

**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 9, 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 8.01. Other Events.

On May 9, 2022, AVITA Medical, Inc. (“the Company”) released a press release announcing that a discussion on the RECELL System will be held during the Symposium for Cosmetic Advances & Laser Education (SCALE) multidisciplinary dermatology meeting taking place May 11-15, 2022, in Nashville, TN. The presentation will discuss the use of the RECELL System for treatment of burn injuries, as well as a clinical trial protocol aimed at establishing safety and effectiveness for repigmentation of stable vitiligo lesions utilizing the RECELL System. A copy of the press release is attached hereto as Exhibit 99.1.

The information under this Item 8.01 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 specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>RECELL® System to be Highlighted at Upcoming Music City SCALE Multidisciplinary Dermatology Meeting</u>
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 10, 2022

AVITA MEDICAL, INC.

By: /s/ Donna Shiroma

Name: Donna Shiroma

Title: General Counsel



**RECELL® System to be Highlighted at Upcoming Music City SCALE
Multidisciplinary Dermatology Meeting**

VALENCIA, Calif. and MELBOURNE, Australia, 09 MAY 2022 — AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH) (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, announced today that a discussion on the RECELL System will be held during the Symposium for Cosmetic Advances & Laser Education (SCALE) multidisciplinary dermatology meeting taking place May 11-15 in Nashville, TN. SCALE is the premier multidisciplinary meeting for aesthetic medicine, plastic surgery and medical dermatology.

The presentation will feature Dr. Jeffrey Carter, FACS, Associate Professor of Surgery and Medical Director, UMCNO Burn Center at LSU Health in New Orleans, who will discuss the use of the RECELL System for treatment of burn injuries. Additionally, Dr. Seemal Desai, FAAD, Diplomate of the American Board of Dermatology, and a Board-Certified Dermatologist, will review the clinical trial protocol aimed at establishing safety and effectiveness for repigmentation of stable vitiligo lesions utilizing the RECELL System. The discussion, “RECELL: A Novel Treatment Strategy for Regenerative & Restorative Skin Conditions” will take place Thursday, May 12 from 2:30-2:40 pm CDT.

“It is important for us to share clinical evidence and peer insights related to the RECELL System with leaders of the dermatology community to help physicians make educated treatment decisions for their patients,” said Dr. Mike Perry, Chief Executive Officer of AVITA Medical. “As we pursue the vitiligo indication, our vision is to offer the community an innovative solution to better serve the millions of people who suffer with this disease.”

Vitiligo is a disease that attacks pigment-producing cells, called melanocytes, resulting in their destruction or malfunction. The result is a loss of pigmentation in patches of skin. Vitiligo affects up to 2% of the population worldwide,ⁱ including an estimated 3-6.5 million Americans.ⁱⁱ Vitiligo has a comparable market size and psychosocial impact to other major dermatology diseases including psoriasis (thick, scaly skin) and atopic dermatitis (red, cracked skin).ⁱⁱⁱ ^{iv} Like these diseases, those living with vitiligo may suffer from poor body image along with low self-esteem, leading to an impaired quality of life.^{vi}

AVITA Medical is currently completing a pivotal trial for the use of the RECELL System for treatment of stable vitiligo. Currently, the RECELL System is indicated in the U.S. for treatment of acute thermal burns. Our vitiligo clinical trial aims to demonstrate safe and effective repigmentation when using the RECELL System in combination with phototherapy. Topline data from the trial will be shared later this year.

AVITA Medical Inc, 28159 Avenue Stanford, Valencia, CA 91355

ABOUT AVITA MEDICAL, INC.

AVITA Medical is a regenerative medicine company with a technology platform positioned to address unmet medical needs in burns, chronic wounds, and aesthetics indications. AVITA Medical's 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 indicated for use in the treatment of acute thermal burns. 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 10,000 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://recellsystem.com/>) for a full description of indications for use and important safety information including contraindications, warnings, and precautions.

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.

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 goal. 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 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.

AVITA Medical Inc, 28159 Avenue Stanford, Valencia, CA 91355

FOR FURTHER INFORMATION:

U.S. Media

Sam Brown, Inc.
Christy Curran
Phone +1-615-414-8668
christycurran@sambrown.com

Investors

Westwicke Partners
Caroline Corner
Phone +1-415-202-5678
caroline.corner@westwicke.com

O.U.S. Media

Rudi Michelson
Phone +61 (0)3 9620 3333
Mobile +61 (0)411 402 737
rudim@monsoon.com.au

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- i Picardo et al. Vitiligo. Nature Reviews Disease Primers. 2015.
 - ii John Harris, MD, PhD – Presentation as part of Incyte Corporate presentation. (Harris, UMass, is a global leader in Vitiligo; AVITA collaborator). <https://investor.incyte.com/static-files/01f77a1c-6351-4348-adc2-597e2bc1f42eSERT>
 - iii National Psoriasis Foundation – Statistics, <https://www.psoriasis.org/psoriasis-statistics/> Accessed 10/5/2020
 - iv The burden of vitiligo: Patient characteristics associated with quality of life. Homan, et al. JAAD. 2009
 - v Comparison of the Psychological Impacts of Asymptomatic and Symptomatic Cutaneous Diseases: Vitiligo and Atopic Dermatitis. Noh, et al. Annals of Derm. 2013
 - vi Willingness-to-pay and quality of life in patients with vitiligo. Radtke, et al. BJD. 2009

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