

### NASDAQ: RCEL ASX: AVH

# Accelerating Our Growth Profile

42<sup>nd</sup> Annual J.P. Morgan Healthcare Conference January 11, 2024

## Forward-Looking Statements & 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 Annual Report on Form 10-K for the year ended December 31, 2022, and Quarterly Reports on Form 10-Q for the guarter ended September 30, 2023. 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 the treatment of thermal burn wounds and full-thickness skin defects and for repigmentation of stable depigmented vitiligo lesions. 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).

## Leadership





Jim Corbett Chief Executive Officer\* *30+ Years of Experience* 



Boston Scientific Baxter (X Alphatec Spine<sup>®</sup>



CATHWORKS



David O'Toole Chief Financial Officer\* *30+ Years of Experience* 







Deloitte.



**Donna Shiroma** General Counsel\* *20+ Years of Experience* 



**\$PDL** BioPharma

Johnson »Johnson



**Terry Bromley** SVP, Global Sales *20+ Years of Experience* 



EMERGENT



Histol Myers Squibb



**Debbie Garner** SVP, Global Marketing & Strategy *20+ Years of Experience* 

📢 Allergan

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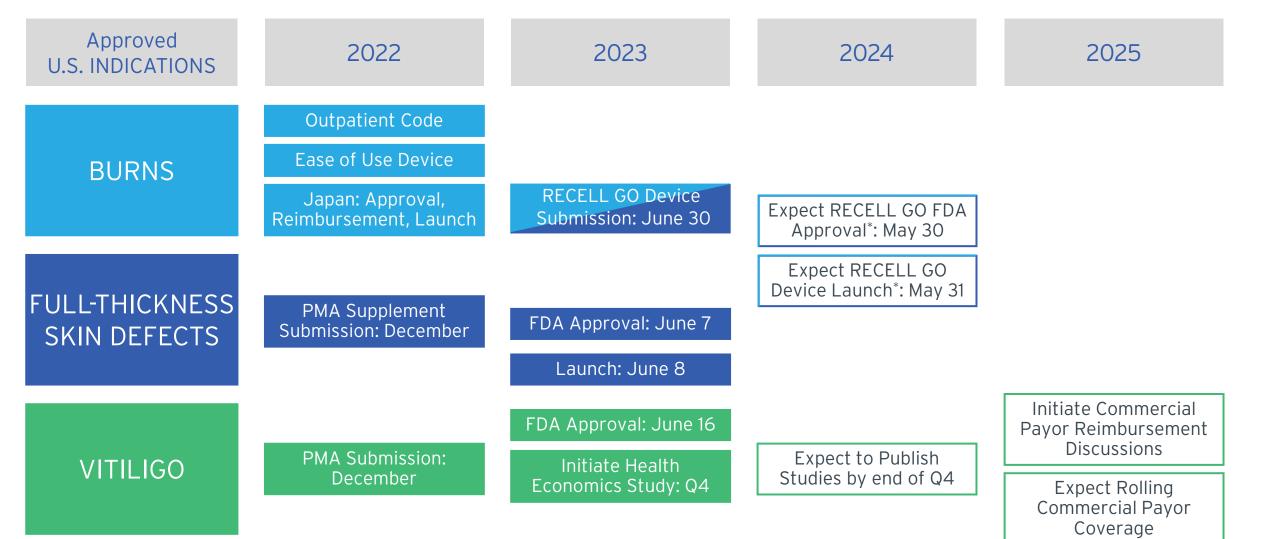
## Investment Overview



>	Commercial-stage company focused on regenerative medicine to transform the standard of care for skin restoration with an innovative cellular technology platform
>	<ul> <li>Current U.S. FDA-Approved Indications for RECELL platform:</li> <li>Thermal burn wounds and full-thickness skin defects ("FTSD")</li> <li>Repigmentation of stable depigmented vitiligo lesions</li> </ul>
	<ul> <li>Commercialization of RECELL:</li> <li>40 sales territories supported by a salesforce of 70: <ul> <li>10 managers, 40 regenerative tissue specialists, 20 clinical training specialists</li> </ul> </li> <li>Approved to sell in ~140 burn centers, half of which are also trauma centers</li> <li>~100 additional trauma centers are currently in the value analysis committee process</li> <li>Total market opportunity of ~435,000 annual procedures: <ul> <li>~400,000 annual FTSD eligible procedures</li> <li>~35,000 annual burn eligible procedures</li> </ul> </li> </ul>
	Accelerated Commercial Revenue Growth: significant growth rates over last four quarters: <b>40%</b> in Q1, <b>42%</b> in Q2, <b>51%</b> in Q3, and estimated <b>50%</b> in Q4 over the same periods in 2022
	<ul> <li>Portfolio Expansion:</li> <li>Recently announced a distribution agreement with Stedical Scientific; AVITA Medical will serve as the exclusive distributor of PermeaDerm in the U.S.</li> </ul>

## **RECELL Platform. Multiple Indications.**



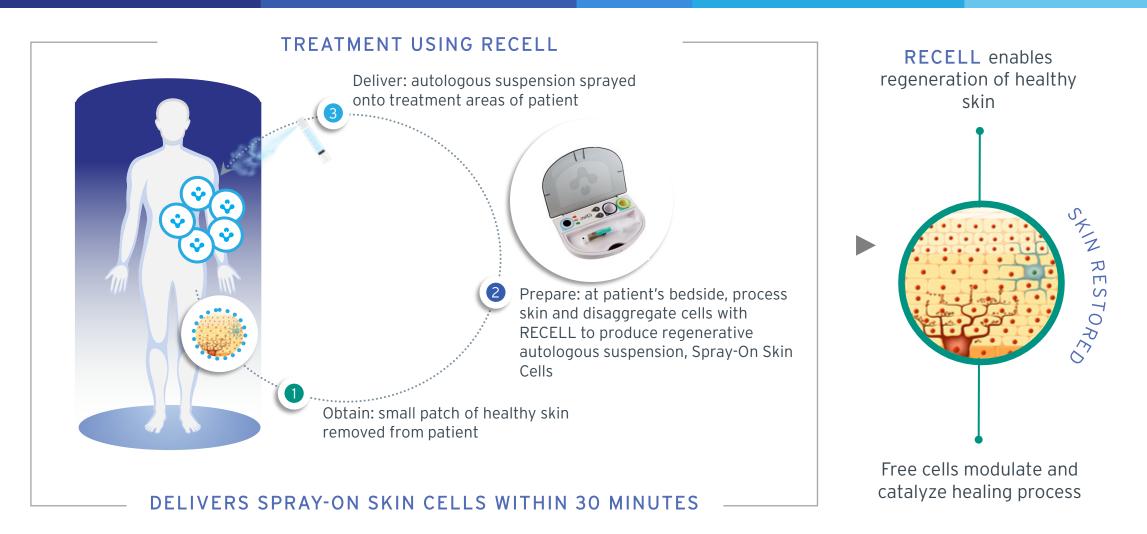


\* Maintains Breakthrough Device designation by the FDA.

## Technology Overview

## What is RECELL?

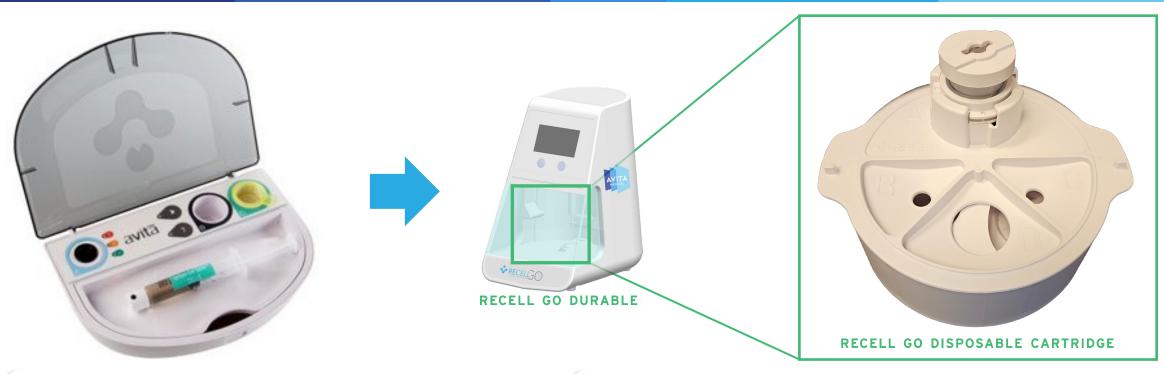




In the U.S., RECELL is approved for thermal burn wounds and full-thickness skin defects, and for repigmentation of stable depigmented vitiligo lesions. Use of RECELL in other indications is either (1) limited by United States law to investigational use; or (2) otherwise prohibited.

## **RECELL Device Evolution**





### FIRST GENERATION DEVICE

- Fewer steps and streamlined workflow, allowing for faster set up
- Reduces time of procedure

### RECELL GO DEVICE

- More controlled cell disaggregation and filtration
- Simple user interface with timer count-down
- Reusable base unit plus single-use sterile cartridge

## Commercial Overview

## RECELL: Full-Thickness Skin Defect Launch

## AVITA MEDICAL

### FTSD UTILIZES IN-PATIENT REIMBURSEMENT:

• Same DRG code as burns; effective immediately

### FTSD UTILIZES OUT-PATIENT TRANSITIONAL PASS-THROUGH CODE (TPTC):

• Same code as burns; effective immediately

### **50% OF THE ~150 BURN CENTERS ARE ALSO TRAUMA CENTERS**

Immediate access to expanded label upon approval

### APPROXIMATELY 30% OF BURNS ARE TREATED OUTSIDE OF BURN CENTERS WITHIN TRAUMA CENTERS

- Expansion into these trauma centers allows sales force to capture remaining portion of burn market
- Value Analysis Committee discussions in trauma centers started in June 2023

### SAME SALES FORCE

- In Q2 2023, expanded commercial organization from 30 to 70, ahead of launch of FTSD
- First half of 2024, plan to expand commercial organization from 70 to 100

### GROWTH

- Synergies enhanced commercial launch of FTSD on June 8, 2023
- AVITA Medical growth over the next three to five years fueled by FTSD and burns in the United States and internationally



### FULL-THICKNESS SKIN DEFECTS INDICATION MEANINGFULLY BROADENS BUSINESS

Sales Team Will Target 800+ Trauma Centers & Burn Centers



Total eligible procedures at targeted call points: 435,000+

## RECELL: Market Sizing for Burn and Full-Thickness Skin Defects



Market Size Prior to FDA Appro	val <sup>1</sup>		Additional Market Opportunity with FDA Approved Expanded Indication of FTSD <sup>1</sup>			
Traumatic Wounds • Degloving (Open Wounds) • Crush • Abrasion • Laceration • Puncture	99,000 2,000 5,000 10,000 2,000	<b>Traumatic Wounds</b> • Gun Shot Wounds • Traumatic Hematoma	1,500 2,500	<ul> <li>Surgical Wounds</li> <li>Laparotomy</li> <li>Abdominoplasty Dehiscenc</li> <li>Hidradenitis Suppurativa</li> </ul>	1,000 e 1,000 1,500	
		Surgical Excision - Canc	er	Chronic Wounds		
<ul> <li>Surgical Wounds</li> <li>Necrotizing Fasciitis</li> <li>Amputation</li> <li>Fasciotomy</li> </ul>	2,000 6,000 1,000	Cancer Excision	136,000	<ul> <li>DFU</li> <li>VLU</li> <li>Non - Pressure Ulcers</li> <li>Pressure Ulcers</li> </ul>	21,000 42,000 51,000 14,000	

#### ~127,000 Annual Eligible Procedures

### > 271,500 Annual Eligible Procedures

Total market opportunity of traumatic, surgical, cancer excision & chronic wounds ~400,000 annual FTSD eligible procedures PLUS ~35,000 annual burn eligible procedures

## Global Commercialization Strategy for RECELL

## AVITA MEDICAL

### FOCUSED MARKET

- Australia
- European Union
- Japan

### STRATEGY

• Plan to expand exclusively through third-party distribution partners

## UPDATE

- In October 2023, engaged first European distribution partner, PolyMedics Innovations, to lead expansion into Germany, Austria, and Switzerland
- Plan to actively identify new distribution partners in focused markets over next 6 to 12 months



On January 10, 2024, AVITA Medical signed distribution agreement with Stedical Scientific to commercialize PermeaDerm<sup>®</sup> Biosynthetic Wound Matrix

### PERMEADERM OVERVIEW

- Biosynthetic wound dressing applied for the treatment and healing of a variety of wounds until healing is achieved
- Technology facilitates healing and provides high level of permeability and biocompatibility, allowing healthcare providers the ability to customize the dressing

### MARKET

• United States

### SALES FORCE

• Same sales force as RECELL

### **KEY TERMS**

- AVITA Medical is the exclusive distributor of PermeaDerm in the U.S.
- Pricing: expect gross margin from sale of PermeaDerm to be 50% of the average sales price
- Term: 5 years, with option to renew for an additional 5 years

## Long-term Horizon: Vitiligo Opportunity



#### RECEIVED FDA APPROVAL IN JUNE 2023, WITH STUDY RESULTS:

- Primary endpoint: proportion of study sites achieving ≥80% repigmentation for RECELL-treated sites vs control at week 24
- Super-superiority was established for the primary endpoint (p<0.025)



## RECELL INDICATION REPRESENTS FIRST-IN-CLASS REPIGMENTATION TRANSPLANTATION OF MELANOCYTES

#### PLANS FOR 2024:

- TONE achieved full enrollment with 109 patients; expect all will have completed 6-month post treatment in July 2024; seeks to evaluate repigmentation and understand impact of repigmentation on improving quality of life following treatment
- Initiating health economics study to capture longitudinal healthcare costs of vitiligo patients; expect to publish end of Q4 2024



#### REIMBURSEMENT TIMING

- Focus will be on commercial payors; decisions determined by geography
- Begin commercial payor coverage discussions in Q2 2025
- Initial phase of coverage expected Q4 2025

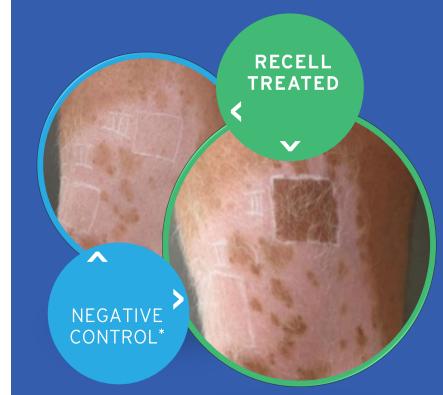


## MARKET GREATER THAN BURNS AND FULL-THICKNESS SKIN DEFECTS, COMBINED

• Vitiligo opens significant market application of RECELL

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Patient from a prior study at six-months RECELL-treated area was 100% repigmented



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.

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



## Average Selling Price

### FDA APPROVED DEVICES

- 1920: \$6,500
- RECELL Ease of Use: \$6,500

### **PENDING FDA APPROVAL**

- RECELL GO:
  - Durable device: to provide at no cost

RECELGO

**RECELL GO DURABLE** 

• Disposable cartridge: \$6,500

RECELL GO DISPOSABLE CARTRIDGE





## **Financial Update**



### **2023 PRELIMINARY FINANCIAL HIGHLIGHTS**

Commercial revenue, excluding BARDA revenue:

- Q4 2023: ~\$14.1 million; increase of ~50% compared to same period in 2022
- 2023: ~\$49.8 million; increase of ~46% compared to full-year 2022

### Gross profit margin:

• 2023: ~84.5%

#### Cash and cash equivalents:

• As of December 31, 2023: approximately \$89.1 million

#### **2024 FINANCIAL GUIDANCE**

Commercial revenue:

- Q1 2024: \$14.8 \$15.6 million; lower bound of ~42% and upper bound of ~50% over same period in 2023
- 2024: \$78.5 \$84.5 million; lower bound of ~57% and upper bound of ~69%

#### DEBT FINANCING FACILITY

- In October, secured debt financing facility for up to \$90 million; \$40 million was borrowed at closing
- Sufficient capital to meet goals and reach profitability during 2025
- Two \$25 million tranches available at our option

## Financial Overview



	Full-Year Ended	Three-Months Ended		
(USD in \$000s)	2022	Mar 31, 2023	Jun 30, 2023	Sep 30, 2023
Commercial Sales	\$34,051	\$10,458	\$11,686	\$13,547
Deferred Commercial Revenue	-	-	-	8
BARDA Service Revenue	\$370	\$92	\$67	\$90
Total Revenue	\$34,421	\$10,550	\$11,753	\$13,645
Gross Profit	\$28,380	\$8,883	\$9,549	\$11,532
Gross Profit Margin	82.4%	84.2%	81.2%	84.5%
Commercial Revenue Growth Rate % <sup>1</sup>	36%	40%	42%	51%
Cash, Cash Equivalents & Marketable Securities	\$86,272	\$77,640	\$68,801	\$60,118
Shares outstanding	25,208,436	25,327,761	25,447,615	25,550,694

#### STRONG COMMERCIAL GROWTH



<ul> <li>Ryan Zimmerman, BTIG (U.S.)</li> <li>Ross Osborn, Cantor (U.S.)</li> <li>Josh Jennings, Cowen (U.S.)</li> <li>Matt O'Brien, Piper (U.S.)</li> </ul>	<ul> <li>Brooks O'Neil, Lake Street (U.S.)</li> <li>John Hester, Bell Potter (AUS)</li> <li>Lyanne Harrison, BofA Global Research (AUS)</li> </ul>	<ul> <li>Scott Power, Morgans (AUS)</li> <li>Chris Kallos, MST (AUS)</li> <li>Shane Storey, Wilsons (AUS)</li> </ul>	NASDAQ RCEL	ASX AVH

(1) Compared to the same period of the prior year.

## Summary

## 2023: A Year of Inflection



#### BURNS

- Core burn centers will continue to penetrate, adopt, and grow
- Utilization to expand as sales force captures remaining 30% of market sitting outside of burn centers



#### FULL-THICKNESS SKIN DEFECTS

- Reimbursement started DAY 1 using same codes and reimbursement as burns
- Represents ~10x expansion of burn center opportunity

#### **RECELL GO**

- Evolutionary design of existing RECELL technology designed to control cell disaggregation process; eases training burden and reduces variability
- Critical component of platform that will accelerate our growth
- Expecting FDA approval on May 30, 2024

#### OUTLOOK OVER NEXT 3 TO 5 YEARS IN U.S.

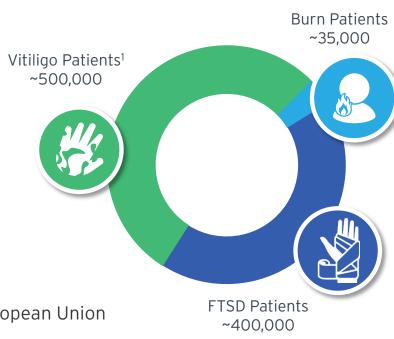
- Growth driven by burns and full-thickness skin defects
- RECELL GO expected to increase adoption rates across our indications
- Plan to actively identify new distribution partnerships in Australia, Japan, and European Union over next 6 to 12 months
- Product portfolio expansion

#### VITILIGO

- FDA approval in June 2023; expect to come to market in 2025
- Conducting post-market study and health economics study to support commercial payor coverage

(1) Approximately 500,000 patients with vitiligo sought treatment in 2022.

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**U.S. MARKET FOR RECELL** 

FTSD and vitiligo greatly expand opportunity



## Looking Ahead: Topics for Next Earnings Call in February 2024





#### PROFITABILITY

• Guidance on the quarter in 2025 in which we have positive cash flow and become profitable



#### COMMERCIAL EXPANSION

• Provide detail on sales force expansion to support growth



### RECELL GO

- Confirm timing of response to FDA's questions
- Expected date of FDA approval



#### PRODUCT PORTFOLIO EXPANSION

• Update on PermeaDerm timeline



Transforming lives.