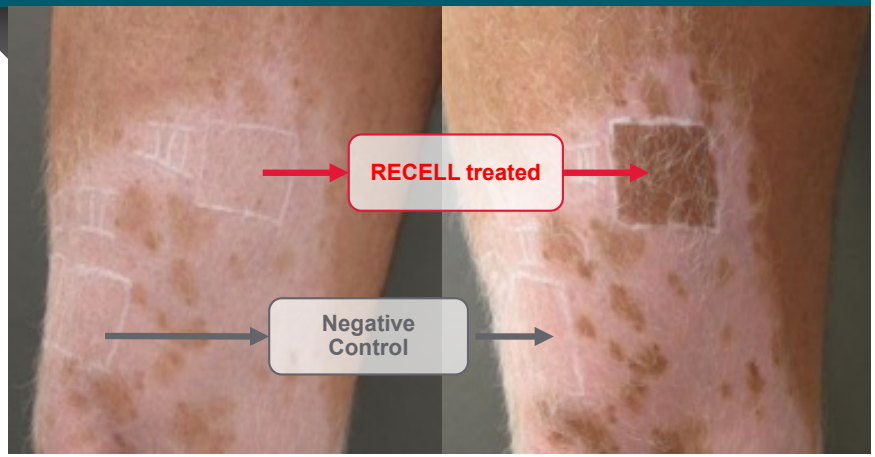
New Vitiligo Study Design Shortens Pathway to Completion

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



U.S. Pivotal Study enrolling; last patient expected in H2 2021

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



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

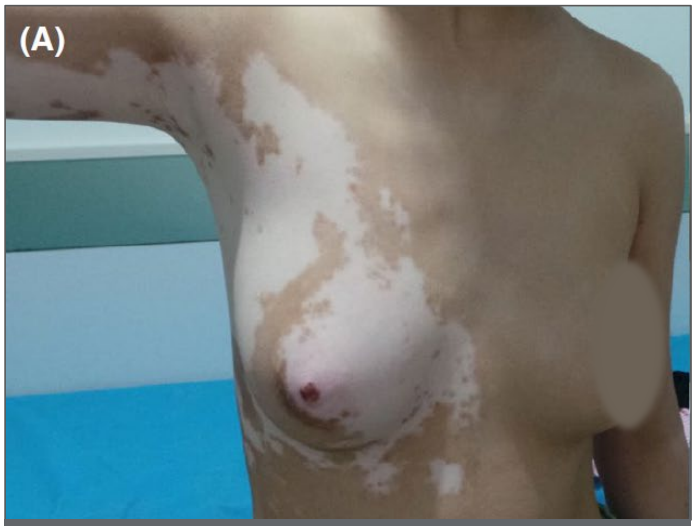
POTENTIAL RECELL BENEFITS

For Stable Vitiligo: Segmental & Non-Segmental

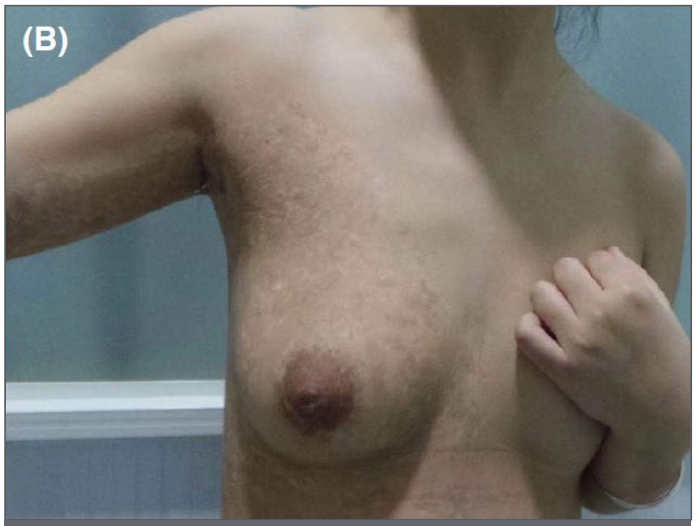
Durable: One-time treatment

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

RECELL Case Study: Repigmentation of the Nipple-Areola Complex after Breast Treatment



Before RECELL®



12 months After RECELL®

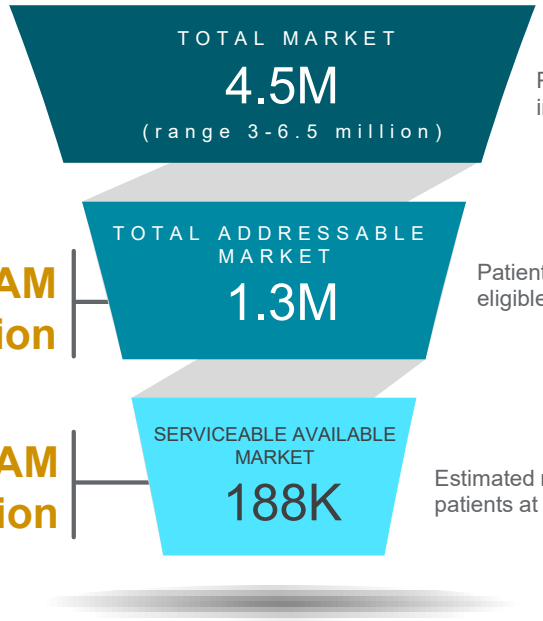
- 23 year old female with vitiligo.
- Donor skin was harvested from adjacent unaffected areas.
- Dermabrasion of the vitiligo patches was performed to the depth of the dermal-epidermal junction.
- The cellular suspension was then sprayed on both the recipient and donor areas (expansion ratio ranged from 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.

Significant Market Opportunity in Repigmenting Stable Vitiligo

OPPORTUNITY ESTIMATION



Prevalence of Vitiligo in the United States

TAM
$5.2 Billion

Patients with Stable Vitiligo, eligible for surgical treatment

SAM
$750 Million

Estimated number of eligible patients at target call points

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

MARKET TAILWINDS

Payers with coverage for vitiligo treatments
(e.g., phototherapy)

Growing reimbursement
(up to $38,000 / patient annually)

United Healthcare
aetna®
BlueCross BlueShield
Cigna

Not exhaustive

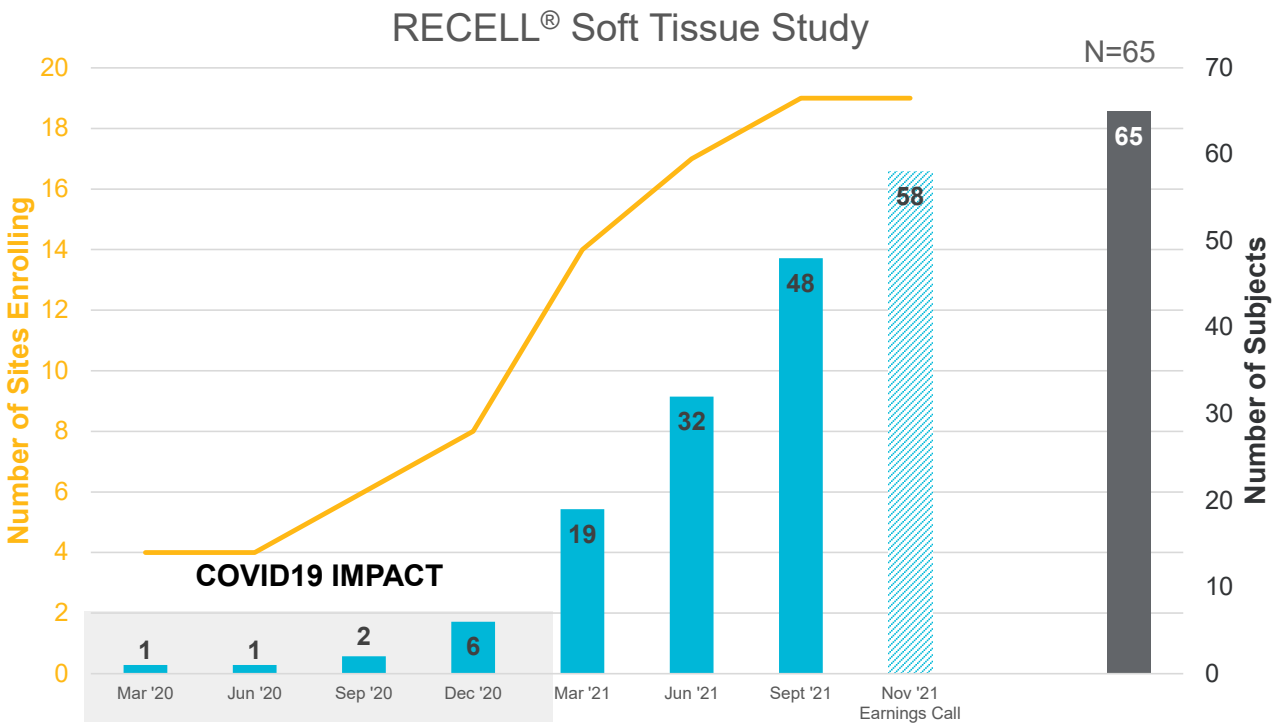
Advancing pipeline of disease stabilizing treatments

JAK inhibitors are in late-stage development. Potential to help build market and expand eligible patients

In the United States, RECELL is not approved for use with patients suffering vitiligo.

Soft Tissue Reconstruction Trial Enrollment is Gaining Momentum

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



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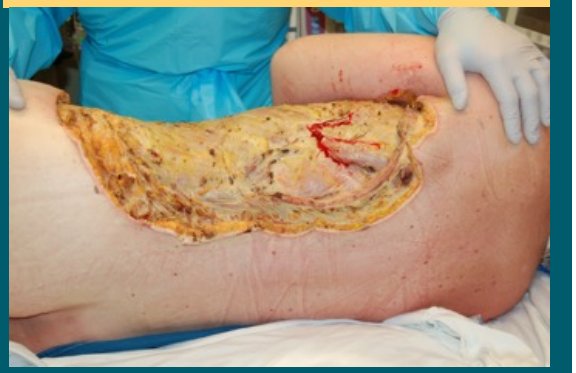
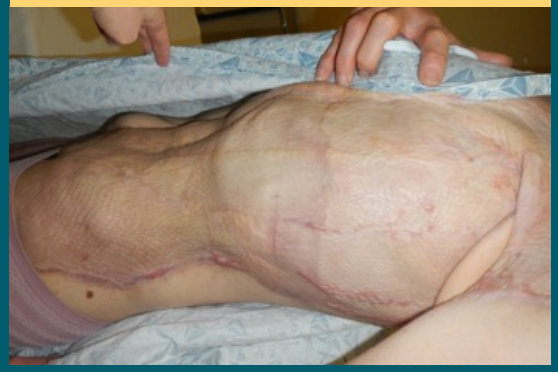
Patient treated for necrotizing fasciitis.

TREATMENT DAY



1 YEAR POST-RECELL TREATMENT



Photos courtesy of Kevin Foster, Valleywise Health Medical Center

Soft Tissue Efforts are Synergistic with Current Commercial Burn Focus

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

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

Same Unmet Needs as Burns

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

Same Treatment Protocol to Burns

Consistent treatment protocol across acute injuries

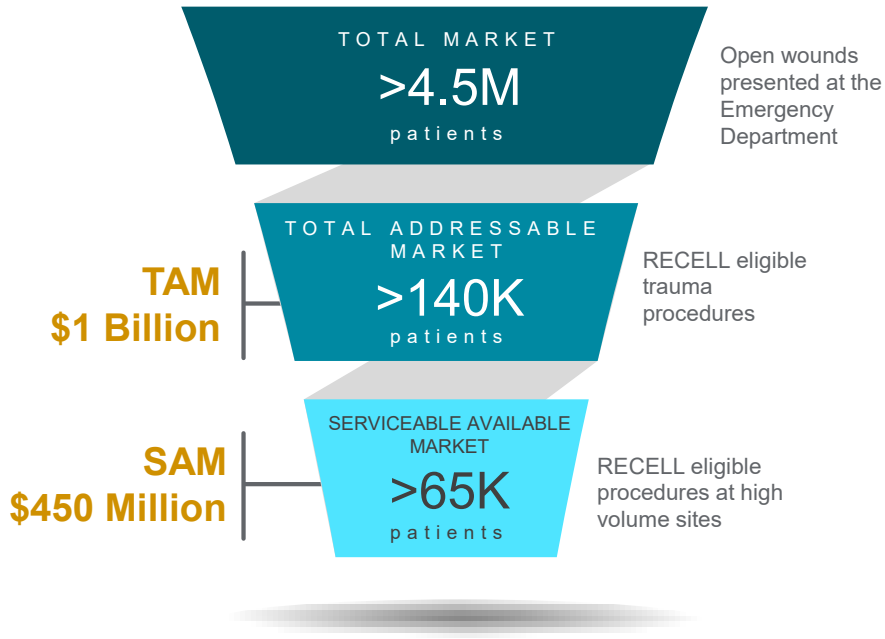
Reimbursement in Place

Able to leverage existing CPT & Outpatient C Code

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.

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

OPPORTUNITY ESTIMATION



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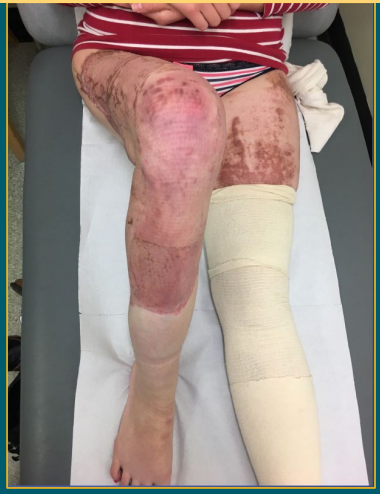
Female, pregnant 28 year old who suffered from a de-gloving Injury

Post Debridement of Injury

6 MONTH POST-RECELL TREATMENT

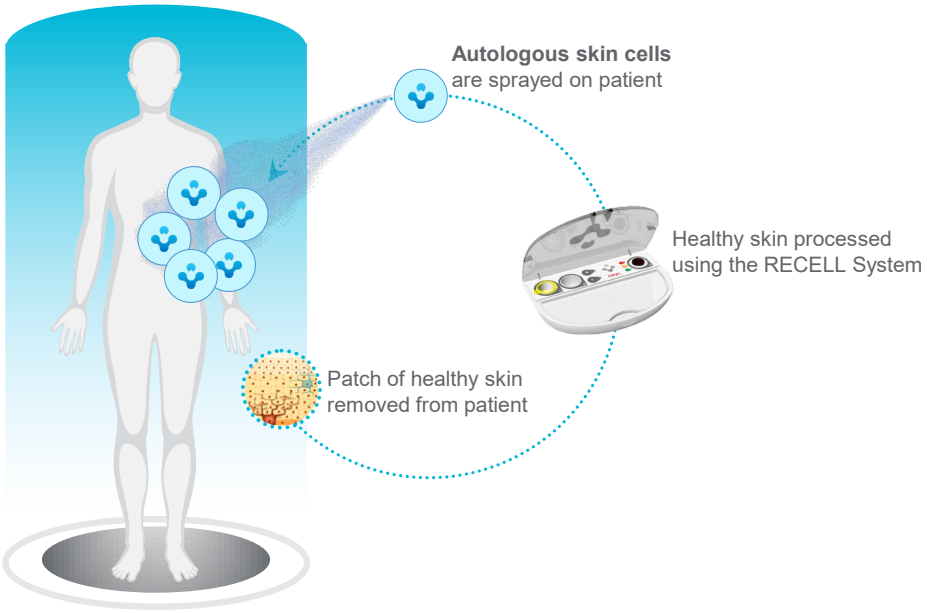


Poster: Use of regenerative suspension in the treatment of a complex de-gloving injury. Ian M Smith,

RECELL in Genetic Skin Defects and Rejuvenation

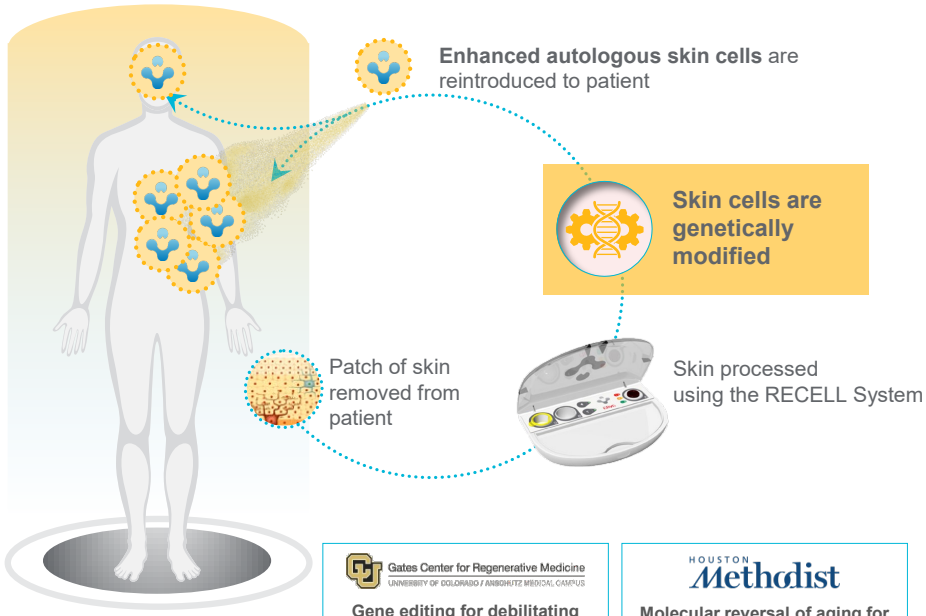
CURRENT PLATFORM

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
UNIVERSITY OF COLORADO / ANSCHUTZ MEDICAL CAMPUS

Gene editing for debilitating orphan skin disorder

HOUSTON Methodist

Molecular reversal of aging for skin rejuvenation

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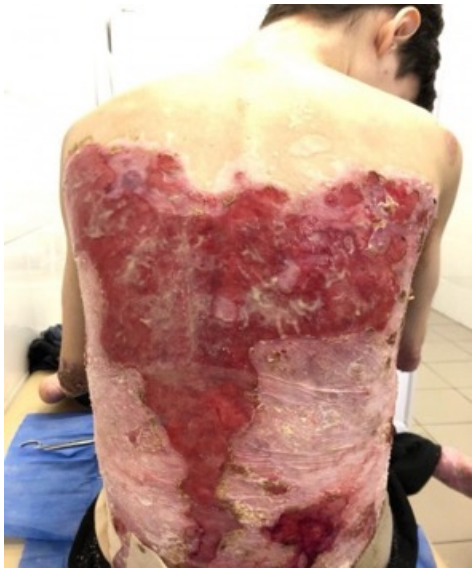
Exploring Cell-Based Gene Therapy for Epidermolysis Bullosa

Preclinical research partnership underway with Gates Center for Regenerative Medicine (University of Colorado), exploring the combination of a novel gene correction approach with AVITA Medical's Spray-On Skin™ Cells technology

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"

Proof-of-concept for delivering genetically modified cells in suspension expected in 2021

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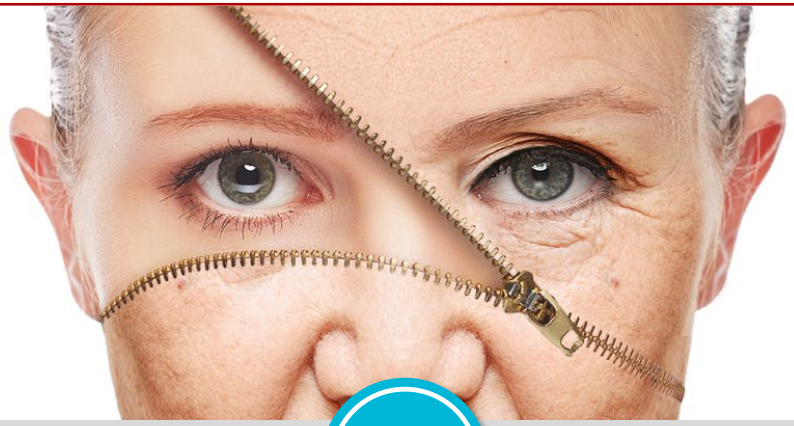
Exploring Novel RNA-Based Approach for Rejuvenation



HOUSTON Methodist LEADING MEDICINE

- **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)

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- 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

Multi-Billion Dollar Market Presents a Sizeable Opportunity

- **>$16.5B** spent in aesthetic procedures per year (US)*
- **>3M** aesthetic procedures per year (US) aimed to improve skin tightness, texture & evenness in skin tone*
- Consumers **desire superior results** over current offerings
- **Personalized, cellular-level approaches** to skin rejuvenation, developed with robust evidence, is an area of significant interest

Sponsored research underway exploring use of telomerase for molecular reversal of skin cell aging

*American Society for Plastic Surgery Annual reports – 2018 and 2019. 2. Goddard et al. Aesthetic Surgery Journal, Volume 40, Issue 4, April 2020, Pages 460–465. 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

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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**

$19.66
Share Price[1]

$480 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 11/05/2021

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

- Soft Tissue Pivotal Trial: 89% Enrolled
- Vitiligo Pivotal Trial: Enrollment 70% Completed or Scheduled
- Transitional Pass-Through Payment Application Approved by CMS for Reimbursement in Outpatients
- Fiscal Q2'22 RECELL® revenue growth of +39% vs same quarter in prior year
- Cumulative U.S. commercial sales since September 2018 FDA approval exceeding $46M
- FDA Approval of Pediatric label expansion
- New Ease of Use RECELL Device Submitted to FDA for Review

Projected Key Milestones

• Vitiligo Pivotal Trial Last Patient Enrolled / Vitiligo Commercial launch • Last patient enrolled in Soft Tissue Trial / Soft Tissue Commercial Launch	Q4 21 / H2 23 Q1 22 / H2 23
• Outpatient Launch • PMDA Approval of Burns in Japan • FDA Approval of New 'Ease of Use' RECELL Device	H1 22
• EB: Initial proof of concept for delivery of genetically modified skin cells in suspension • Telomerase/Rejuvenation: Initial proof of concept on impact of telomerase on human skin in a mouse model	Q4 21

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.