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): February 28, 2023

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; Item 8.01 Other Events.

On February 28, 2023, AVITA Medical, Inc. (the "Company"), held a webinar briefing and presentation for shareholders and prospective investors. Jim Corbett, CEO, and Sean Ekins, acting CFO, presented the webinar, which covered highlights from the Company's recent Fourth Quarter 2022 Earnings Conference Call, and concluded with Q&A. Webcasts of both events are available on the Company's website under Investor Events and Presentations. A slide deck presented during the webinar is attached hereto as Exhibit 99.1.

The information under Item 7.01, Item 8.01, and Exhibit 99.1, 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

Exhibit No.	Description of Exhibit
99.1	Investor Presentation
104	Cover page Interactive Data File (embedded within 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: March 2, 2023

AVITA MEDICAL, INC.

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

Exhibit 99.1

One Platform.
Multiple Indications.

Accelerating Our Growth Profile

Q4 2022 Investor Presentation

NASDAQ: RCEL ASX: AVH

©Copyright 2023 AVITA Medical. All Rights Reserve

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 Annual Report on Form 10-K for the year ended December 31, 2022. 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).

Who is AVITA Medical?

Regenerative medicine company transforming the standard of care for skin restoration with its innovative cellular technology platform, the **RECELL® System**

RECELL System includes autologous cell harvesting device that prepares, produces, and delivers regenerative cellular suspension, **Spray-On Skin™ Cells**, within 30 minutes at the point of care.

Spray-On Skin Cells contain cells necessary to regenerate patient's outer layer of natural, healthy skin as well as cells that modulate and **catalyze healing process**

Current U.S. indication: acute thermal burns

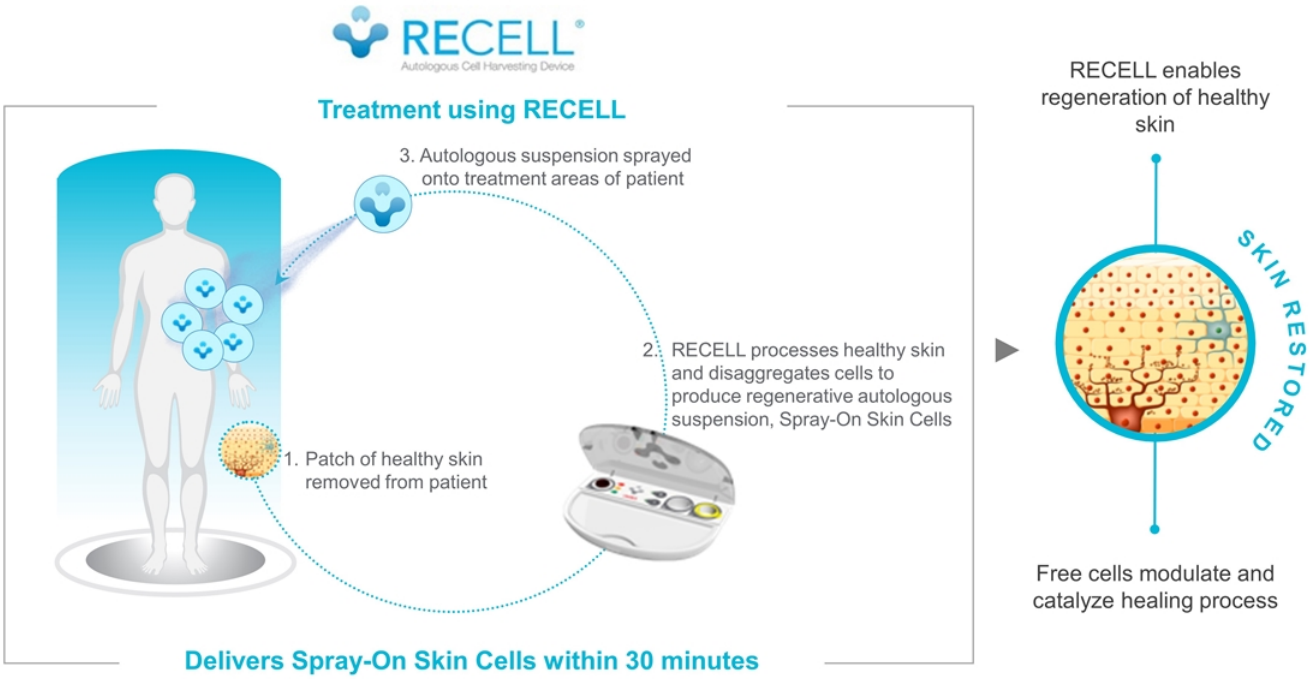
Pending U.S. indications: PMA supplement for soft tissue repair, PMA application for vitiligo

Core advantages:

- Utilizes small skin sample from patient; significantly less skin relative to conventional skin graft treatment
- Suspension created at patient's beside within 30 minutes, further supports healing at the cellular level
- Multi-cell regenerative therapy in single point-of-care procedure, reducing hospital length of stay

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.

What is RECELL?



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.

One Platform. Multiple Indications.

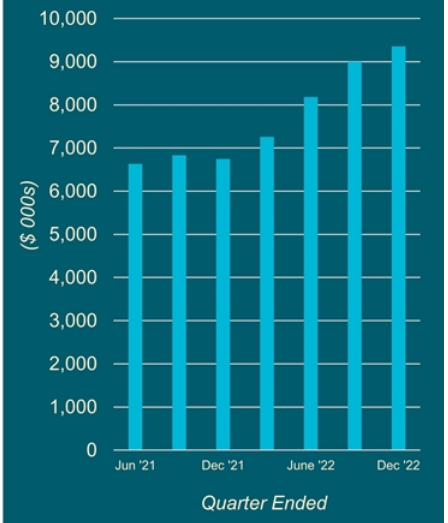
U.S. INDICATION	2022	2023	2024	2025
BURNS (Approved)	Outpatient Code Ease of Use Device Japan: Approval, Reimbursement, Launch			
SOFT TISSUE (Expected July 2023)	PMA Supplement Submission: December	Automated Device Submission: Q2 FDA Approval: June Launch: July 1	Automated Device Approval: Q1	
VITILIGO (Expected July 2023)	PMA Submission: December	FDA Approval: June Pilot Launch: July 1		RECELL In-Office Reimbursement: January Launch: January

Year in Review: Continued Growth and Expansion

2022 Accomplishments

- Commercial Revenue Growth:
  - Fourth quarter 2022: 37% same quarter prior year
- New RECELL Device:
  - FDA approval and launch of new “Ease of Use” device
- Japan:
  - PMDA approval of Burns; favorable reimbursement; initial stocking order in Q3
- Soft Tissue Repair:
  - Topline results from pivotal trial: met both co-primary endpoints of statistically superior donor skin sparing and statistically non-inferior healing rates
  - Received FDA Breakthrough Device Designation
  - Submitted PMA supplement
- Vitiligo:
  - Topline results from pivotal trial: achieved primary effectiveness endpoint of super-superior response rate
  - Received FDA Breakthrough Device Designation
  - Submitted PMA application

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



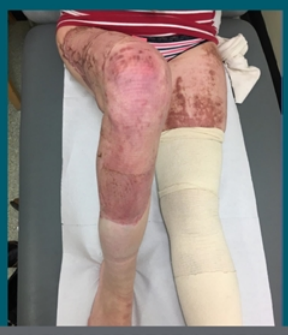
Soft Tissue Repair Opportunity

- Submitted PMA Supplement in December 2022
- Expect FDA approval in June 2023
- Following approval, launching July 2023
- Significant synergies between Burns and Soft Tissue Repair; drives growth over the next 3+ years

Soft Tissue Repair expands business to encompass all acute wounds

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

POST DEBRIDEMENT OF INJURY



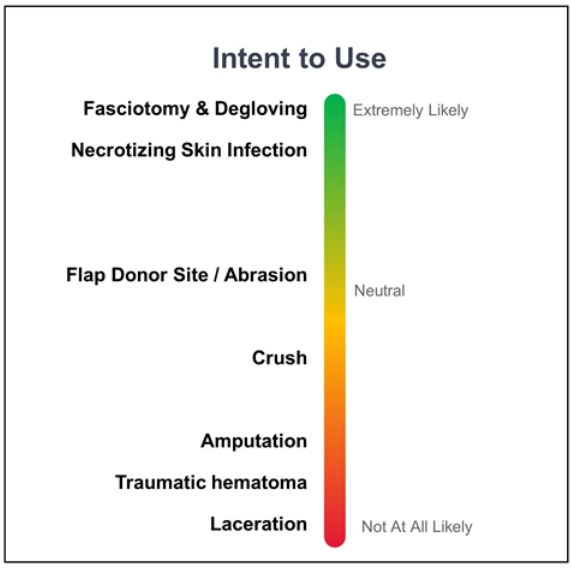
6 MONTH POST-RECELL TREATMENT

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

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.

1. 2017 centers for disease control. Open wounds category summary. https://www.cdc.gov/nchs/data/nhamcs/web_tables/2017_ed_web_tables-508.pdf
2. RECELL eligible calculated using annual unique skin graft patients for trauma wounds per Definitive Healthcare/ .33 (% of time skin grafts used per market research. Includes most ideal wounds (degloving, fasciotomy, skin infection, abrasion, crush) plus lacerations and amputations)

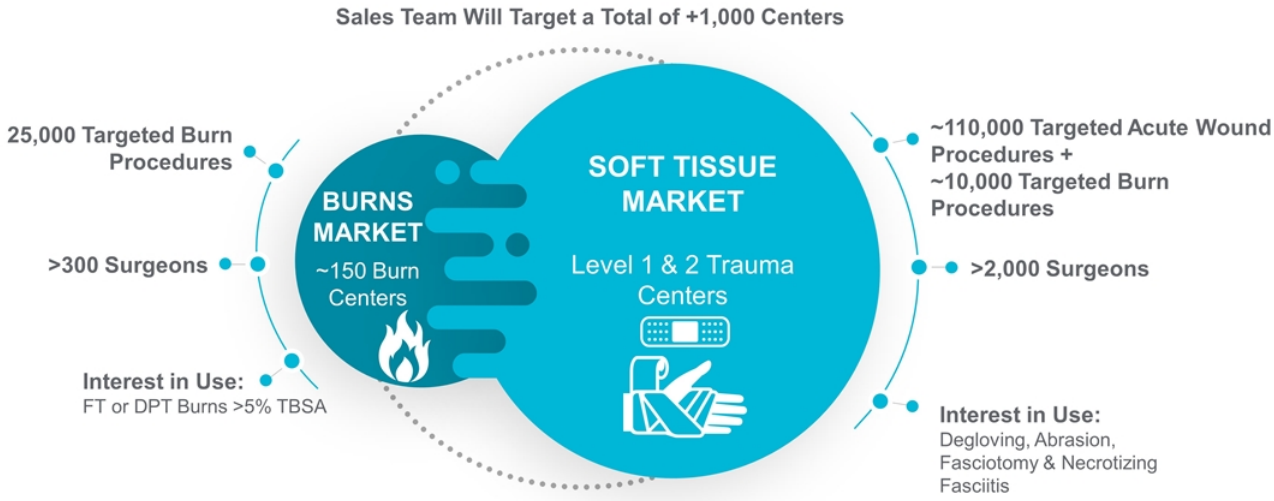
RECELL's Perceived Advantages Vary Depending on Wound Type



Unlike with Burns, most surgeons would consider RECELL for small wounds

Overlap of Burns and Soft Tissue Repair

Existing Burns Market Broadened by Soft Tissue Repair



Eligible procedures at targeted call points: 145,000+

Synergies of Burns and Soft Tissue Repair

- Soft Tissue Repair in-patient reimbursement: same DRG code as Burns; *effective immediately* upon FDA approval
- Soft Tissue Repair out-patient transitional pass-through code (TPTC): same code as Burns; *effective immediately* upon FDA approval
- Of ~150 burn centers, 50% are also either level 1 or level 2 trauma centers; *immediate access* to expanded label upon approval
- Approximately 30% of Burns are treated outside of burn centers within level 1 or level 2 trauma centers; thus, expansion into these trauma centers *allows sales force to capture remaining portion of burn market*
- In April 2023, existing sales force to start Value Analysis Committee discussions in level 1 and level 2 trauma centers
- *Expanding sales force during Q2 2023* ahead of July 1 launch of Soft Tissue Repair
- AVITA Medical growth over the next three to five years fueled by Soft Tissue Repair and Burns

Synergies enhance commercial launch of Soft Tissue Repair in July 2023

Vitiligo Opportunity

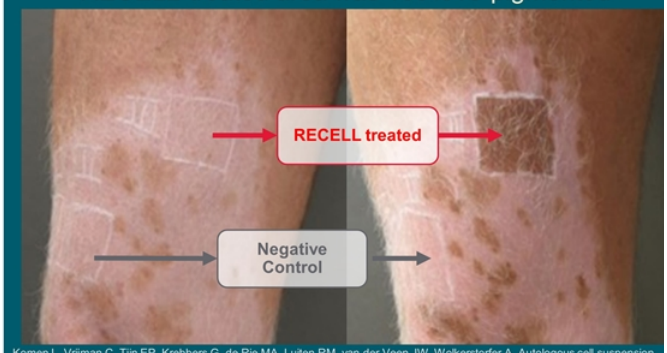
- Submitted PMA application in December 2022 with study results:
  - Primary endpoint: proportion of study sites achieving ≥80% re-pigmentation for RECELL-treated sites vs Control at Week 24
  - Super-superiority was established for the primary endpoint ($p<0.025$)
- Expect FDA approval in June 2023
- Proposed RECELL indication represents first-in-class re-pigmentation transplantation of melanocytes
- Plans for 2023 – 2024:
  - Build podium presence
  - MD initiated research to refine patient selection
- Vitiligo market five times the size of combined Burns and Soft Tissue Repair
- Vitiligo opens significant market application of RECELL
- Site of service reimbursement for RECELL in office expected Jan 2025

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.

avita

First-in-class re-pigmentation transplantation of melanocytes

Patient from a prior study at six-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.

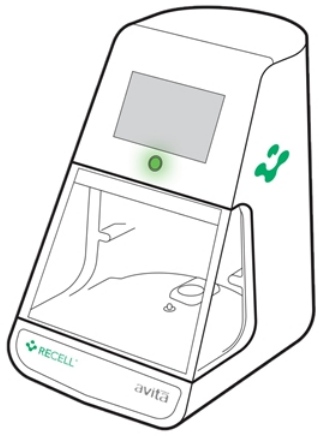
RECELL treatment against "control" unmatched at six months

*NB-UVB protocol per Vitiligo Working Group recommendations JAAD 2017.
In the United States, RECELL is not approved for treatment of vitiligo.

Growth Enabler: Automated Device for All Indications

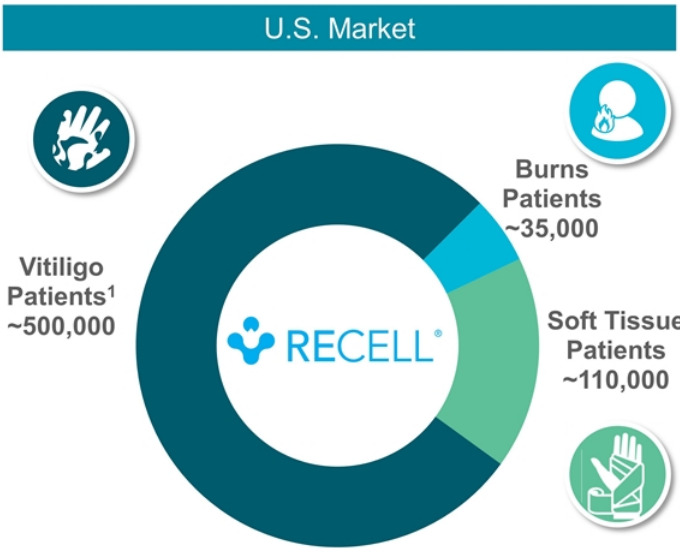
KEY UPDATES

- New RECELL Automated Device in development for Soft Tissue Repair / Burns *(automated device for Vitiligo to follow)*:
  - FDA Submission expected in June 2023
  - FDA Approval expected by January 2024
- Protected by issued patents in the U.S. and certain other countries for automated device, which provides a further barrier to entry for potential competitors



2023: A Year of Inflection

- Expecting FDA approvals for two indications: Soft Tissue Repair and Vitiligo
- Soft Tissue Repair: launching in July 2023; ~5x market expansion will fuel revenue growth
- Vitiligo: ~5x patient population of Burns and Soft Tissue Repair, combined; pursuing site of service reimbursement for RECELL in physician setting
- International expansion strategy by end-of-year 2023



Soft Tissue Repair and Vitiligo greatly expand U.S. market opportunity

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

Financial Overview: Q4 2022

(USD in $000s)	Unaudited Three-Months Ended December 31		Unaudited 12-Months Ended December 31	
	2021	2022	2021	2022
Commercial Sales	6,843	9,363	25,091	34,051
BARDA Sales	93	92	7,934	370
Total Revenue	**6,936**	**9,455**	**33,025**	**34,421**
Gross Profit	6,119	8,108	26,921	28,380
BARDA Income	206	1,026	1,590	3,215
Cash, Cash Equivalents & Marketable Securities	104,852	86,272	104,852	86,272

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)
- John Hester, Bell Potter (AUS)
- Chris Kallos, MST (AUS)
- Shane Storey, Wilsons (AUS)

NASDAQ ticker symbol: RCEL

ASX ticker symbol: AVH

Looking Ahead

Financial Guidance

Commercial revenue, excluding BARDA revenue:

- Q1 2023: $10 - $11 million
- 2023: $49 – $51 million

Future Milestones

- Expansion of U.S. field sales organization in Q2 2023: from 30 to ~70 professionals
- Expected approval of PMA supplement for soft tissue repair indication in June 2023 followed by commercial launch on July 1, 2023
- Expected approval of PMA application for vitiligo indication in June 2023
- Anticipate FDA submission of automation program by June 30, 2023

Summary

Burns
- Core Burn centers will continue to penetrate, adopt and grow
- Burns utilization will expand, accessing ~30% of market not currently called on by AVITA Medical Burns sales team
- Strong healthcare economics drive in-patient adoption; TPTC broadens coverage

Soft Tissue Repair
- Represents ~5x expansion of Burn Center market opportunity in level 1 and level 2 trauma centers
- Reimbursement starts DAY 1 using same codes and reimbursement as Burns

Vitiligo
- Represents ~5x patient population of Burns and Soft Tissue Repair, combined
- Opens significant market application of RECELL
- Pursuing site of service reimbursement for RECELL within the physician setting, expected January 2025

Outlook over next 3 to 5 years in U.S.
- AVITA Medical growth driven by Burns and Soft Tissue Repair
- Vitiligo comes to market adoption in 2025
- International expansion plans by end-of-year 2023

Near-term growth driven by Burns and Soft Tissue Repair market expansion

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.

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.