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): August 29, 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 7.01 Reg Fd Disclosure.

On August 29, 2022, AVITA Medical, Inc. posted a Company Update slide deck to its website. A copy of the slide deck is attached hereto as Exhibit 99.1.

The information under Item 7.01 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 a specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Company Update
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: August 30, 2022

AVITA MEDICAL, INC.

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

Exhibit 99.

One Platform.
Endless Possibilities.

August 2022

NASDAQ: RCEL ASX: AVH

Legal Disclaimers

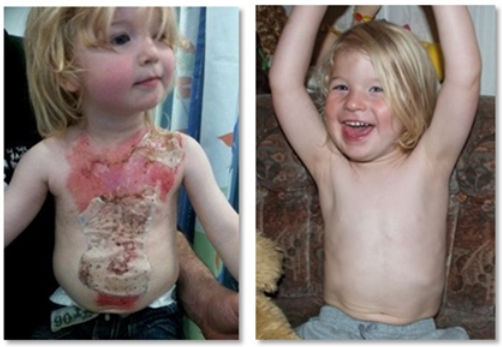
Certain statements in this presentation and the accompanying oral commentary are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this presentation, including statements regarding 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 June 30, 2022, and our most recent Transition Report on Form 10-KT period from July 1, 2021 to December 31, 2021. We are providing this information as of its date and do not undertake any obligation to update or revise it, whether as a result of new information, future events or circumstances or otherwise, except as required by law. Additional information may be available in press releases or other public announcements and public filings made after the date of this presentation.

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

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

Transforming Lives with Skin Regeneration

- **RECELL® System: FDA approved for the treatment of acute thermal burns**
  - Proprietary Spray-On Skin™ offers life changing benefits
  - Point of care technology that is safe & effective
  - Published health economic model demonstrating hospital cost savings
- **Deep scientific and clinical pedigree**
  - 2 randomized controlled trials and 1st PMA in burns in > 20yrs
  - >15,000 patients, >330 publications and presentations
- **Ongoing platform expansion: Multi-billion Dollar U.S. market opportunity**
  - Platform technology with numerous adjacent applications
  - PMA label expansion underway with PMA supplements for two indications in 2022
  - Proof of concept established for cell-based gene therapy and aesthetics



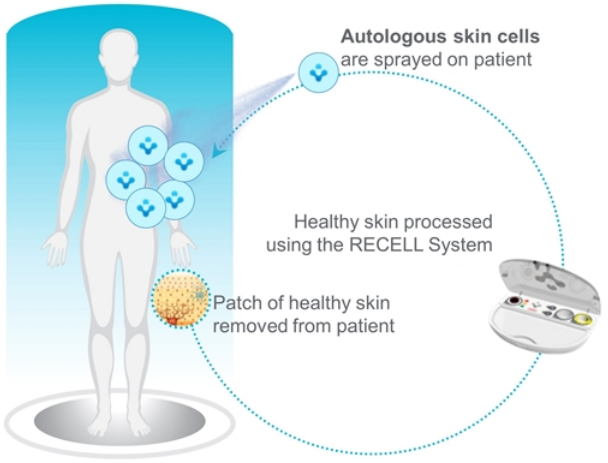
Revolutionary treatment using a patient's own skin for life-changing outcomes

* In the US, RECELL is approved for acute thermal burns in patients > 18 years ("ATB") only (see www.avitamedical.com)). Use of RECELL in other indications is either (1) limited by United States law to investigational use; or (2) otherwise prohibited.

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 could potentially benefit 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.

Value Creation

Recent Key Accomplishments

- Commercial Revenue Growth YoY of +39% in the First Half of 2022 and +23% in the Second Quarter 2022
- Soft Tissue Pivotal Trial: Topline Results
- Vitiligo Pivotal Trial: Enrollment & 6-month Follow-up Complete
- FDA Approval & Launch of New “Ease of Use” RECELL Device
- PMDA Approval of Burns in Japan and cases completed
- Initial Proof of Concept for EB and Rejuvenation (Delivery of Modified Skin Cells in Suspension)

Projected Key Milestones

• Top Line Results and Vitiligo FDA Submission / Vitiligo Commercial launch	H2 ’22 / H2 ’23
• Soft Tissue FDA Submission / Soft Tissue Commercial Launch	H2 ’22 / H2 ’23
• Reimbursement & Commercial Launch of Burns in Japan	H2 ’22
• FDA Meeting Regarding IND Enabling Studies (EB & Rejuvenation)	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

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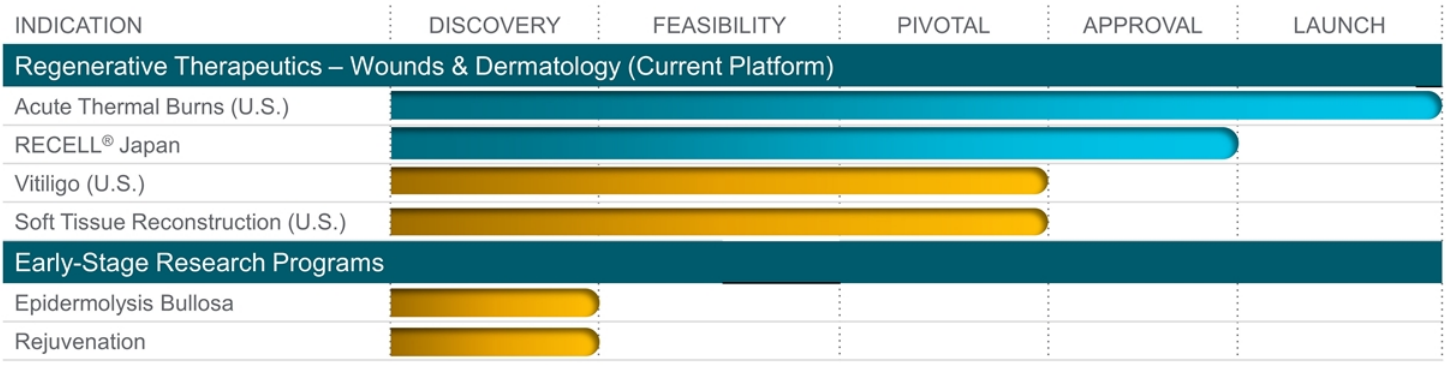
Focused Pipeline with Strong Growth Potential



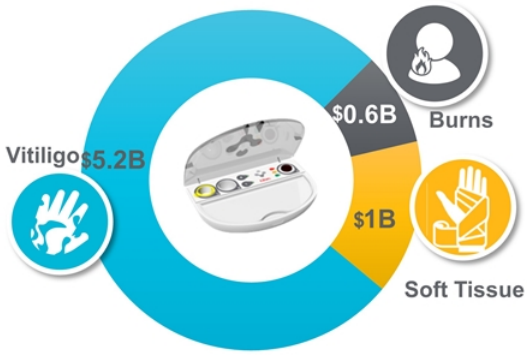
Focused Effort on Business Development to Supplement Pipeline

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.

Market Opportunity of Pipeline Exceeds $22 Billion

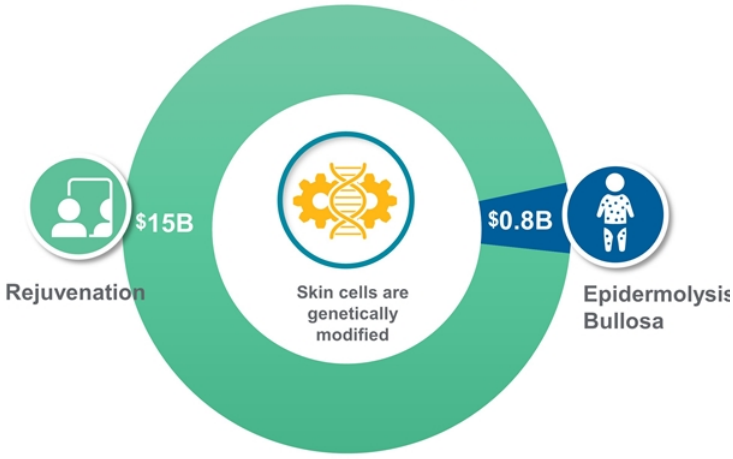
EXISTING PLATFORM

~$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)*	1,852	255
DEFECTS/ VITILIGO	453	58
CHRONIC WOUNDS	143	19

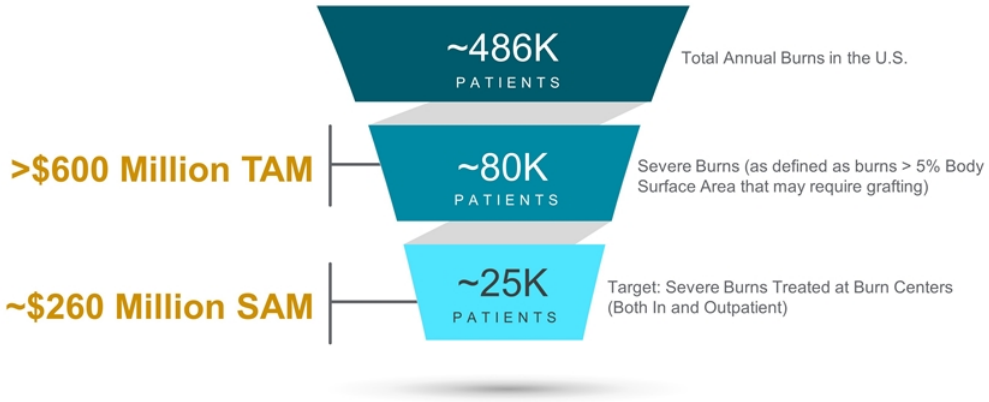
Highly De-risked Pipeline with >15,000 Patients Treated Globally

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.

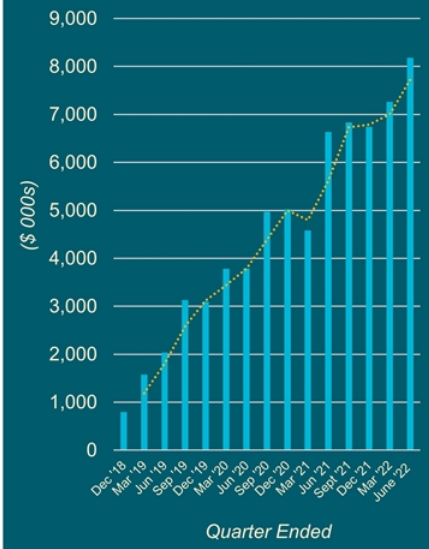
Thermal Burns: U.S. Target Market Expanded to Include Small Burns and Outpatient

Patient Funnel and Addressable Market



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

Strong U.S. RECELL Commercial Growth



New Ease of Use Device FDA Approved & Launched

New Device

Reduced number of steps

Simplified Process

Improved Usability

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

Only 1 Set of Hands Required in the Sterile Field; Steps Reduced By 33%

* Market Research March 2020 HCPs

Approval of Burns Received in Japan

BACKGROUND

AVITA Medical Commercial Partner:

COSMOTEC, an M3 Company

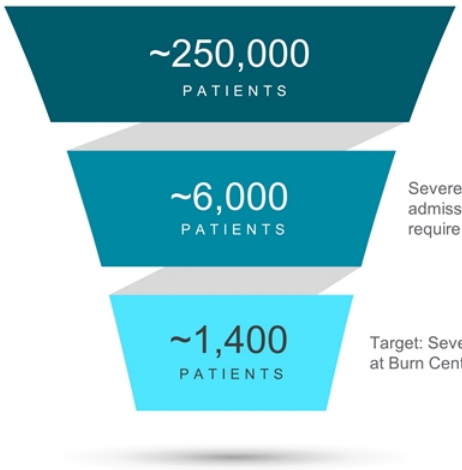
INDICATION: Burns

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

LAUNCH:

Following Ministry of Health, Labour, and Welfare (MHLW) decision on reimbursement pricing, anticipated Q4 ’22

PATIENT FUNNEL - BURNS ADDRESSABLE MARKET

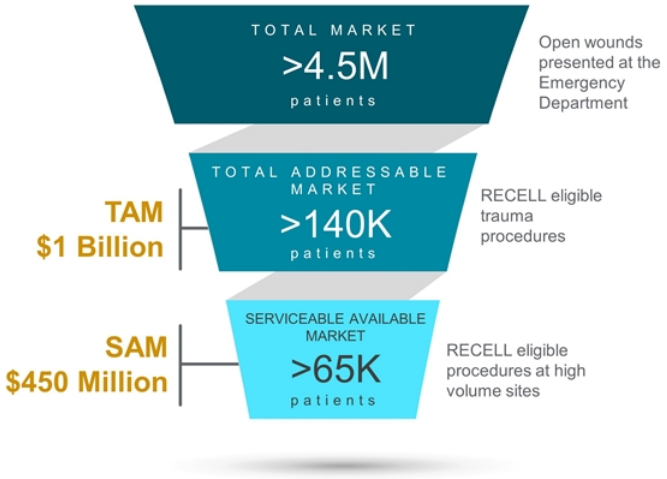


Reimbursement and Commercial Launch Anticipated in Q4 ’22

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

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.

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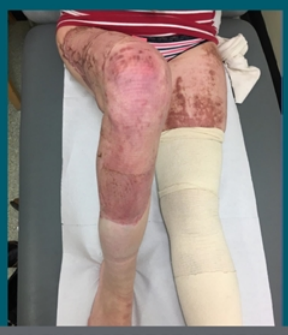
Female, pregnant 28-year-old who suffered from a de-gloving Injury

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,

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

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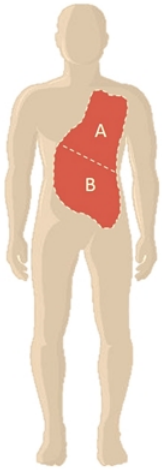
Soft Tissue Indication on Track for FDA Submission



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

Effectiveness Data

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

Safety Data

Preliminary review of adverse events shows consistency with prior RECELL experience

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

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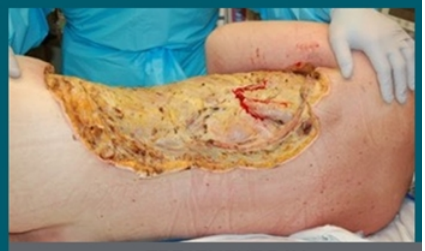
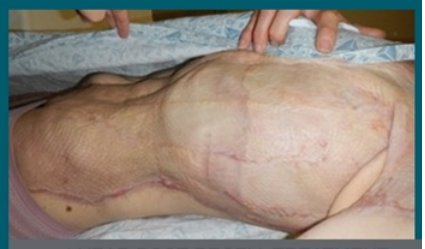
Patient treated for necrotizing fasciitis



TREATMENT DAY

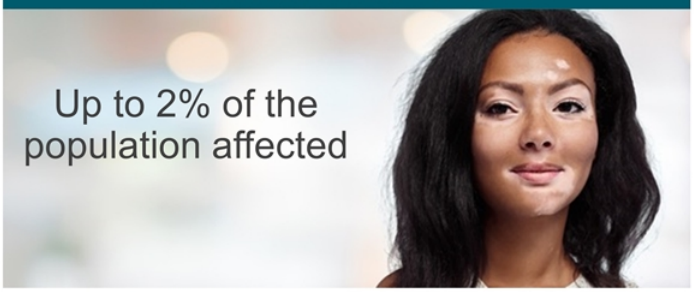


1 YEAR POST-RECELL TREATMENT

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

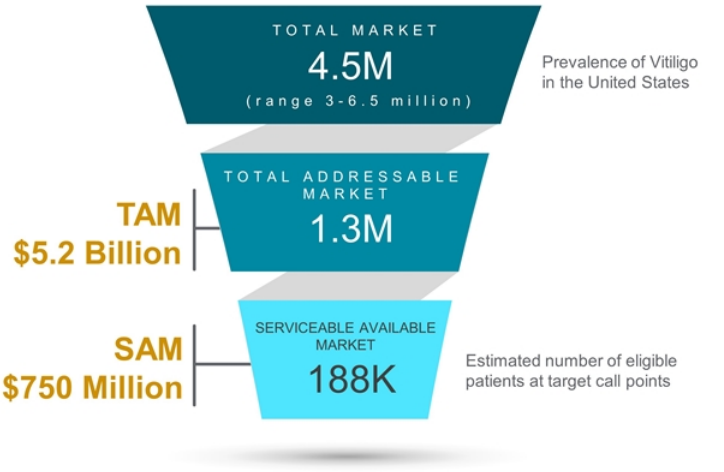
Vitiligo: Debilitating Disease with a Large Market Opportunity

UNADDRESSED PATIENT POPULATION



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

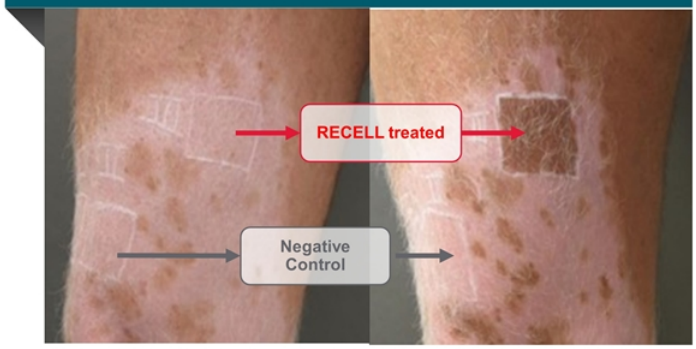
Advances in Vitiligo: An Update on Medical and Surgical Treatments. A. Dillon, et al. J Clin Aesth Derm. 2017. Willingness-to-Pay and Quality of Life in Patients with Vitiligo. Radtke, et al. BJD. 2009.
In the U.S., RECELL is approved for acute thermal burns. Use of RECELL in other indications is either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

Vitiligo Indication on Track for FDA Submission

KEY UPDATES

- Blinded Within-Subject Study to Evaluate the Safety & Effectiveness of RECELL for Repigmentation of Stable Vitiligo
  - Study 6-month follow-up completed
  - FDA Submission expected in H2 ’22
  - Approval expected in H2 ’23
- New Vitiligo Automated Device in development

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

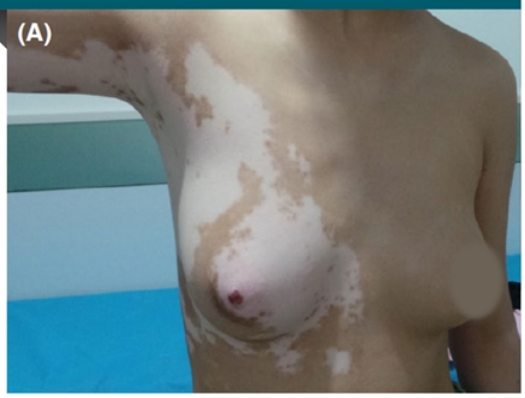
For Stable Vitiligo: Segmental & Non-Segmental

Durable: One-time treatment

*NB-UVB protocol per Vitiligo Working Group recommendations JAAD 2017.
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).

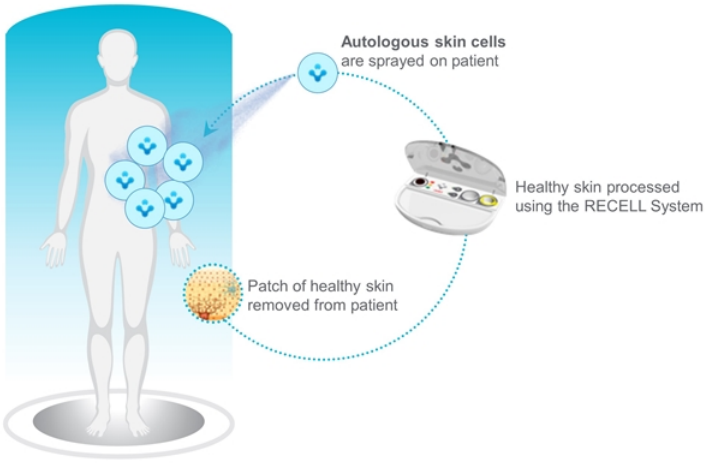
Established Track Record in Vitiligo: 1,000 patients treated internationally & 12 peer-reviewed publications showing positive outcomes

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.

RECELL in Genetic Skin Defects and Rejuvenation

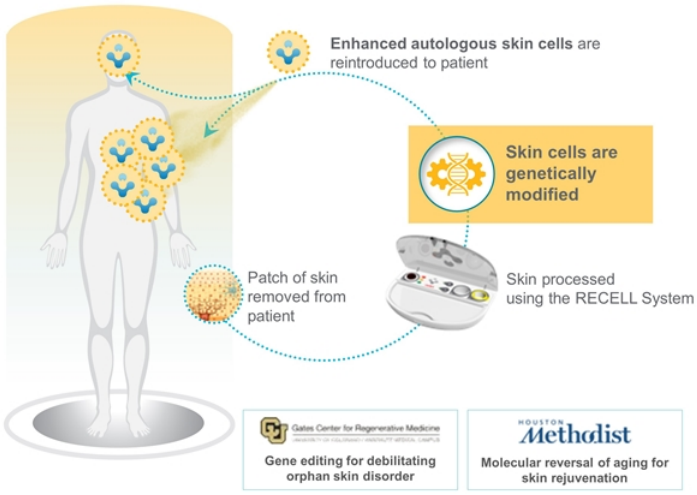
CURRENT PLATFORM

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



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Cell and Gene Therapy Development Activity

FOUR KEY STEPS

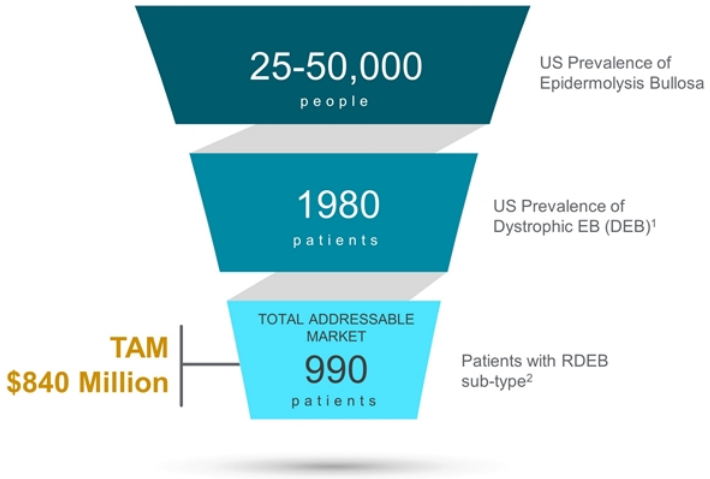
- **Proof of Concept**
- **FDA Interaction**
- **IND-enabling Studies**
- **First-in-human (IND)**

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

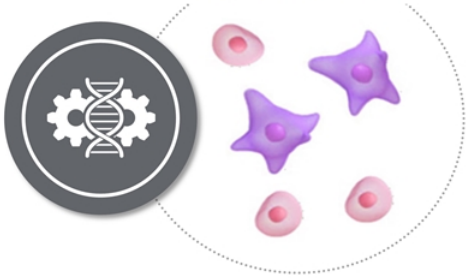
~$840M target US market opportunity, assuming $850,000[4] per patient / treatment

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

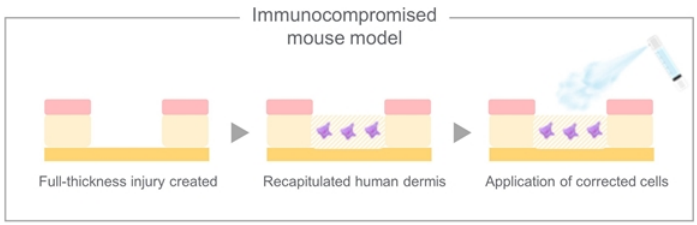
Skin Regeneration from Corrected Autologous Skin Cell Suspension

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



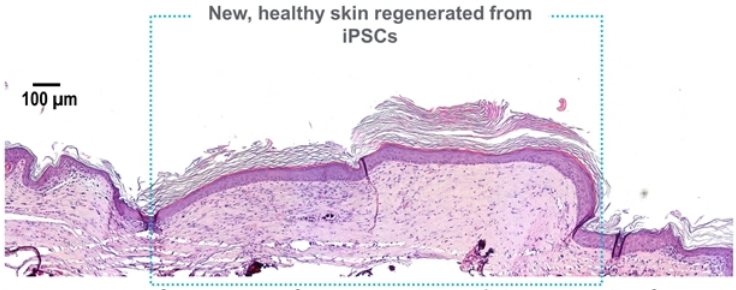
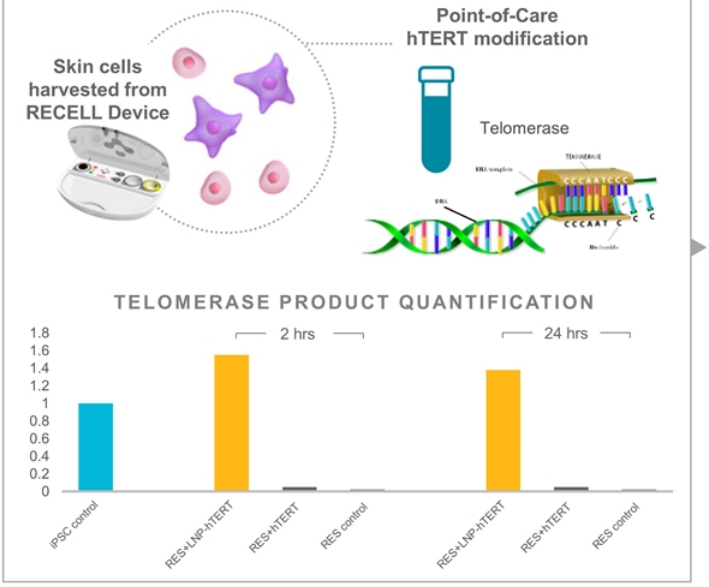


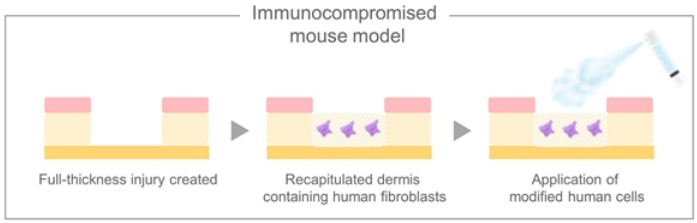
Image courtesy of Gates Center for Regenerative Medicine, University of Colorado

Reverse Aging of Skin Cells Derived using the RECELL Device

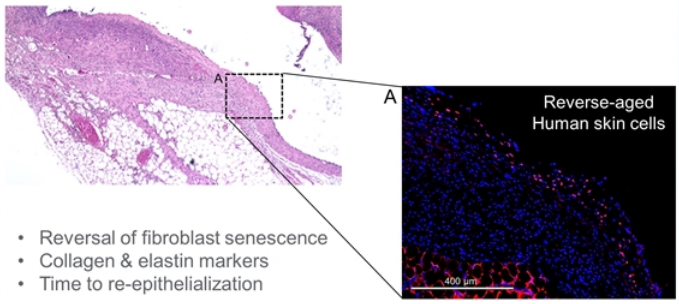
Successful delivery of mRNA-hTERT & expression in Skin Cells Derived from RECELL



In Vivo Evaluation of mRNA-hTERT Modified Skin Cells



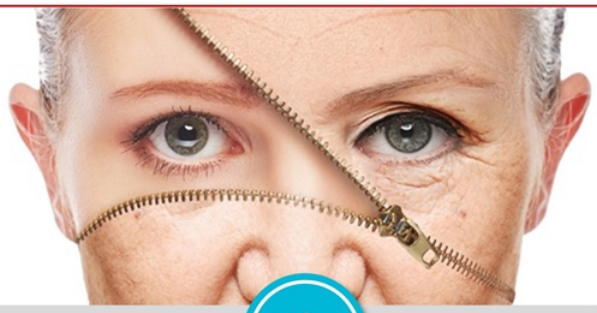
On-going Characterization



- 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

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- **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]

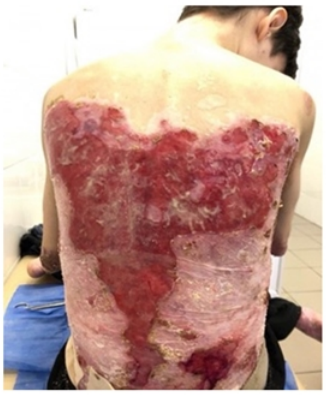
$15 Billion TAM

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.

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.

Corporate

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Financial Overview

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

Analysts

- Matt O'Brien, Piper (U.S.)
- Josh Jennings, Cowen (U.S.)
- Ryan Zimmerman, BTIG (U.S.)
- Brooks O'Neil, Lake Street (U.S.)
- Lyanne Harrison, BofA Global Research (AUS)
- Shane Ponraj, MorningStar (AUS)
- Chris Kallos, MST (AUS)
- John Hester, Bell Potter (AUS)
- Shane Storey, Wilsons (AUS)

NASDAQ ticker symbol: RCEL

ASX ticker symbol: AVH

A Global Total of 19 Granted Patents & 25 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 and Systems for Identifying a Cell Suspension with Therapeutic Potential and Related Compositions	Methods and systems for validating the use of a cell suspension for administration to a patient
Regenerative Bioactive Suspension Derived From Freshly Disaggregated Tissue	Cell-free supernate form of RES, which has standalone regenerative activity

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 through 2040

AVITA Medical owns granted patents in USA, China, Japan, Australia, France, Germany, Italy, Spain, United Kingdom, Brazil and Hong Kong, as well as pending patent applications in USA, Australia, China, Canada, EPO, Japan, and Hong Kong.

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

Value Creation

Recent Key Accomplishments

- Commercial Revenue Growth YoY of +39% in the First Half of 2022 and +23% in the Second Quarter 2022
- Soft Tissue Pivotal Trial: Topline Results
- Vitiligo Pivotal Trial: Enrollment & 6-month Follow-up Complete
- FDA Approval & Launch of New “Ease of Use” RECELL Device
- PMDA Approval of Burns in Japan and cases completed
- Initial Proof of Concept for EB and Rejuvenation (Delivery of Modified Skin Cells in Suspension)

Projected Key Milestones

• Top Line Results and Vitiligo FDA Submission / Vitiligo Commercial launch	H2 ’22 / H2 ’23
• Soft Tissue FDA Submission / Soft Tissue Commercial Launch	H2 ’22 / H2 ’23
• Reimbursement & Commercial Launch of Burns in Japan	H2 ’22
• FDA Meeting Regarding IND Enabling Studies (EB & Rejuvenation)	H2 ’22

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

Risk Factors and Disclosures

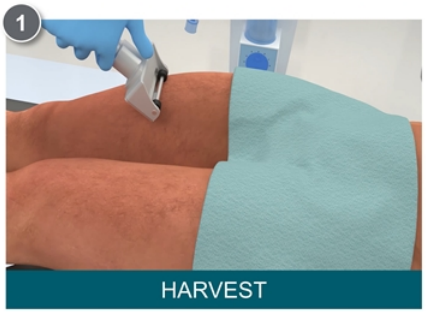
- There are numerous risk factors involved with the Company's business. Some of these risks can be mitigated by the use of safeguards and appropriate systems and controls, but some are outside the control of the Company and cannot be mitigated. Accordingly, an investment in the Company carries no guarantee 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.
- Clinical Studies to Support Any Regulatory Applications for Additional Commercial Applications: The Company cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. As a result, we may not achieve the expected clinical milestones necessary for approval by the FDA, or other regulators, for the use of RECELL® System for additional applications in the United States or other countries. A failure or delay in a clinical study or regulatory application can occur at any stage. Delays can be costly and could negatively affect our ability to complete clinical trials for our product candidates. If we are not able to successfully complete clinical trials, we will not be able to obtain regulatory approval for the use of our product for additional applications, all of which could have a material adverse effect on our business, financial condition and results of operations.

Important Safety Information

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

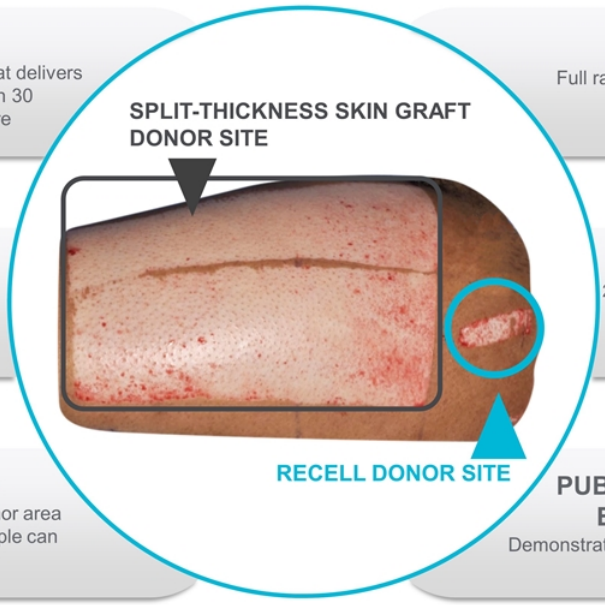
RECELL Process For Autologous Cell Harvesting and Application



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

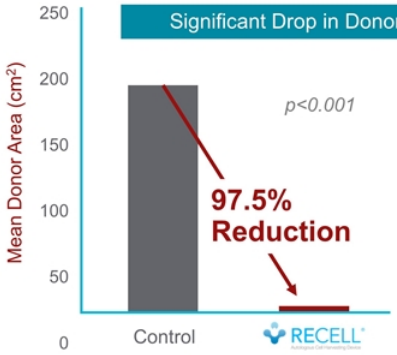
1st Premarket Approval Treatment in Burns in 20 Years

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



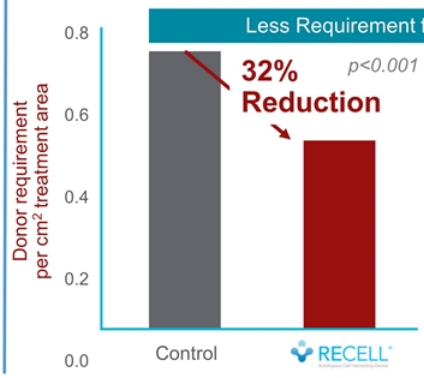
Decrease in donor site pain and scarring

- 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

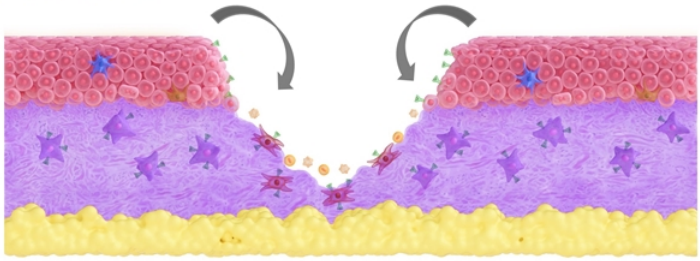
- RECELL System achieved definitive closure comparable to Standard of Care with significantly less donor skin
- At eight weeks post treatment, 92% of the burn sites treated with the RECELL System achieved complete healing versus 85% for the sites treated with the standard of care

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

RECELL "Free Edge" Advantage

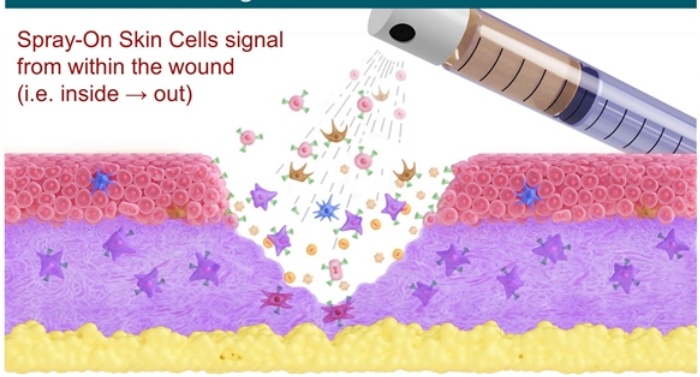
Healing Process without RECELL

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

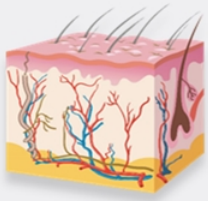
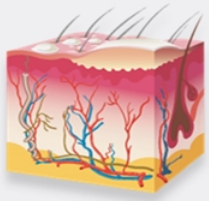
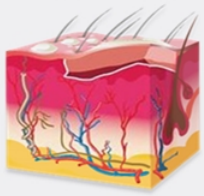
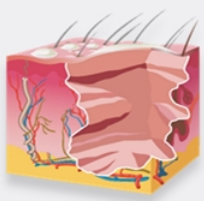
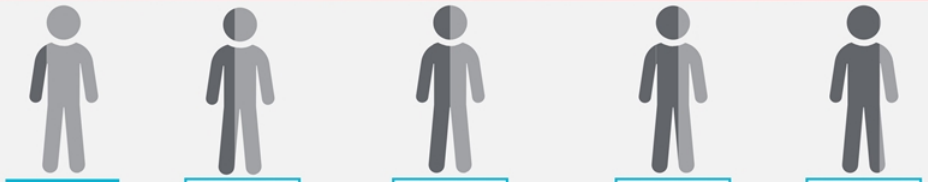
Stem Cell

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

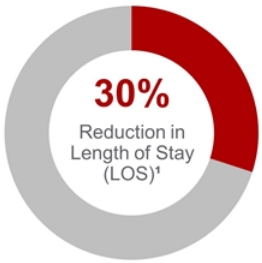
For more information on RECELL's indication for use, please go to www.recellsystem.com.

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

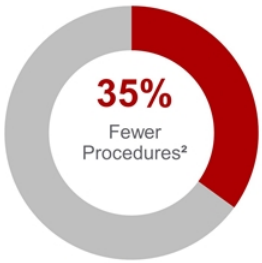
RECELL saves the hospital money in in-patient scenarios where the burn is 10% Total Body Surface Area (TBSA) or greater

Transforming Care

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



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