

**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): May 12, 2022**

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

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

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

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

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

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

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

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

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

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

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

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

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

**Item 2.02. Results of Operations and Financial Condition; Item 7.01 Reg Fd Disclosure.**

On May 12, 2022, AVITA Medical, Inc. (the "Company"), reported financial results for its first quarter 2022, and certain other business updates. A webcast of the event is available on the Company's website under Investor Events and Presentations. In conjunction with the report, the Company released a press release attached hereto as Exhibit 99.1 and a slide deck attached hereto as Exhibit 99.2.

The information under Item 2.02, Item 7.01, Exhibit 99.1, and Exhibit 99.2 is preliminary, has not been audited, and is subject to change. The information disclosed is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 and shall not be deemed incorporated by reference into any filing made under the Securities Act of 1933 except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	<a href="#">AVITA Medical Reports First Quarter 2022 Financial Results</a>
99.2	<a href="#">Company Update</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

**SIGNATURE**

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

Date: May 17, 2022

**AVITA MEDICAL, INC.**

By: /s/ Donna Shiroma

Name: Donna Shiroma

Title: General Counsel



## AVITA Medical Reports First Quarter 2022 Financial Results

May 12, 2022

VALENCIA, Calif. and MELBOURNE, Australia, May 12, 2022 (GLOBE NEWSWIRE) — 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 reported financial results for its first quarter ended March 31, 2022.

### Financial Highlights and Recent Updates:

- Reported commercial revenue, which excludes BARDA revenue, of \$7.4 million a 61% increase compared to \$4.6 million in the corresponding period in the prior year
- Reported total revenue, which includes BARDA revenue, of \$7.5 million compared to \$8.8 million in the corresponding period in the prior year, which included \$4.1 million in BARDA revenue
- In February 2022, FDA approved our premarket approval application (PMA) supplement for RECELL® Autologous Cell Harvesting Device, an enhanced RECELL system aimed at providing clinicians a more efficient user experience and simplified workflow
- In February 2022, Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) approved our application for commercialization of the RECELL system in burns
- As of March 31, 2022, the Company had \$95.0 million in cash, cash equivalents, and marketable securities, with no debt

“Our commercial team performed well this quarter driving further adoption and penetration within burn centers, and our clinical team continued to move the soft tissue reconstruction and vitiligo trials forward,” said Dr. Mike Perry, AVITA Medical Chief Executive Officer. “We are well positioned to drive revenue growth ahead and we look forward to topline data readouts from our soft tissue reconstruction and vitiligo clinical trials in the second half of this year.”

### First Quarter of Year 2022 Financial Results

Our commercial revenue, which excludes BARDA revenue, was \$7.4 million in the current year, an increase of \$2.8 million or 61%, compared to \$4.6 million the corresponding period in the prior year. Total revenue, which includes BARDA revenue, was \$8.8 million in the corresponding period in the prior year which included \$4.1 million in BARDA related revenue that resulted from our delivery of units to managed inventory for BARDA for emergency response preparedness. The increase in commercial revenue was largely driven by broader utilization among our customer base as well as deeper penetration within individual customer accounts.

Gross profit margin was 76% and is flat compared to the corresponding period in the prior year.

Total operating expenses increased by 21% to \$16.0 million compared to \$13.2 million in the corresponding period in the prior year. The increase in operating expenses is primarily attributable to higher share-based compensation, salary, and benefits. Higher share-based compensation expenses are associated with acceleration of expense for certain performance milestones being met in the current quarter. Higher salary and benefits are driven by the expansion of our workforce to support the overall operations, an increase in field resources to expand our market coverage and hiring of an executive at the end of March 2021.

Net loss increased by 58% or \$3.5 million to \$9.5 million, or \$0.38 per share, compared to a net loss of \$6.0 million, or \$0.26 per share, in the corresponding period of the prior year.

Adjusted EBITDA\* loss increased by 42%, or \$1.9 million to \$6.4 million, over the \$4.5 million recognized in the corresponding period in the prior year. A table reconciling non-GAAP measures is included in this press release for reference.

### Calendar Year 2022 Revenue Guidance

Commercial revenues in calendar year 2022 are projected to be approximately \$30 million, excluding BARDA revenues, which represents a 20% increase year-over year. We project BARDA revenues of approximately \$0.3 million in calendar year 2022, as compared to \$7.9 million in calendar year 2021, since we completed delivery of RECELL units into the national stockpile in 2021.

\* Adjusted EBITDA is a non-GAAP financial measure. See the appendix to this release for a discussion of Non-GAAP financial measures, including a reconciliation to the most closely correlated GAAP measure.

### Webcast and Conference Call Information

The Company will host a conference call to discuss the first quarter financial results after market close on Thursday May 12, 2022, at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time (being 6:30 a.m. Australian Eastern Standard Time on Friday May 13, 2022). The conference call can be accessed live over the phone at (833) 614-1538 for U.S. callers or at (706) 634-6548 international callers, using conference ID:2592487. The live webinar can be accessed at <https://ir.avitamedical.com>.

#### **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 Medical's 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://reccellsystem.com/>) for a full description of indications for use and important safety information including contraindications, warnings, and precautions.

In February 2022, the FDA reviewed and approved the PMA supplement for RECELL Autologous Cell Harvesting Device, an enhanced RECELL System aimed at providing clinicians a more efficient user experience and simplified workflow. The RECELL System is a device that enables healthcare professionals to produce a suspension of Spray-On Skin™ Cells using a small sample of the patient's own skin for the treatment of acute thermal burns.

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](http://www.avitamedical.com).

#### **\* Use of Non-GAAP Measure**

AVITA Medical's reported earnings are prepared in accordance with generally accepted accounting principles in the United States, or GAAP, and represent earnings as reported to the Securities and Exchange Commission. AVITA Medical has provided in this release certain financial information that has not been prepared in accordance with GAAP. AVITA Medical's management believes that the non-GAAP adjusted EBITDA described in the release, which includes adjustments for specific items that are generally not indicative of our core operations, provides additional information that is useful to investors in understanding AVITA Medical's underlying performance, business and performance trends, and helps facilitate period-to-period comparisons and comparisons of its financial measures with other companies in AVITA Medical's industry. However, the non-GAAP financial measures that AVITA Medical uses may differ from measures that other companies may use. Non-GAAP financial measures are not required to be uniformly applied, are not audited and should not be considered in isolation or as substitutes for results prepared in accordance with GAAP.

#### **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:**

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**AVITA MEDICAL, INC.**  
**Consolidated Balance Sheets**  
(In thousands, except share and per share data)  
(Unaudited)

	As of	
	March 31, 2022	December 31, 2021
<b>ASSETS</b>		
Cash and cash equivalents	\$ 23,535	\$ 55,511
Marketable securities	59,835	29,649
Accounts receivable, net	3,481	3,118
BARDA receivables	682	308
Prepays and other current assets	1,146	1,213
Restricted cash	201	201
Inventory	1,803	2,132
<b>Total current assets</b>	<b>90,683</b>	<b>92,132</b>
Marketable securities, long-term	11,684	19,692
Plant and equipment, net	1,171	1,262
Operating lease right-of-use assets	1,375	1,544
Intangible assets, net	416	443
Other long-term assets	1,162	942
<b>Total assets</b>	<b>\$ 106,491</b>	<b>\$ 116,015</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Accounts payable and accrued liabilities	2,397	2,708
Accrued wages and fringe benefits	2,914	5,363
Other current liabilities	1,186	1,075
<b>Total current liabilities</b>	<b>6,497</b>	<b>9,146</b>
Contract liabilities	882	952
Operating lease liabilities, long-term	726	918
Other long-term liabilities	571	375
<b>Total liabilities</b>	<b>8,676</b>	<b>11,391</b>
Contingencies (Note 12)		
Shareholders' Equity:		
Common stock, \$0.0001 par value per share, 200,000,000 shares authorized, 24,955,581 and 24,925,743 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	3	3
Preferred stock, \$0.0001 par value per share, 10,000,000 shares authorized, no shares issued or outstanding at March 31, 2022 and December 31, 2021	—	—
Additional paid-in capital	335,417	332,484
Accumulated other comprehensive income	7,781	8,060
Accumulated deficit	(245,386)	(235,923)
<b>Total shareholders' equity</b>	<b>97,815</b>	<b>104,624</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$ 106,491</b>	<b>\$ 116,015</b>

**AVITA MEDICAL, INC.**  
**Consolidated Statements of Operations**  
(In thousands, except share and per share data)  
(Unaudited)

	<u>Three Months Ended March 31,</u>	
	<u>2022</u>	<u>2021</u>
Revenues	\$ 7,539	\$ 8,765
Cost of sales	(1,778)	(2,146)
Gross profit	5,761	6,619
BARDA income	734	570
Operating expenses:		
Sales and marketing expenses *	(4,828)	(3,649)
General and administrative expenses *	(7,534)	(5,422)
Research and development expenses *	(3,620)	(4,109)
Total operating expenses	(15,982)	(13,180)
Operating loss	(9,487)	(5,991)
Interest expense	—	(3)
Other income	28	7
Loss before income taxes	(9,459)	(5,987)
Income tax expense	(4)	(10)
Net loss	<u>\$ (9,463)</u>	<u>\$ (5,997)</u>
Net loss per common share:		
Basic	\$ (0.38)	\$ (0.26)
Diluted	\$ (0.38)	\$ (0.26)
Weighted-average common shares:		
Basic	24,937,999	22,734,335
Diluted	24,937,999	22,734,335

\* Total operating expenses include impact of share-based compensation as follows:

	<u>Three-months ended March 31,</u>	
	<u>2022</u>	<u>2021</u>
Sales and marketing expenses	\$ 329	\$ 238
General and administrative expenses	2,327	930
Research and development expenses	276	165
Total	<u>\$ 2,932</u>	<u>\$ 1,333</u>

**Reconciliation of reported Net Loss (GAAP) to Adjusted EBITDA (NON-GAAP) Measure – Unaudited**

	<u>Three months ended March 31,</u>	
	<u>2022</u>	<u>2021</u>
Net Loss	\$ (9,463)	\$ (5,997)
Depreciation expense	129	137
Patent Amortization	34	30
Share-based expense	2,932	1,333
Interest Expense	—	3
Income Tax Expense	4	10
Adjusted EBITDA (Non-GAAP)	<u>\$ (6,364)</u>	<u>\$ (4,484)</u>

**avita**<sup>medical</sup>

**One Platform.  
Endless Possibilities.**

May 2022

NASDAQ: RCEL

ASX: AVH



Certain statements in this presentation and the accompanying oral commentary are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this presentation, including statements regarding our future financial condition, technology platform, development strategy, prospective products, pipeline and milestones, regulatory objectives, expected payments from and outcomes of collaborations, and likelihood of success, are forward-looking statements. Such statements are predictions only and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, among others, the costs, timing and results of clinical trials and other development activities; the uncertainties inherent in the initiation and enrollment of clinical trials; the uncertainties associated with the COVID-19 pandemic; the unpredictability of the timing and results of regulatory submissions and reviews; market acceptance for approved products and innovative therapeutic treatments; competition; the possible impairment of, inability to obtain and costs of obtaining intellectual property rights; and possible safety or efficacy concerns, general business, financial and accounting risks and litigation. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. More information concerning AVITA Medical as well as the aforementioned risks and uncertainties is available in our public filings with the U.S. Securities and Exchange Commission, including our most recent Quarterly Report on Form 10-Q for the quarter ended March 31, 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<sup>®</sup> 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).

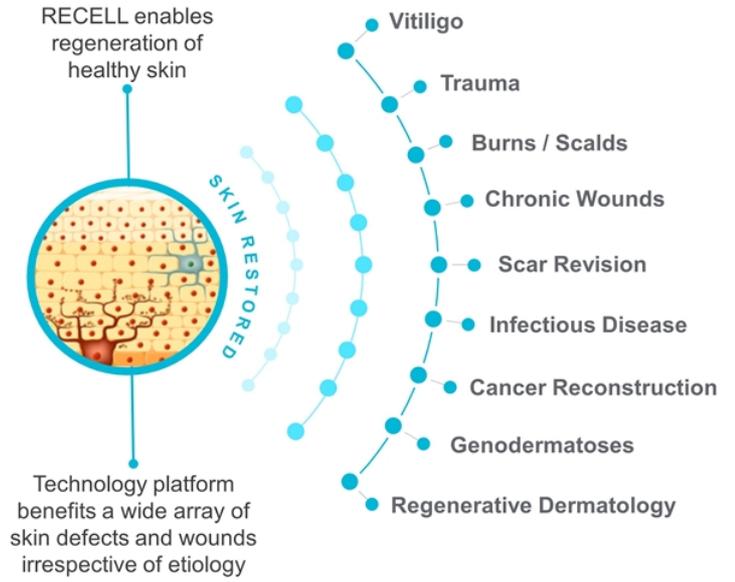
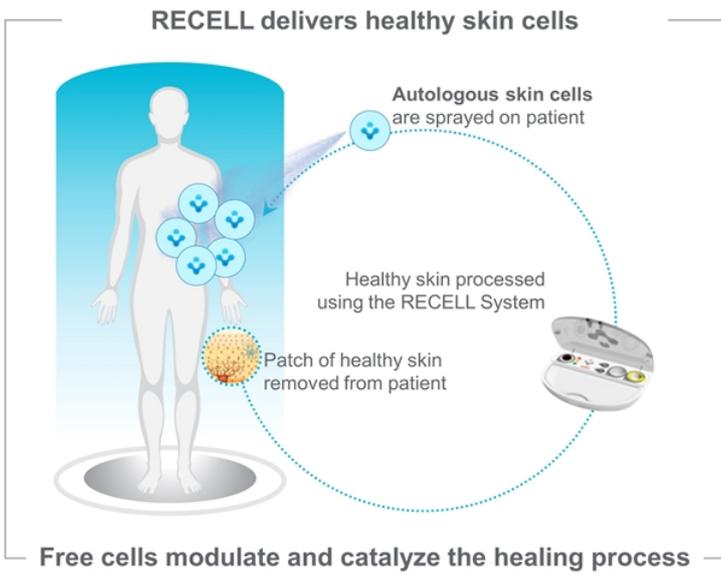
- **RECELL® System: FDA approved for the treatment of acute thermal burns**
  - Proprietary Spray-On Skin™ offers life changing benefits
  - Point of care technology that is safe & effective
  - Published health economic model demonstrating hospital cost savings
- **Deep scientific and clinical pedigree**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



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

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In the U.S., RECELL is approved for acute thermal burns. Use of RECELL in other indications is either (1) limited by United States law to investigational use; or (2) otherwise prohibited.

Recent Key Accomplishments 	Projected Key Milestones 										
<ul style="list-style-type: none"> <li>• First Quarter 2022 Revenue Growth of +61% YoY</li> <li>• FDA Approval of New “Ease of Use” RECELL Device</li> <li>• Vitiligo Pivotal Trial: Enrollment Complete</li> <li>• Soft Tissue Pivotal Trial: Enrollment Completed</li> <li>• TPT Payment Created by CMS for Hospital Outpatient Setting</li> <li>• PMDA Approval of Burns in Japan</li> <li>• Initial Proof of Concept for EB and Rejuvenation (Delivery of Modified Skin Cells in Suspension)</li> </ul>	<table border="1"> <tbody> <tr> <td>• Launch of New “Ease of Use” RECELL Device</td> <td>Q2 '22</td> </tr> <tr> <td>• FDA Meeting Regarding IND Enabling Studies (EB &amp; Rejuvenation)</td> <td>H2 '22</td> </tr> <tr> <td>• Reimbursement &amp; Launch of Burns in Japan</td> <td>H2 '22</td> </tr> <tr> <td>• Top Line Results and Vitiligo FDA Submission / Vitiligo Commercial launch</td> <td>H2 '22 / H2 '23</td> </tr> <tr> <td>• Top Line Results and Soft Tissue FDA Submission / Soft Tissue Commercial Launch</td> <td>H2 '22 / H2 '23</td> </tr> </tbody> </table>	• Launch of New “Ease of Use” RECELL Device	Q2 '22	• FDA Meeting Regarding IND Enabling Studies (EB & Rejuvenation)	H2 '22	• Reimbursement & Launch of Burns in Japan	H2 '22	• Top Line Results and Vitiligo FDA Submission / Vitiligo Commercial launch	H2 '22 / H2 '23	• Top Line Results and Soft Tissue FDA Submission / Soft Tissue Commercial Launch	H2 '22 / H2 '23
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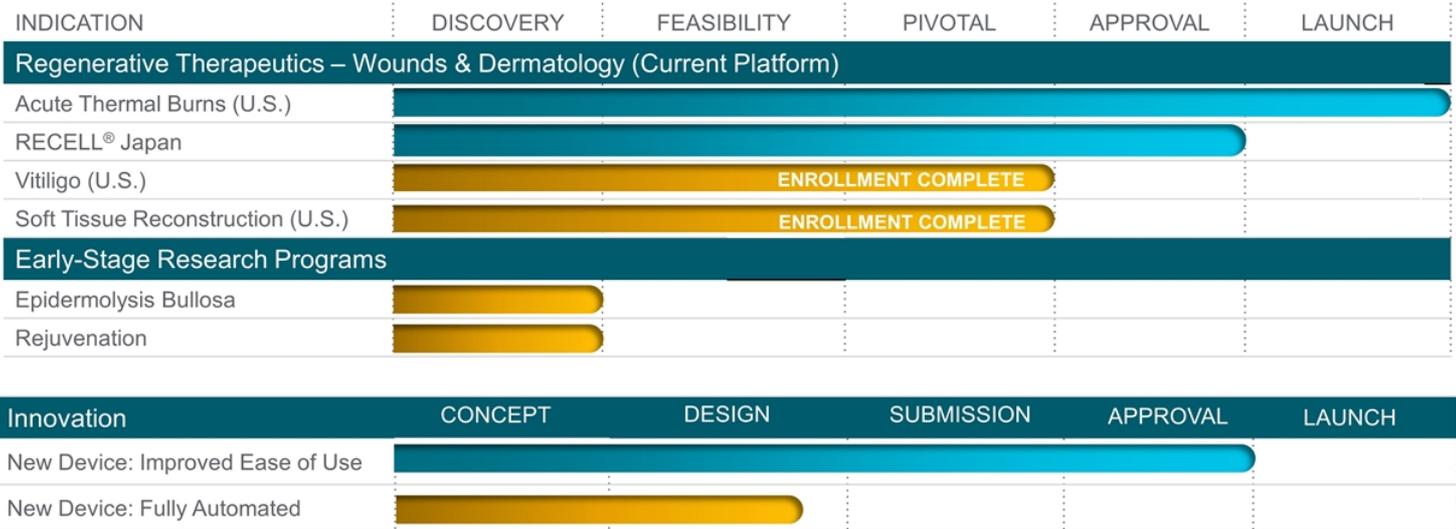
Quarters referenced in calendar year. As of January 1, 2022 Avita Medical is reporting on a calendar year basis.



## Development Pipeline and Growth Potential

avita<sup>medical</sup>

# Focused Pipeline with Strong Growth Potential

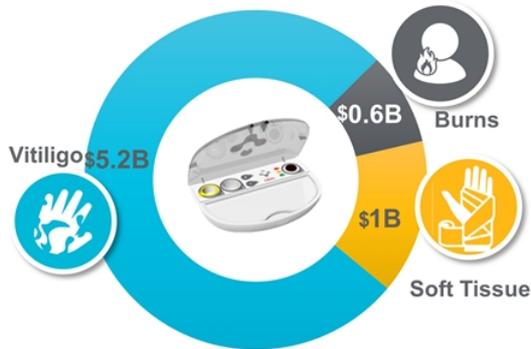


## Focused Effort on Business Development to Supplement Pipeline

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.

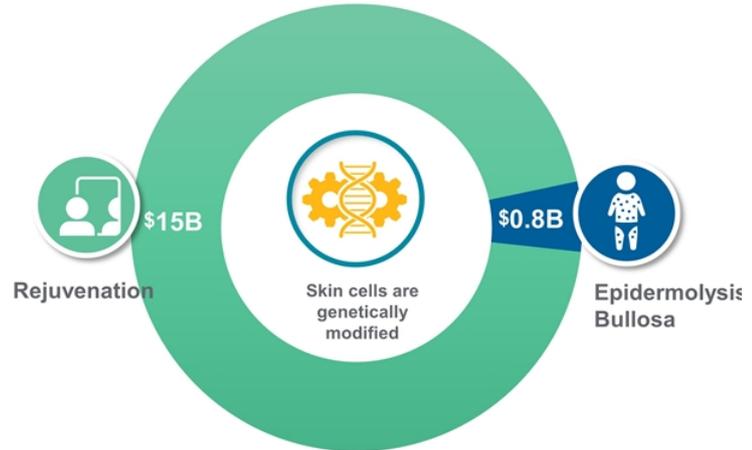
## EXISTING PLATFORM

~\$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
<b>ACUTE WOUNDS</b> <i>(Including Thermal Burns)</i>	1,839	255
<b>DEFECTS/ VITILIGO</b>	453	58
<b>CHRONIC WOUNDS</b>	143	19

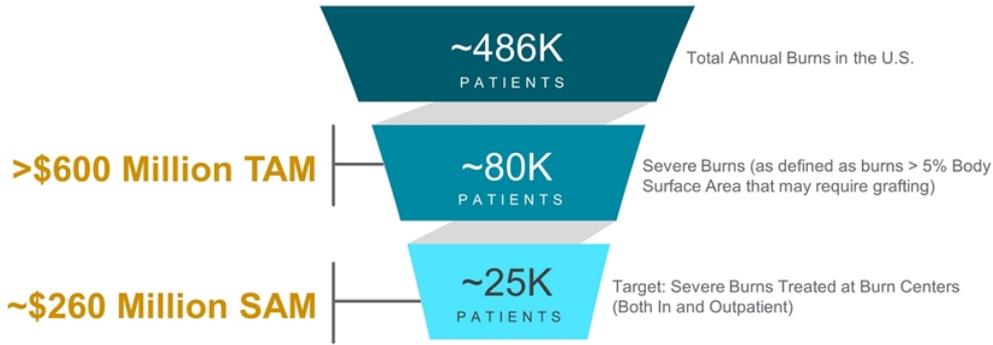
Highly De-risked Pipeline with >15,000 Patients Treated Globally

**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.

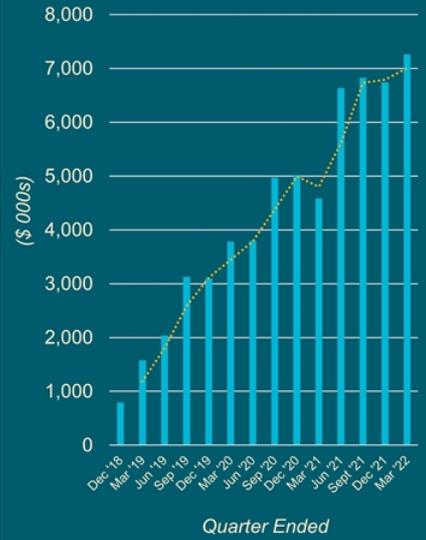
# Thermal Burns: U.S. Target Market Expanded to Include Small Burns and Outpatient

Patient Funnel and Addressable Market

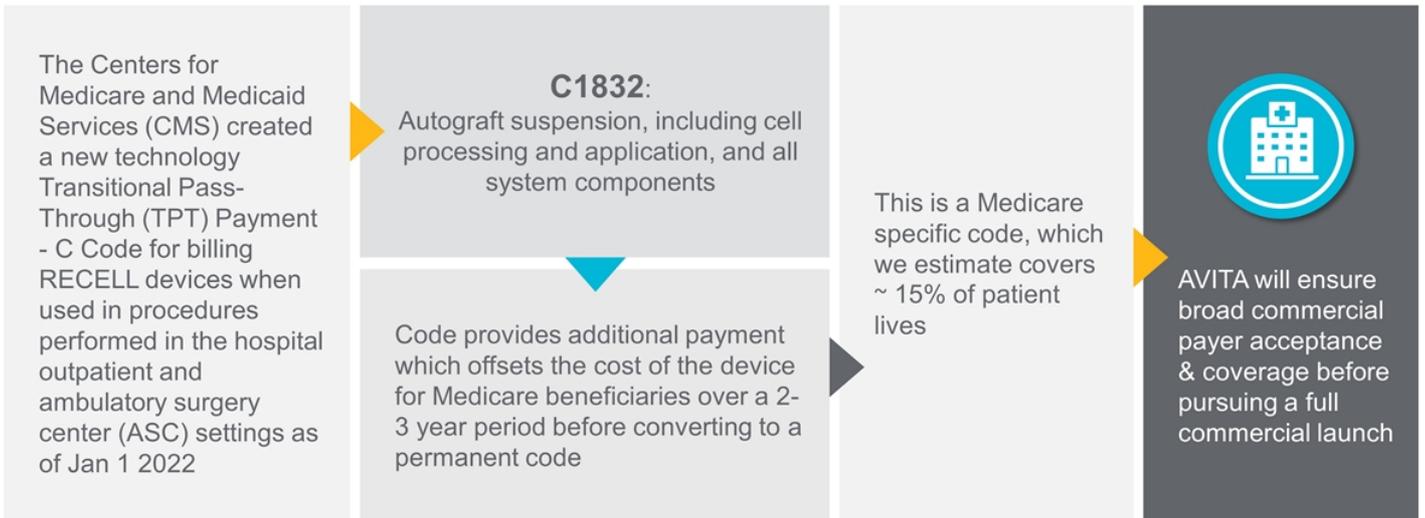


Outpatient Pass Through Code Opens Doors to Small Burns and Expands Serviceable Market Opportunity

U.S. RECELL Commercial Sales Since Approval



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



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



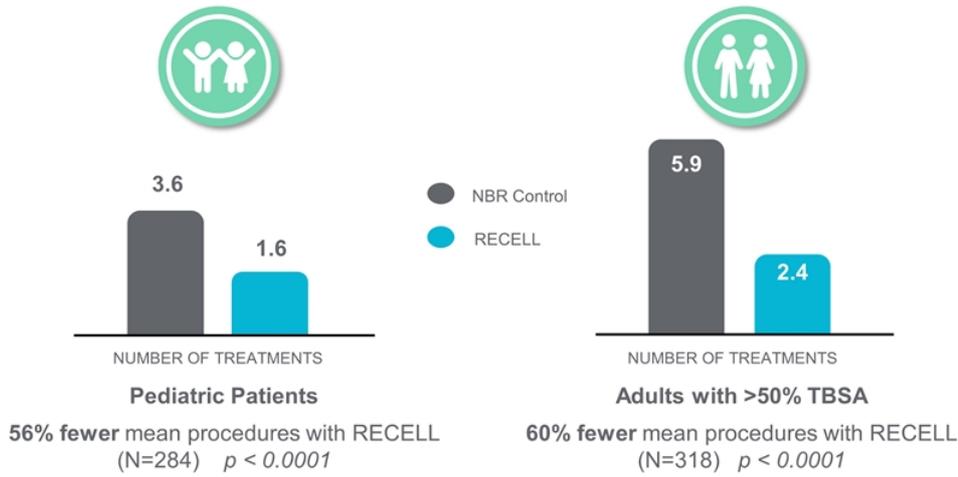
94% of surveyed users of the RECELL System believe it will **reduce their workload/allow them to perform other duties\***

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

\* Market Research March 2020 HCPs

# FDA Approval in Pediatric Full-Thickness & Larger Burns

## FEWER PROCEDURES REQUIRED FOR DEFINITIVE CLOSURE VS CONVENTIONAL AUTOGRAFT<sup>1</sup>



~25% of all burns occur in children

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

1. Instructions for Use, RECELL® Autologous Cell Harvesting Device  
2. NBR – National Burns Repository  
\* N = 41, \*will significantly or somewhat impact RECELL usage\*

## BACKGROUND



AVITA Commercial Partner:  
COSMOTEC, an M3 Company

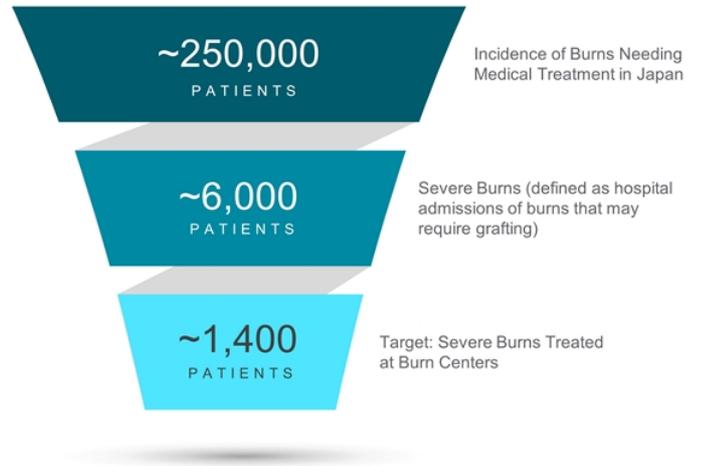


INDICATION: Burns  
Soft Tissue and Vitiligo to Follow Based on U.S. Pivotal Clinical Data



LAUNCH:  
Following Ministry of Health, Labour, and Welfare (MHLW) decision on reimbursement pricing, anticipated Q4 2022

## PATIENT FUNNEL - BURNS ADDRESSABLE MARKET



Reimbursement and Commercial Launch Anticipated in Q4 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\\_2/36#F2](https://injuryprevention.bmj.com/content/26/Suppl_2/36#F2) and Cosmotec estimates

## SIGNIFICANT UNMET NEED

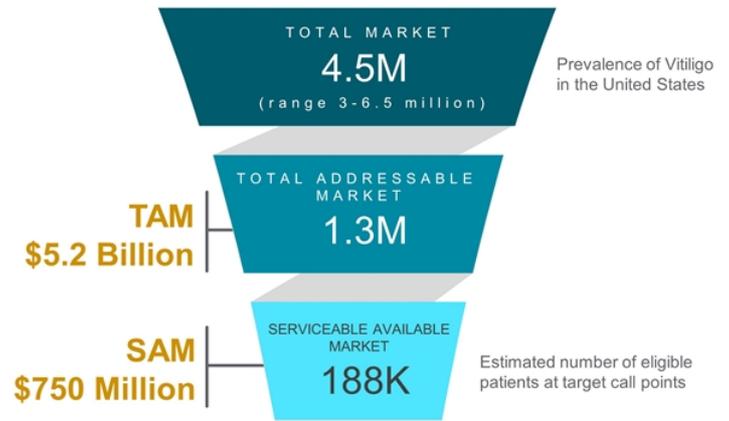


Up to 2% of the population affected

**No FDA-approved medical treatments;** extremely low patient and physician satisfaction with existing products

**Vitiligo impacts quality of life (QoL) –** 25% of patients with vitiligo reported a DLQI >10, which indicates severe QoL reductions, compared with 34% in psoriasis patients

## OPPORTUNITY ESTIMATION

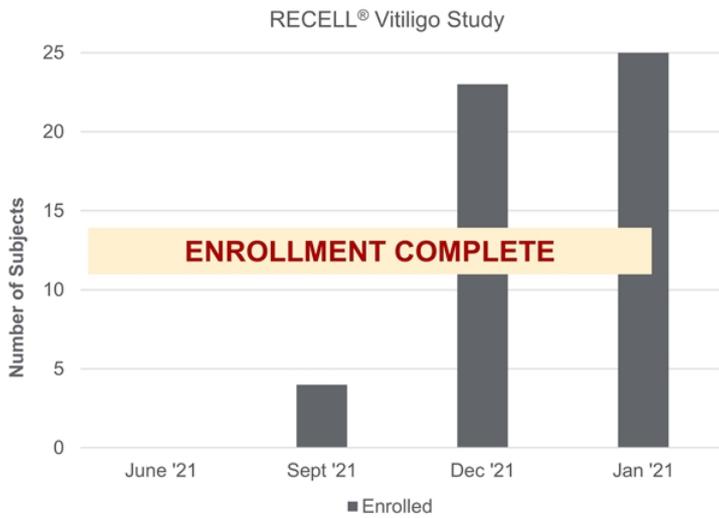


Concentrated HCP base: Estimating <1,000 procedural dermatologists and plastic surgeons with interest in treating vitiligo

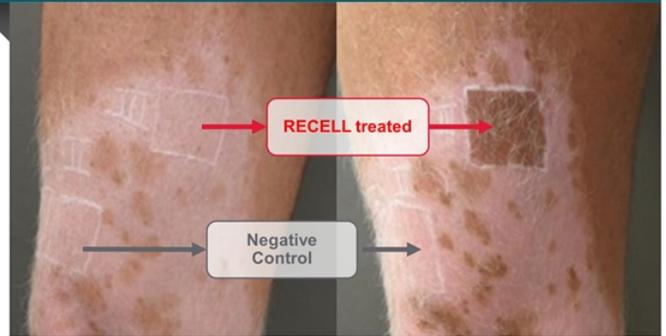
Advances in Vitiligo: An Update on Medical and Surgical Treatments. A. Dillon, et al. J Clin Aesth Derm. 2017. Willingness-to-Pay and Quality of Life in Patients with Vitiligo. Radtke, et al. BJD. 2009. In the U.S., RECELL is approved for acute thermal burns. Use of RECELL in other indications is either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

# Vitiligo Study Enrollment Complete

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



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



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

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

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



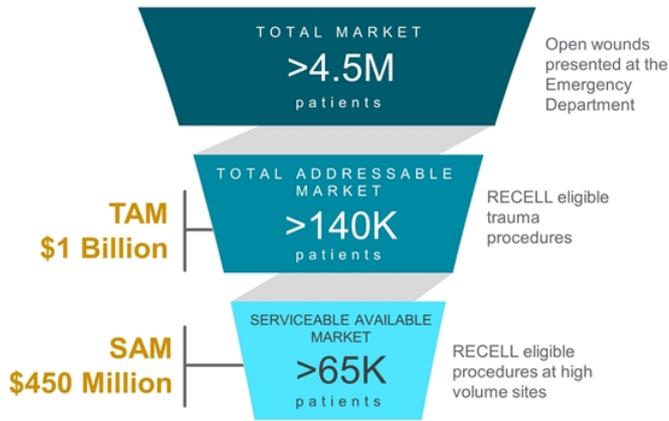
- 23 year old female with vitiligo.
- Donor skin was harvested from adjacent unaffected areas.
- Depigmented epidermis was removed using dermabrasion.
- The cellular suspension was then sprayed on both the recipient and donor areas (expansion ratio ranged from 1:20-1:40).

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

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

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

## OPPORTUNITY ESTIMATION



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



POST DEBRIDEMENT OF INJURY



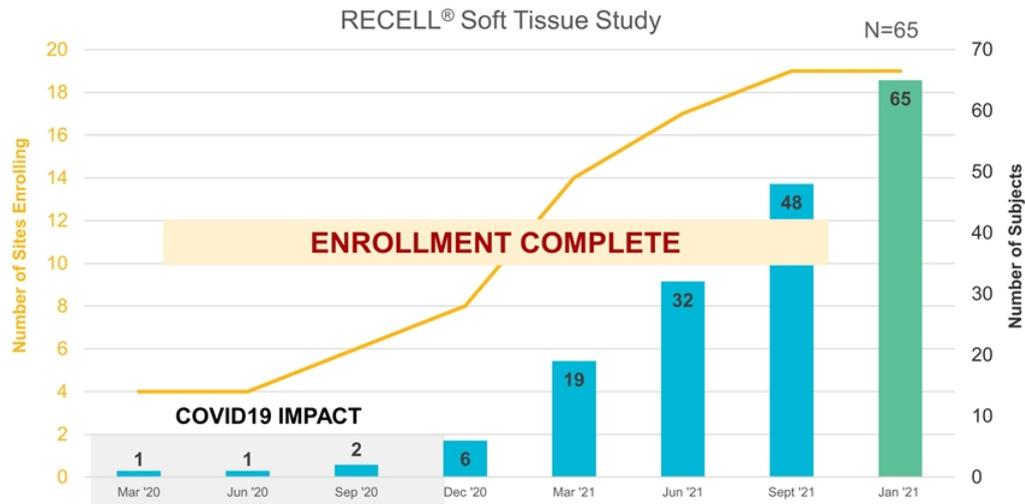
6 MONTH POST-RECELL TREATMENT

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

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

# Early Completion of Soft Tissue Reconstruction Trial

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



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

In the U.S., RECELL is approved for acute thermal burns. Use of RECELL in other indications is either (1) limited by United States law to investigational use; or (2) otherwise prohibited.

Patient treated for necrotizing fasciitis



Photos courtesy of Kevin Foster, Valleywise Health Medical Center

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

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



**Reimbursement in Place**

Able to leverage existing CPT & Outpatient C Code

**Same Treatment Protocol to Burns**

Consistent treatment protocol across acute injuries

**Same Unmet Needs as Burns**

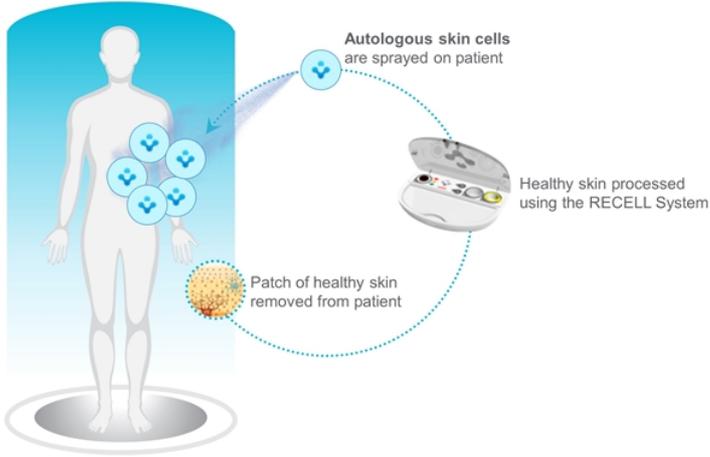
Reduction of donor site morbidity & donor site requirements are top unmet needs

Large opportunity that leverages existing burns infrastructure

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

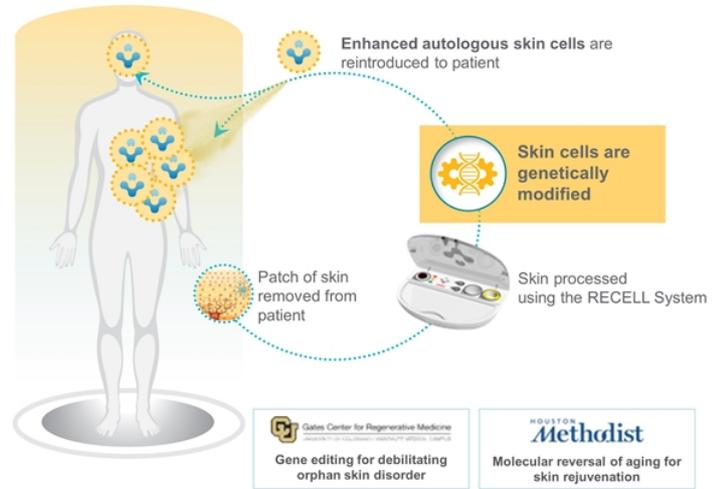
## CURRENT PLATFORM

Treatment using RECELL for harvesting and direct reintroduction of the patient's own healthy skin cells



## FUTURE PLATFORM

RECELL as a platform for treatment using the patient's corrected skin cells





FOUR  
KEY  
STEPS

Proof of Concept



FDA Interaction



IND-enabling Studies



First-in-human (IND)



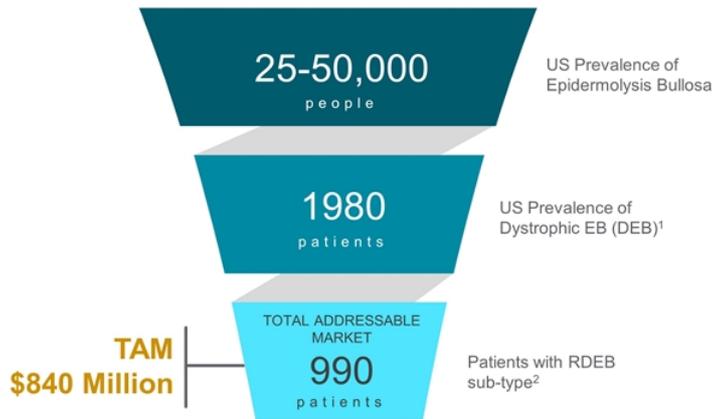
Program Objective:

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

# Sizeable Market Opportunity Estimated in EB, Given Orphan Pricing Potential

## OPPORTUNITY ESTIMATION

## POTENTIAL COMPETITIVE ADVANTAGES



Suspension is potentially more cost effective to generate, transport and apply vs cultured sheet grafts



iPSC-based technology enables banking of cells for future treatments



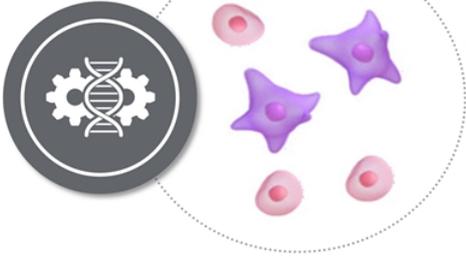
*Ex vivo* gene editing of skin cells has a safety advantage over *in vivo* gene therapeutics

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

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

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

Correction of RDEB Single-Site Mutation



## In Vivo Evaluation of Gene-corrected Skin Cells

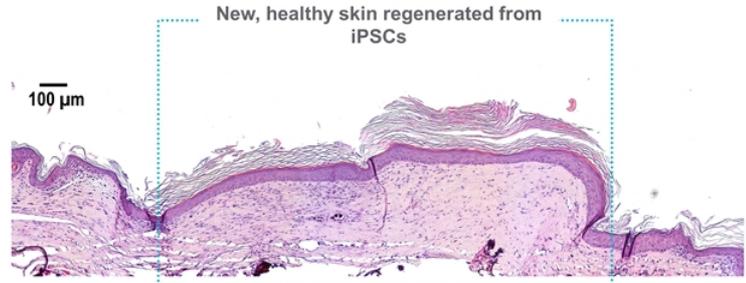
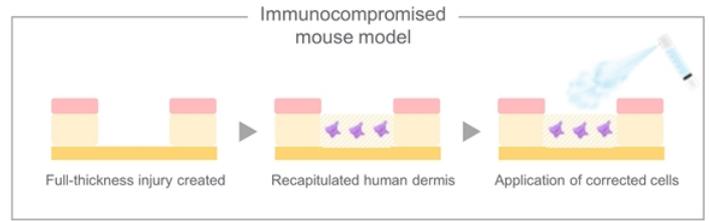


Image courtesy of Gates Center for Regenerative Medicine, University of Colorado

## THE CHALLENGE



### DEBILITATING

Skin fragility, disability, cancer

### HIGH UNMET NEED

No FDA-approved treatment, only palliative measures

### COST BURDEN

Care of \$200K-\$500K per year per patient

## THE OPPORTUNITY



**CURATIVE:** Technology for precise correction of genetic defect & banking for future use (vs ameliorating symptoms)



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



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



# Exploring Novel RNA-Based Approach for Rejuvenation

avita<sup>medical</sup>



HOUSTON  
**Methodist**  
LEADING MEDICINE



avita<sup>medical</sup>

- **Patented RNA technology** for delivery of telomerase enzyme to aged cells
- **Demonstrated reversal of aging** and return of functionality in cells of progeria patients (human model of accelerated aging)

- Patented and proprietary **Spray-On Skin™ Cells technology and device (RECELL)**
- **Expertise in skin** regeneration, including in preclinical models
- Strong track record and expertise in clinical development and commercialization

## Patient Funnel and Addressable Market

~8.3M

PEOPLE/Yr

People Who Underwent Facial Aesthetic Procedures Aimed at Improving Skin Tightness, Texture & Evenness in Skin Tone<sup>1</sup>

~1M

PATIENTS/Yr

Target: People Who Undergo Aggressive Facial Lifting & Tightening Procedures<sup>2</sup>

**\$15 Billion TAM**

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

\*1. 2020 Plastic Surgery Statistics Report. 2. 2020 Plastic Surgery Statistics Report (Defined as Facelifts, Ablative Laser, Dermabrasion, Non-Surgical Skin Tightening) In the U.S., RECELL is approved for acute thermal burns in patients > 18 years. Use of RECELL in other indications is either (1) limited by United States law to investigational use; or (2) otherwise prohibited.



Corporate

avita<sup>medical</sup>

# Financial Overview

(USD in \$000s)	12 Months Ended June 30				Unaudited 12 Months Ended December 31		Unaudited 12 Months Ended March 31	
	2018	2019	2020	2021	2020	2021	2021	2022
Commercial Sales	929	5,474	14,263	21,483	17,918	25,091	4,622	7,446
BARDA Sales	-	-	-	7,749	-	7,934	4,143	93
<b>Total Revenue</b>	<b>929</b>	<b>5,474</b>	<b>14,263</b>	<b>29,232</b>	<b>17,918</b>	<b>33,025</b>	<b>8,765</b>	<b>7,539</b>
Gross Profit	383	4,203	11,290	23,283	14,660	26,921	6,619	5,761
BARDA Income	7,734	5,921	3,926	2,055	2,534	1,590	570	734
Cash, Cash Equivalents & Marketable Securities	10,986	20,174	73,639	110,746	59,765	104,852	114,879	95,054

## 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**

## 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**



**Dr. Michael S. Perry**  
CEO  
>30 years experience



**Michael Holder**  
CFO  
>30 years experience



**Erin Liberto**  
CCO  
>20 years experience



**Andrew Quick**  
CTO  
>25 years experience



**Kathy McGee**  
COO  
>25 years experience



**Donna Shiroma**  
General Counsel  
>20 years experience

Affiliations:

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

Affiliations:

ImmuneCyte  
PREMIER  
CAROLINA LONGEVITY INSTITUTE

Affiliations:

Allergan  
Johnson & Johnson

Affiliations:

Boston Scientific  
AB  
sonova  
SummaMed Corp.

Affiliations:

Shire  
at  
advanced tissue  
SmithNephew

Affiliations:

ASCEND THERAPEUTICS  
A BESINS HEALTHCARE Company  
Pioneers in Women's Health  
PDL BioPharma  
Johnson & Johnson

Recent Key Accomplishments
<ul style="list-style-type: none"> <li>• First Quarter 2022 Revenue Growth of +61% YoY</li> <li>• FDA Approval of New “Ease of Use” RECELL Device</li> <li>• Vitiligo Pivotal Trial: Enrollment Complete</li> <li>• Soft Tissue Pivotal Trial: Enrollment Completed</li> <li>• TPT Payment Created by CMS for Hospital Outpatient Settings</li> <li>• PMDA Approval of Burns in Japan</li> <li>• Initial Proof of Concept for EB and Rejuvenation (Delivery of Modified Skin Cells in Suspension)</li> </ul>

Projected Key Milestones	
<ul style="list-style-type: none"> <li>• Launch of New “Ease of Use” RECELL Device</li> <li>• FDA Meeting Regarding IND Enabling Studies (EB &amp; Rejuvenation)</li> <li>• Reimbursement &amp; Launch of Burns in Japan</li> <li>• Top Line Results and Vitiligo FDA Submission / Vitiligo Commercial launch</li> <li>• Top Line Results and Soft Tissue FDA Submission / Soft Tissue Commercial Launch</li> </ul>	<ul style="list-style-type: none"> <li>Q2 '22</li> <li>H2 '22</li> <li>H2 '22</li> <li>H2 '22 / H2 '23</li> <li>H2 '22 / H2 '23</li> </ul>

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

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

- **INDICATIONS FOR USE:** The RECELL® Autologous Cell Harvesting Device is indicated for the treatment of acute thermal burn wounds. The RECELL device is used by an appropriately-licensed healthcare professional at the patient's point of care to prepare autologous RES® Regenerative Epidermal Suspension for direct application to acute partial-thickness thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients. .
- **CONTRAINDICATIONS:** RECELL is contraindicated for: the treatment of wounds clinically diagnosed as infected or with necrotic tissue, the treatment of patients with a known hypersensitivity to trypsin or compound sodium lactate (Hartmann's) solution, patients having a known hypersensitivity to anesthetics, adrenaline/epinephrine, povidone-iodine, or chlorhexidine solutions.
- **WARNINGS:** Autologous use only. Wound beds treated with a cytotoxic agent (e.g., silver sulfadiazine) should be rinsed prior to application of the cell suspension. RECELL is provided sterile and is intended for single-use. Do not use if packaging is damaged or expired. Choose a donor site with no evidence of cellulitis or infection and process skin immediately. A skin sample should require between 15 and 30 minutes contact with Enzyme. Contact in excess of 60 minutes is not recommended. RECELL Enzyme is animal derived and freedom from infectious agents cannot be guaranteed.
- **PRECAUTIONS:** RECELL is not intended for use without meshed autograft for treatment of full-thickness burn wounds. The safety and effectiveness of RECELL without meshed autograft have not been established for treatment of partial-thickness burn wounds: on the hands and articulating joints, >320 cm<sup>2</sup>, in patients with wounds totaling >20% total body surface area (TBSA). The safety and effectiveness of RECELL with autografting have not been established for treatment of full-thickness burn wounds: on the hands and articulated joints, and in patients younger than 28 days of age (neonates).
- **SPECIAL PATIENT POPULATIONS:** The safety and effectiveness of RECELL have not been established for treatment of acute thermal partial-thickness burn wounds in pediatric patients younger than 18 years of age.

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

avita<sup>medical</sup>



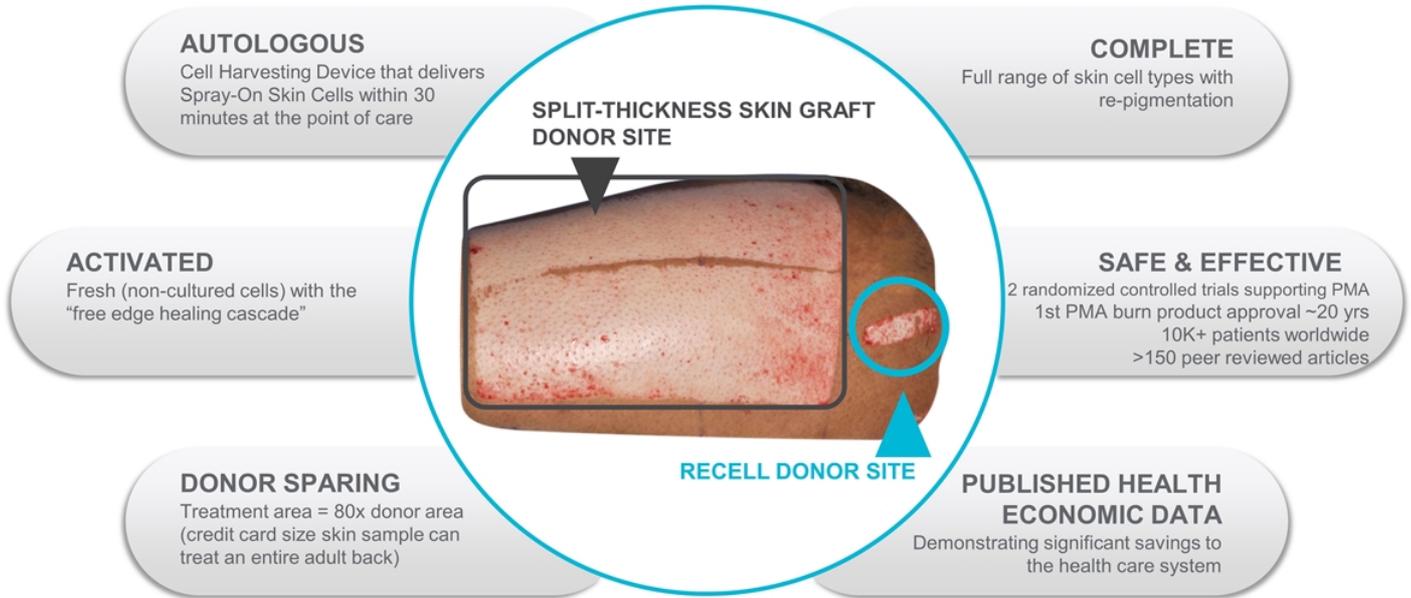
Zed, treated with the RECELL<sup>®</sup> System

In the U.S., RECELL is approved for acute thermal burns. Use of RECELL in other indications is either (1) limited by United States law to investigational use; or (2) otherwise prohibited.



# RECELL Spray-On Skin™

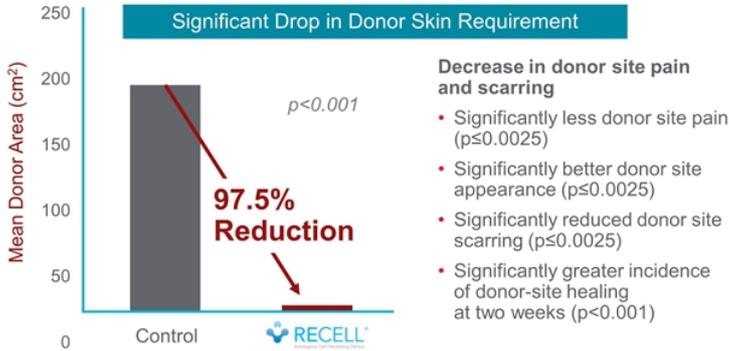
## Treats 80cm<sup>2</sup> of Skin from a 1cm<sup>2</sup> Biopsy



Dual multi-center, randomized, controlled premarket approval studies

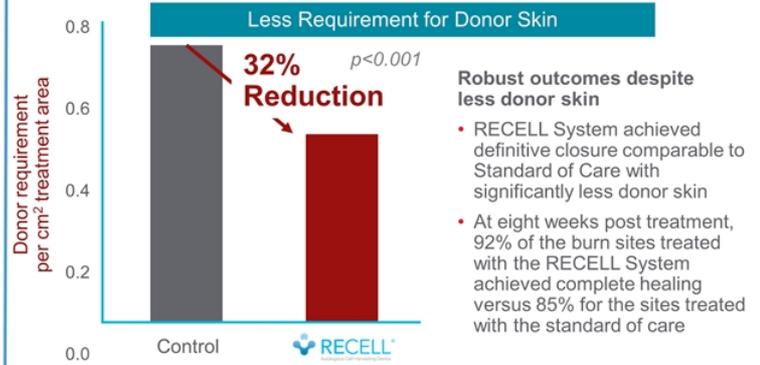
## Pivotal Trial #1 (101 Patients) RECELL (alone) versus SoC (STSG) in Second-Degree Burns

Published in JBICR and Presented at ABA



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

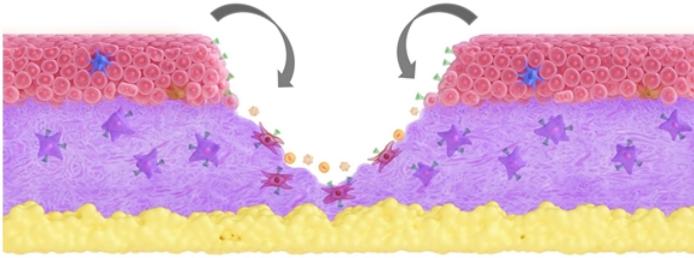
Published in Burns and Presented at ABA



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

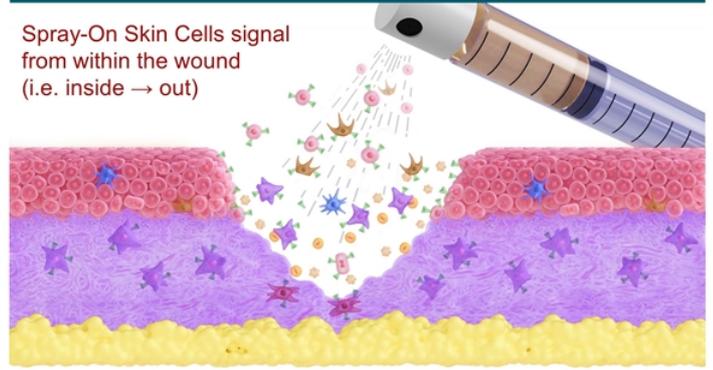
## Healing Process *without* RECELL

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



## Healing Process *with* RECELL

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



Cytokine

Inflammatory Cell

Myofibroblast

Growth Factor

Receptor

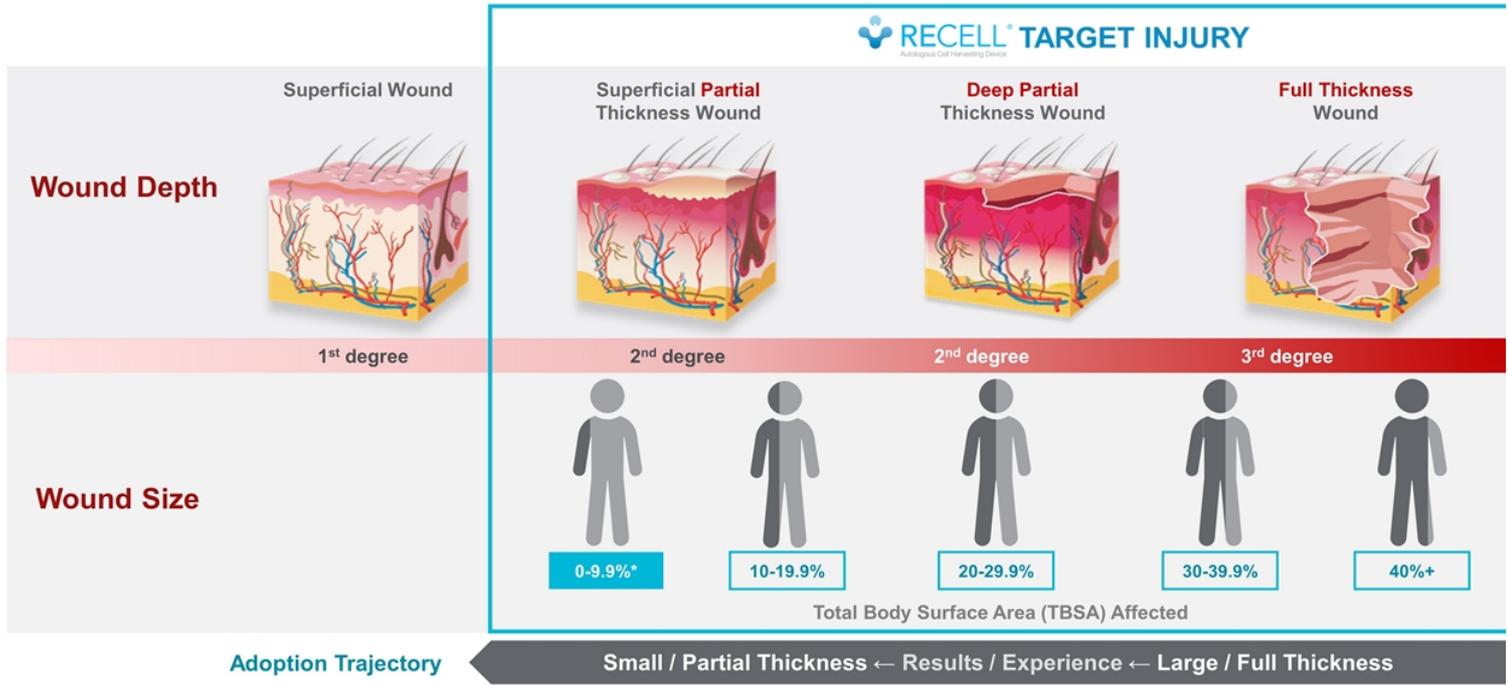
Fibroblast

Keratinocyte

Stem Cell

Melanocyte

Langerhans Cell



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

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

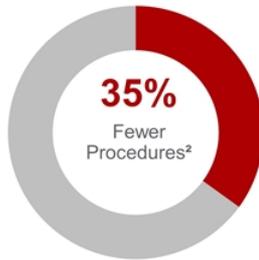
RECELL saves the hospital money in in-patient scenarios where the burn is 10% Total Body Surface Area (TBSA) or greater

## Transforming Care

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



Fewer procedures and faster healing times get patients home more quickly



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



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

## VALIDATED MODEL

- 21 abstracts on RECELL health economics since launch
- 17+ Burn Centers contributing to the RECELL abstracts and publications
- Two publications
- Customized Budget Impact calculator
- Leader of health economics in burns

1. Park JH, Heggie KM, Edgar DW, Bulsara MK, Wood FM. Does the type of skin replacement surgery influence the rate of infection in acute burn injured patients? Burns 2013;39:1386-90. <https://doi.org/10.1016/j.burns.2013.03.015>

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