# 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): September 20, 2022**

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

| Delaware | 001-39059 | 85-1021707 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| 28159 Avenue Stanford, Suite 220, Valencia, CA 91355 | 661.367.9170 |
|---|---|
| (Address of principal executive offices, including Zip Code) | (Registrant's telephone number, including area code) |

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

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

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

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

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

**Item 7.01 Reg Fd Disclosure; Item 8.01. Other Events.**

On September 20, 2022, AVITA Medical, Inc. (the "Company") hosted an Investor Webinar and Presentation led by Dr. Mike Perry, the Company's CEO, and Michael Holder, the Company's CFO at 3:30pm PDT (being September 21, 2022 at 8:30am AEST). A recording of the Investor Webinar as well as a copy of the slides used in the presentation may be found at the Investors page of the Company's website at www.avitamedical.com. A copy of the slide deck is attached hereto as Exhibit 99.1.

The information under Item 7.01 and in Item 9.01 below is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 and shall not be deemed incorporated by reference into any filing made under the Securities Act of 1933 except as expressly set forth by a specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Investor Webinar Briefing Presentation |
| 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: September 22, 2022

**AVITA MEDICAL, INC.**

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

Exhibit 99.1

# One Platform.
# Endless Possibilities.


Investor Webinar Briefing
September 20, 2022 (U.S.) /
September 21, 2022 (AU)

NASDAQ: RCEL ASX: AVH

# Legal Disclaimers

Certain statements in this presentation and the accompanying oral commentary are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this presentation, including statements regarding our future financial condition, technology platform, development strategy, prospective products, pipeline and milestones, regulatory objectives, expected payments from and outcomes of collaborations, and likelihood of success, are forward-looking statements. Such statements are predictions only and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, among others, the costs, timing and results of clinical trials and other development activities; the uncertainties inherent in the initiation and enrollment of clinical trials; the uncertainties associated with the COVID-19 pandemic; the unpredictability of the timing and results of regulatory submissions and reviews; market acceptance for approved products and innovative therapeutic treatments; competition; the possible impairment of, inability to obtain and costs of obtaining intellectual property rights; and possible safety or efficacy concerns, general business, financial and accounting risks and litigation. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. More information concerning AVITA Medical as well as the aforementioned risks and uncertainties is available in our public filings with the U.S. Securities and Exchange Commission, including our most recent Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, and our most recent Transition Report on Form 10-KT period from July 1, 2021 to December 31, 2021. We are providing this information as of its date and do not undertake any obligation to update or revise it, whether as a result of new information, future events or circumstances or otherwise, except as required by law. Additional information may be available in press releases or other public announcements and public filings made after the date of this presentation.

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

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

# Transforming Lives with Skin Restoration

## AVITA MEDICAL OVERVIEW

- Regenerative medicine company leading the development and commercialization of first-in-class devices and autologous cellular therapies for skin restoration
- Patented RECELL® technology, a new treatment paradigm for burn injuries
- Leveraging proven RECELL® platform to advance new indications in acute traumatic wounds and vitiligo, as well a pipeline of cell and gene therapies

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.

# Why AVITA Medical?

**Strong IP Estate**
Total of 19 granted patents, 25 pending applications, and automated devices in development with associated established IP protection

**First PMA in Burns in 20+ Years**
PMA-approved Class III* device for burn care sets precedent and creates a significant barrier to entry

**Proven Health Economic Outcomes**
Published health economic model demonstrates significant savings to patients and the health care system


**World-Class Executive Team**
Executive management team has 150+ years of experience with proven track records across medical device, biotech, and pharmaceutical companies

**Best-in-Class Field Team**
Highly experienced team averaging over 15 years of Burn Care Experience

**Robust Clinical Outcomes**
Efficacy of platform is well studied; de-risked pipeline with >15,000 patients treated globally

* FDA's designation of RECELL as a Class III device established precedent for future similar devices to require pivotal clinical data and PMA submissions for FDA approval. This is the highest level of rigor for a U.S. device approval.

# Year in Review: Continued Growth and Expansion

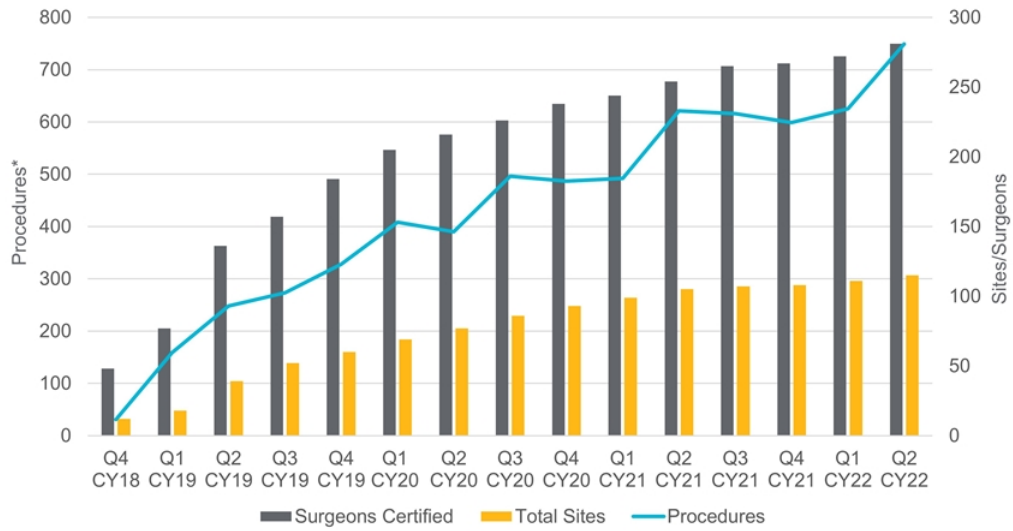
## Recent Accomplishments

- Commercial Revenue Growth:
  - Year-to-date 2022: +39% year-over-year
  - Second Quarter 2022: +23% same quarter prior year
- New “Ease of Use” RECELL Device:
  - FDA approval and launch
- Japan:
  - PMDA approval of Burns and cases completed
  - Favorable reimbursement and commercial launch in Burns
- Pivotal Trials Topline Results :
  - Acute traumatic wounds: statistically superior donor sparing and comparable healing rates
  - Vitiligo: achieved primary effectiveness endpoint of super-superior response rate

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

### Strong U.S. RECELL Commercial Growth

# Strong Adoption of RECELL Reflected in Key Leading Indicators




Accomplishments Since Approval

93% Burn Surgeons Certified

84% Burn Sites Activated

~6,5000 Procedures*

> $71 Million in U.S. RECELL Revenue Since Approval

*Data is compiled based on information voluntarily provided by our customers and is subject to change.

# New Ease of Use Device FDA Approved & Launched

**New Device**


Reduced number of steps

Simplified Process

Improved Usability

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

**Steps Reduced By 33%**

* Market Research March 2020 HCPs

# Approval of Burns and Favorable Reimbursement in Japan

## BACKGROUND

COMMERCIAL PARTNER: COSMOTEC, an M3 Company

INDICATION: Burns

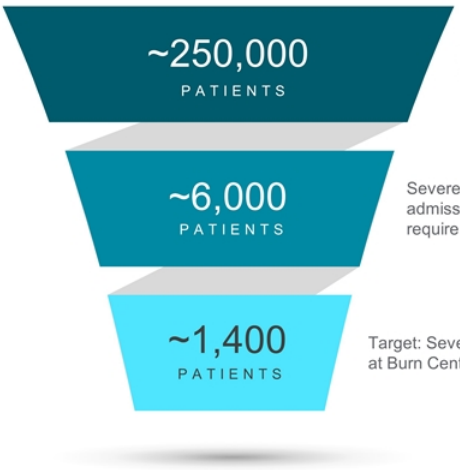
Additional Indication(s) to Follow Based on U.S. Pivotal Clinical Data

PMDA APPROVAL: Q1 2022

LAUNCHED: Q3 2022

Ministry of Health, Labour, and Welfare (MHLW) granted favorable reimbursement pricing in September 2022

## PATIENT FUNNEL - BURNS ADDRESSABLE MARKET *

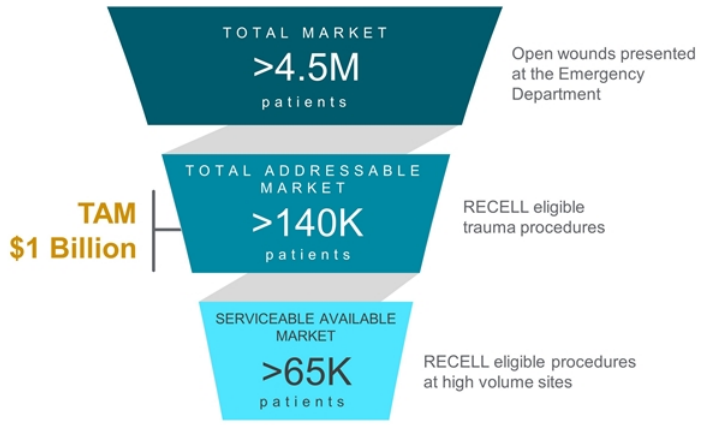



## Commercial Launch Underway

* Furue M, Yamazaki S, Jimbow K, Tsuchida T, Amagai M, Tanaka T et al. Prevalence of dermatological disorders in Japan: a nationwide, cross-sectional, seasonal, multi-center, hospital-based study. J Dermatol. 2011 April; 38(4):310-20, Japan Health System Review, 2018. Additional estimates based on data from 2016 JSBI National Burns Repository, https://injuryprevention.bmj.com/content/26/Suppl_2/i36#F2 and Cosmotec estimates

# Acute Traumatic Wound Opportunity

## OPPORTUNITY ESTIMATION




## Soft Tissue Repair Expands Burns Business to Encompass All Acute Wounds

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

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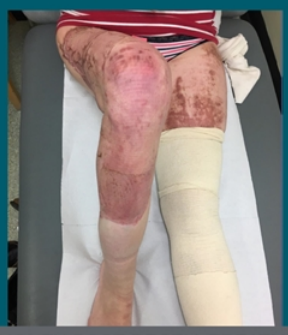
Female, pregnant 28-year-old who suffered from a de-gloving injury

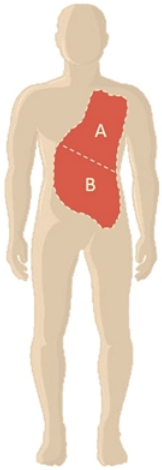
POST DEBRIDEMENT OF INJURY



6 MONTH POST-RECELL TREATMENT

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

# Acute Traumatic Wounds Indication on Track for FDA Submission




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

## Effectiveness Data

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

## Safety Data

Preliminary review of adverse events shows consistency with prior RECELL experience

**FDA Submission Expected in H2 2022 with Approval in H2 2023**

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.

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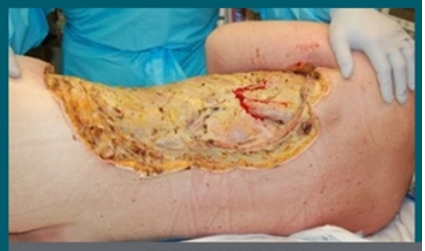
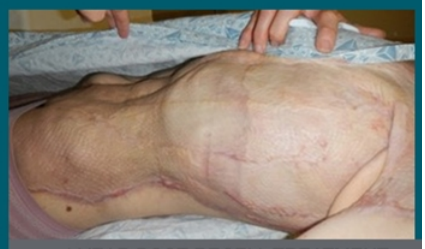
Patient treated for necrotizing fasciitis



TREATMENT DAY

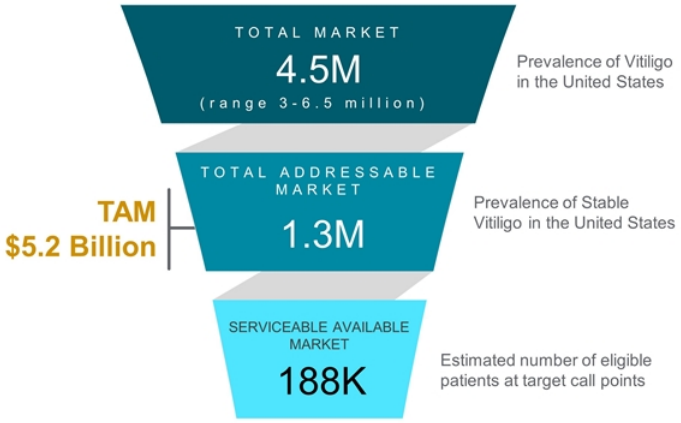


1 YEAR POST-RECELL TREATMENT

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

# Vitiligo Opportunity

## OPPORTUNITY ESTIMATION




**Targeting <1,000 procedural dermatologists and plastic surgeons who, along with patients, have extremely low satisfaction with existing products**

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.

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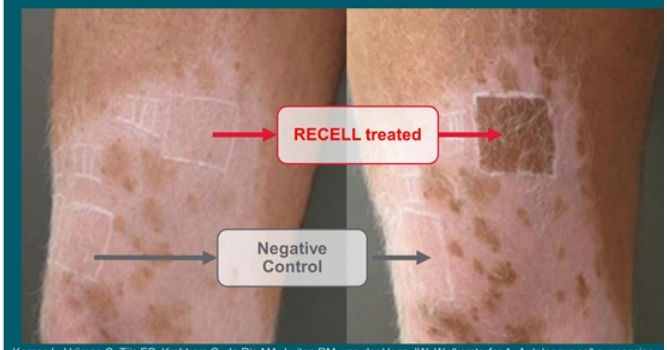
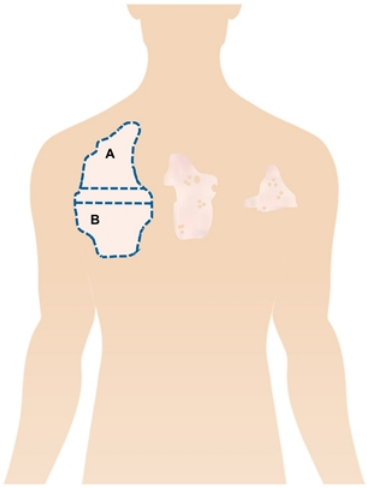
Patient from a prior study at 6 months
RECELL-treated area was 100% re-pigmented




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.

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

# Vitiligo Indication on Track for FDA Submission



Within-subject comparison

## Effectiveness Data

Study achieved its primary effectiveness endpoint of super-superiority

## Safety Data

Preliminary review of adverse events shows consistency with prior RECELL experience

**Primary Endpoint**

Proportion of study sites achieving ≥80% repigmentation for RECELL-treated sites vs Control at Week 24

**Treatment**

Laser ablation
+ RECELL® (1:20)
+ NB-UVB

**Control**

NB-UVB alone

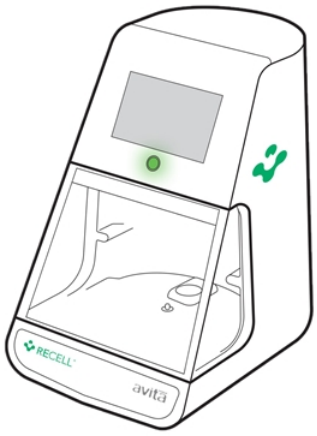
Primary Endpoint Met; FDA Submission End of 2022

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

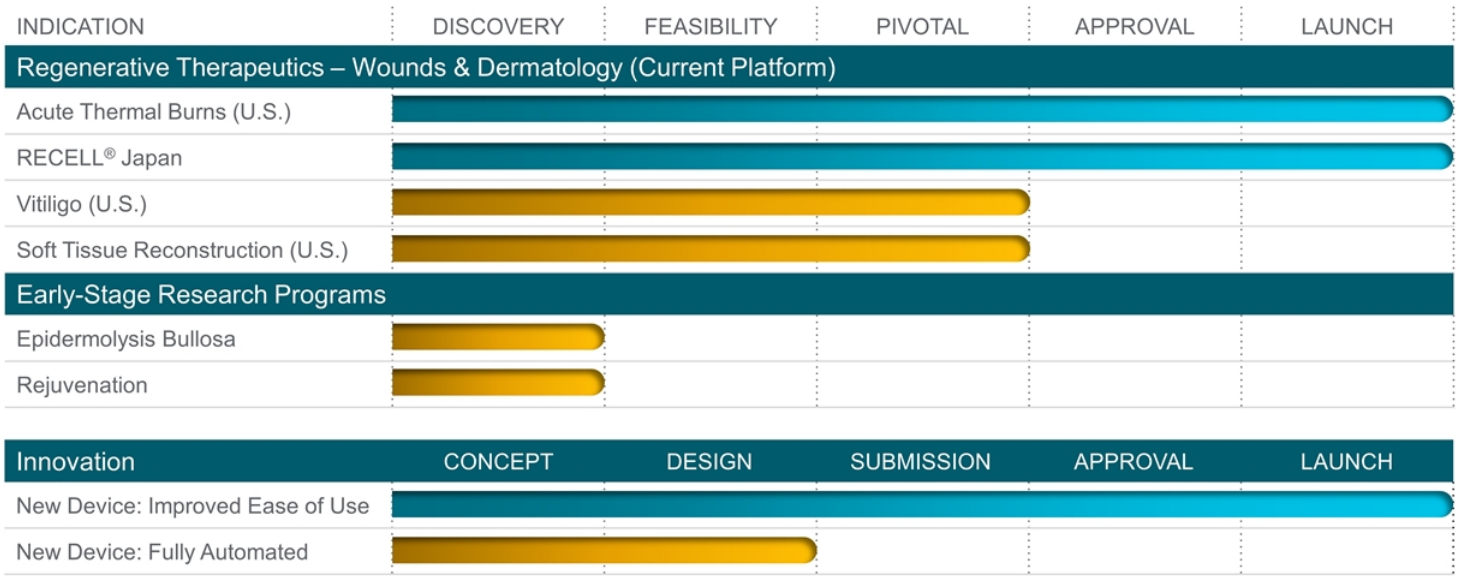
# New RECELL Device: Automated

## KEY UPDATES

- New RECELL Automated Device in development for Vitiligo:
  - FDA Submission expected in H2 2023
  - FDA Approval expected in H2 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



# Summary: Focused Pipeline with Strong Growth Potential




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.

# Projected Key Milestones

## Platform Expansion and Automation

**Vitiligo:**

| | |
|---|---|
| • FDA Submission | H2 2022 |
| • FDA Approval | H2 2023 |

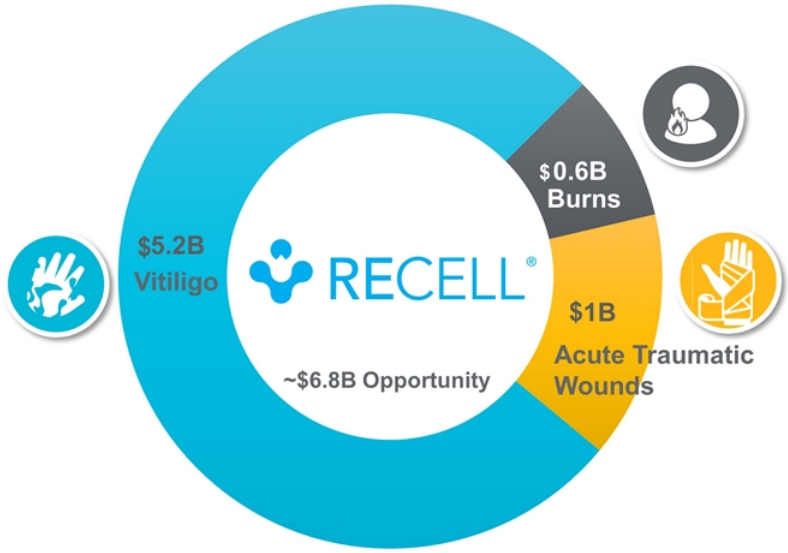
**Soft Tissue:**

| | |
|---|---|
| • FDA Submission | H2 2022 |
| • FDA Approval | H2 2023 |

**Automated Vitiligo Device:**

| | |
|---|---|
| • FDA Submission | H2 2023 |
| • FDA Approval | H2 2024 |

# Current Platform Has Significant Market Opportunity




~ $7 Billion in Combined TOTAL ADDRESSABLE MARKET


# Corporate

avita medical

# Financial Overview

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

Analysts

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

NASDAQ ticker symbol: RCEL

ASX ticker symbol: AVH

# AVITA Leadership Team

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

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

**Michael Holder**
CFO
*>30 years experience*

Affiliations:
- ImmuneCyte
- PREMIER
- CAROLINA LONGEVITY INSTITUTE

**Erin Liberto**
CCO
*>20 years experience*

Affiliations:
- Allergan
- Johnson & Johnson

**Andrew Quick**
CTO
*>25 years experience*

Affiliations:
- Boston Scientific
- AB
- sonova
- SonaMed Corp

**Kathy McGee**
COO
*>25 years experience*

Affiliations:
- Shire
- at advanced tissue
- SmithNephew

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

Affiliations:
- ASCEND THERAPEUTICS A BESINS HEALTHCARE Company
- PDL BioPharma
- Johnson & Johnson

# 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.


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.