



NASDAQ: RCEL

ASX: AVH

# Accelerating Our Growth Profile

Investor Presentation  
Third Quarter 2023



# 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 quarter 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



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



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



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



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



**Boston Scientific**

**Baxter**

**Alphatec Spine®**

**Vertos**  
MEDICAL

**CATHWORKS**



**Johnson & Johnson**



**EMERGENT™**



\* Denotes executive officer.

# Investment Overview



Commercial-stage company focused on regenerative medicine to transform the standard of care for skin restoration with innovative cellular technology platform, the RECELL® System



Current U.S. FDA-Approved Indications:

- Thermal burn wounds and full-thickness skin defects (“FTSD”)
- Repigmentation of stable depigmented vitiligo lesions



Commercialization:

- 40 sales territories supported by a salesforce of 70:
  - 40 regenerative tissue specialists
  - 20 clinical training specialists
  - 10 managers
- Approved to sell in ~140 burn centers, half of which are also trauma centers
- Near-term target of 100 additional trauma centers
- Total market opportunity of ~435,000 annual procedures:
  - ~400,000 annual FTSD eligible procedures
  - ~35,000 annual burn eligible procedures



Accelerated Commercial Revenue Growth: significant commercial revenue growth rates over last three quarters: **40%** in Q1, **42%** in Q2, and **51%** in Q3, over the same period the prior year

# One Platform. Multiple Indications.

Approved U.S. INDICATIONS	2022	2023	2024	2025
BURNS	Outpatient Code			
	Ease of Use Device			
	Japan: Approval, Reimbursement, Launch	RECELL GO Device Submission: June 30	Expect RECELL GO FDA Approval*: May 30	
FULL-THICKNESS SKIN DEFECTS			Expect RECELL GO Device Launch*: May 31	
	PMA Supplement Submission: December	FDA Approval: June 7		
		Launch: June 8		
VITILIGO		FDA Approval: June 16		Initiate Commercial Payor Reimbursement Discussions
	PMA Submission: December	Initiate Health Economics Study: Q4	Expect to Publish Studies by Q4	Expect Rolling Commercial Payor Coverage

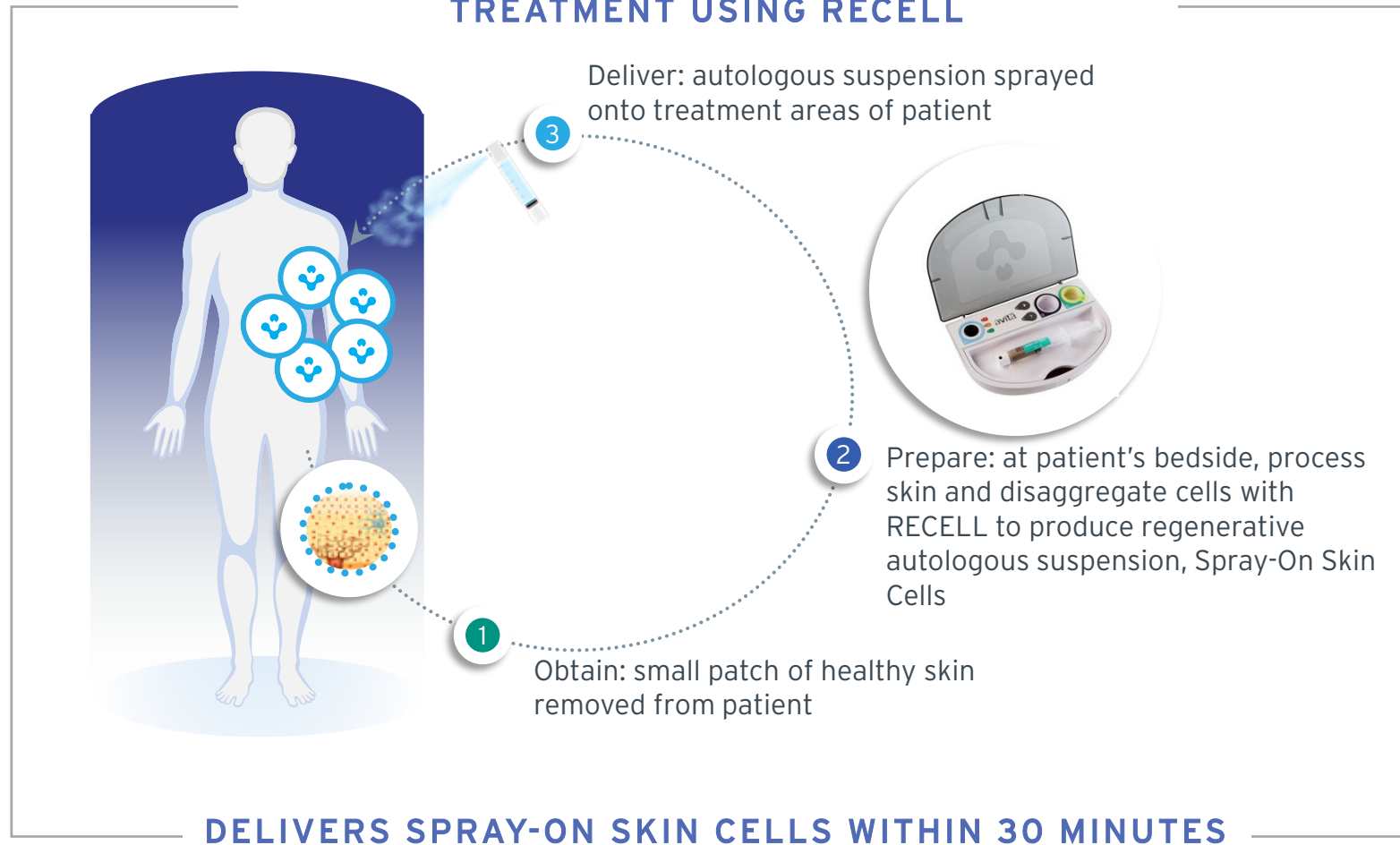
\* Maintains Breakthrough Device designation by the FDA.

# Technology Overview

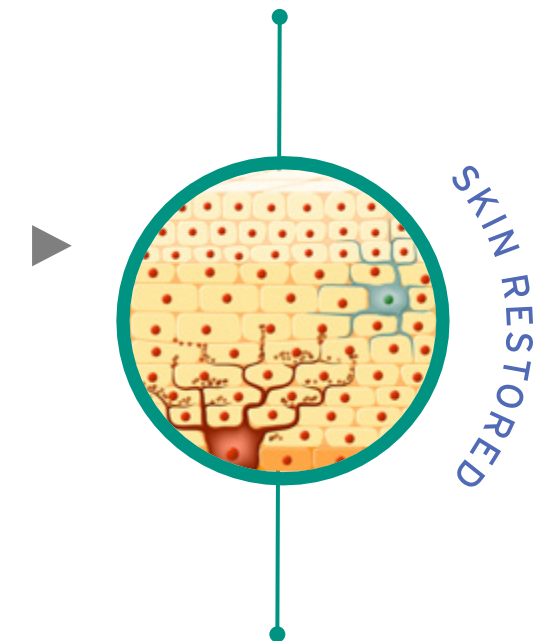


# What is RECELL?

## TREATMENT USING RECELL



**RECELL** enables regeneration of healthy skin



Free cells modulate and catalyze healing process

# RECELL Device Evolution

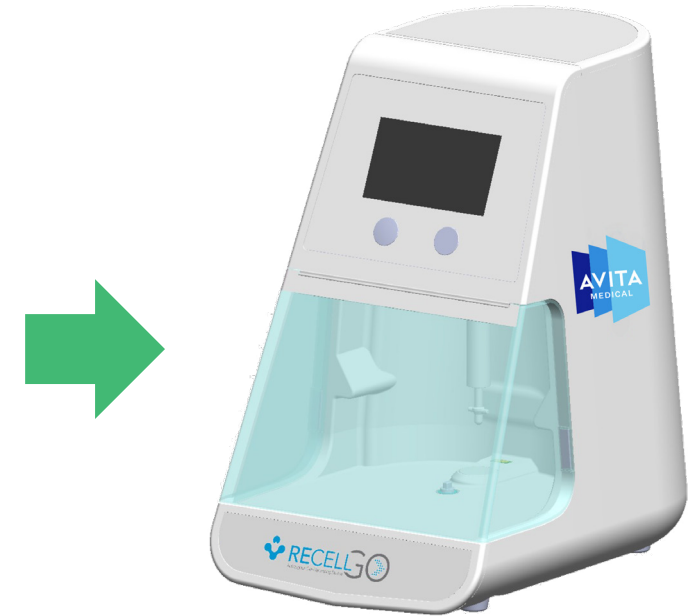


## FIRST GENERATION DEVICE



## EASE OF USE 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

# Burns & Full-Thickness Skin Defects



## FDA APPROVALS

- Burns: September 20, 2018
- FTSD: June 7, 2023



## U.S. LAUNCH

- Burns: January 2019
- FTSD: immediately following approval on June 8, 2023, with expanded commercial team



## MARKET UPDATE

- Burns: core burn centers continue to penetrate, adopt, and grow
- FTSD: near-term target of 100+ trauma centers; meaningfully broadens wound healing business with its expanded label



## OUTLOOK

- Burns and FTSD will drive growth over the next 3+ years

Female, pregnant 28-year-old who suffered from a degloving injury



^  
POST  
DEBRIDEMENT  
OF INJURY



^  
6 MONTH POST-  
RECELL  
TREATMENT

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.

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

# Burn and Full-Thickness Skin Defects: Market Sizing

Market Size Prior to FDA Approval <sup>1</sup>		Additional Market Opportunity with FDA Approved Expanded Indication of FTSD <sup>1</sup>			
<b>Traumatic Wounds</b>		<b>Traumatic Wounds</b>		<b>Surgical Wounds</b>	
• Degloving (Open Wounds)	99,000	• Gun Shot Wounds	1,500	• Laparotomy	1,000
• Crush	2,000	• Traumatic Hematoma	2,500	• Abdominoplasty Dehiscence	1,000
• Abrasion	5,000			• Hidradenitis Suppurativa	1,500
• Laceration	10,000				
• Puncture	2,000				
<b>Surgical Wounds</b>		<b>Surgical Excision - Cancer</b>		<b>Chronic Wounds</b>	
• Necrotizing Fasciitis	2,000	• Cancer Excision	136,000	• DFU	21,000
• Amputation	6,000			• VLU	42,000
• Fasciotomy	1,000			• Non - Pressure Ulcers	51,000
				• Pressure Ulcers	14,000
<b>~127,000 Annual Eligible Procedures</b>		<b>&gt; 271,500 Annual Eligible Procedures</b>			

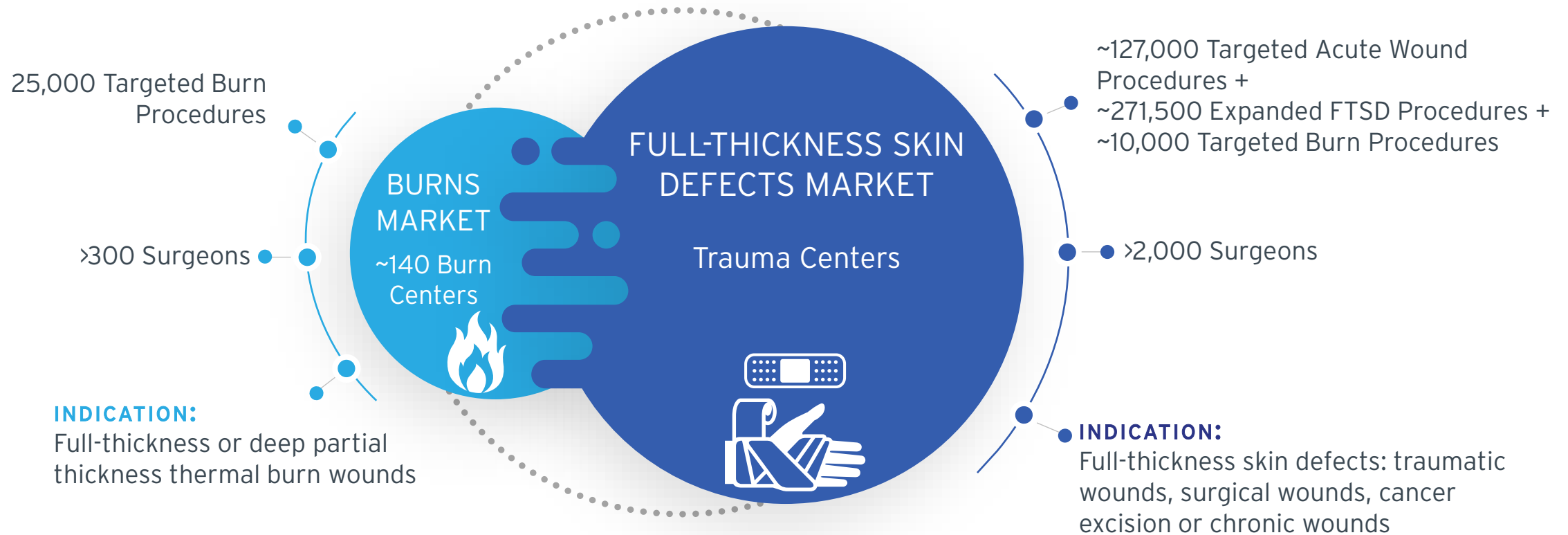
Total market opportunity of traumatic, surgical, cancer excision & chronic wounds  
 ~400,000 annual FTSD eligible procedures  
 PLUS ~35,000 annual burn eligible procedures

(1) Market size derived from third-party claims reports and internal analysis based on skin graft CPT codes tied to diagnosis code of specified wound types.

# Synergies Between Burns and Full-Thickness Skin Defects

## FULL-THICKNESS SKIN DEFECTS INDICATION MEANINGFULLY BROADENS BUSINESS

Sales Team Will Target a Total of 800 - 1000 Call Points



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

# Full-Thickness Skin Defect Launch

## **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 April 2023

## **SAME SALES FORCE**

- In Q2 2023, expanded commercial organization from 30 to 70, ahead of launch of FTSD

## **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

# Global Commercialization Strategy

## 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



# Long-term Horizon: Vitiligo Opportunity



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

- Primary endpoint: proportion of study sites achieving  $\geq 80\%$  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 2023 - 2024:

- Expect full enrollment of post-market study, TONE, February 2024; will evaluate repigmentation and measure mental quality of life following treatment
- Initiating health economics study to capture longitudinal healthcare costs of vitiligo patients; expect to publish by Q4 2024



## REIMBURSEMENT TIMING

- Focus will be on commercial payors; decisions determined by geography
- Begin commercial payor coverage discussions in Q1 2025
- Initial phase of coverage expected Q3 2025

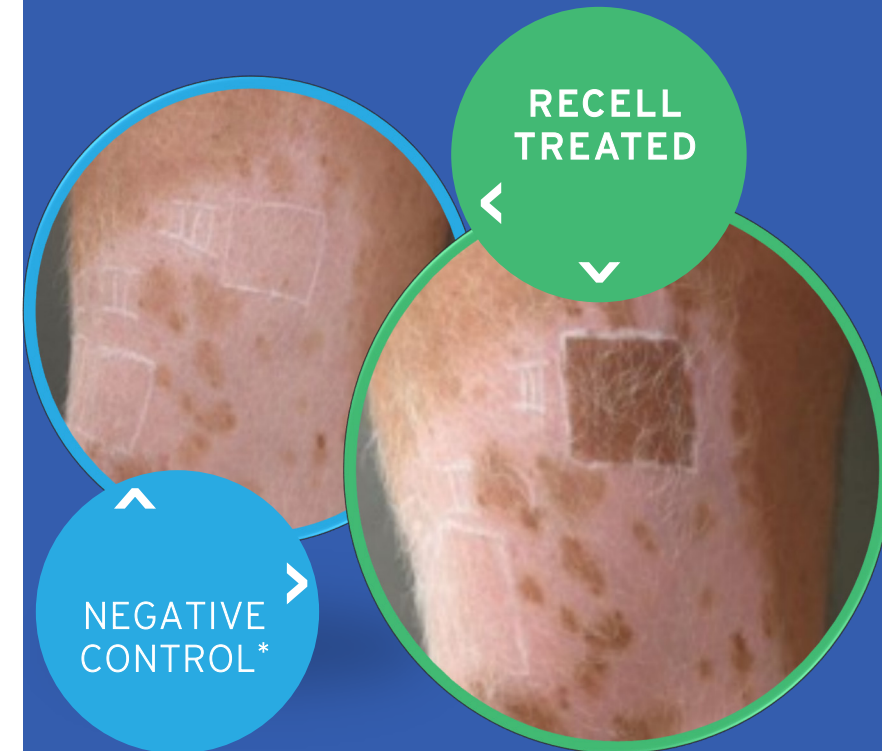


## MARKET GREATER THAN BURNS AND FULL-THICKNESS SKIN DEFECTS, COMBINED

- 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.

# Financials



# Average Selling Price

## FDA APPROVED DEVICES

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

## PENDING FDA APPROVAL

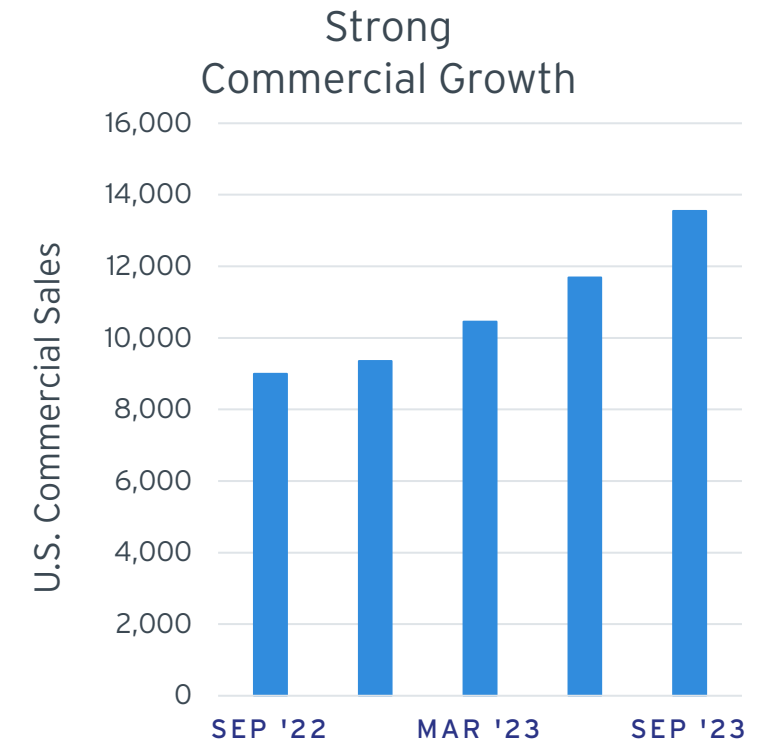
- RECELL GO:
  - Durable device: loan at no cost
  - Disposable cartridge: \$6,500



# Financial Overview



(USD in \$000s)	Full-Year Ended	Three-Months Ended		
	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
<b>Total Revenue</b>	<b>\$34,421</b>	<b>\$10,550</b>	<b>\$11,753</b>	<b>\$13,645</b>
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



## ANALYSTS

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

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

# Financial Update

## 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 GUIDANCE

### Commercial revenue, excluding BARDA revenue:

- Q4 2023: \$13.8 - \$14.8 million; lower bound of 47% and upper bound of 57%
- 2023: \$49.5 - \$50.5 million; lower bound of 45% and upper bound of 48%

### Gross profit margin:

- 2023: 83% to 85%

# 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.

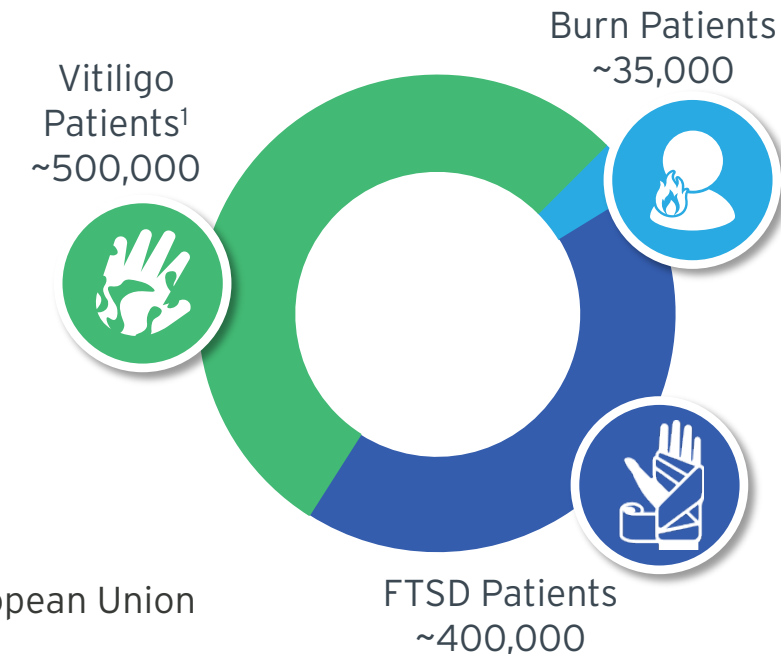
- Growth driven by burns and full-thickness skin defects
- RECELL GO expected to increase adoption rates across our indications
- Plan to actively identify new distribution partnerships in Australia, Japan, and European Union over next 6 to 12 months



## 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

## U.S. Market FTSD AND VITILIGO GREATLY EXPAND OPPORTUNITY



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

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



## COMMERCIAL REVENUE GUIDANCE

- Full year 2024, including Q1 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 the FTSD market growth



## RECELL GO

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



## VITILIGO

- Update on TONE study timeline

*Transforming lives.*