# 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): August 12, 2021**

# 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 2.02. Results of Operations and Financial Condition.**

On August 12, 2021, Avita Medical, Inc. (the "Company"), issued a press release announcing an earnings call scheduled for August 26, 2021 to discuss fiscal fourth quarter 2021 financial results and certain other business updates. A copy of the press release is furnished herewith as Exhibit 99.1 to this report.

**Item 8.01. Other Events.**

On August 16, 2021, the Company issued a press release announcing that the U.S. Food and Drug Administration (FDA) has approved the Company's request to amend its pivotal clinical trial evaluating the safety and effectiveness of the RECELL® System for the repigmentation of stable vitiligo lesions to a streamlined single-arm trial design. A copy of the press release is furnished herewith as Exhibit 99.2 to this report.

The information disclosed under Item 8.01, and in Exhibits 99.1 and 99.2 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 | AVITA Medical to Announce Fiscal Fourth Quarter 2021 Financial Results |
| 99.2 | FDA Approves IDE Amendment to a Single-Arm Design for AVITA Medical's Pivotal Study of the RECELL® System for Vitiligo Treatment |

**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: August 17, 2021

**AVITA THERAPEUTICS, INC.**

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

**AVITA Medical to Announce Fiscal Fourth Quarter 2021 Financial Results**

August 12, 2021

VALENCIA, Calif., and MELBOURNE, Australia, Aug. 12, 2021 (GLOBE NEWSWIRE) — AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH), 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 it plans to release its fiscal fourth quarter 2021 financial results after the market closes on Thursday, August 26, 2021. In conjunction with such release, the Company plans to host a conference call and webcast on August 26 at 1:30 p.m. Pacific Time / 4:30 p.m. Eastern Time (being 6:30 a.m. Australian Eastern Standard Time on Friday, August 27) to discuss its financial results and recent highlights.

Interested parties may access the live call via telephone by dialing (833) 614-1538 for domestic callers or (706) 634-6548 for international callers, using conference ID: 3858364. The live webinar of the call may be accessed by visiting the Events section of the Company's website at ir.avitamedical.com. A replay of the webinar will be available on the Company's website shortly after the conclusion of the call.

Authorized for release by the Chief Financial Officer of AVITA Medical, Inc.

**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 letter 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 letter 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 letter 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 letter. 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 letter speak only as of the date of this release, and we undertake no obligation to update or revise any of these statements.*

*This press release was authorized by the review committee of AVITA Medical, Inc.*

**FOR FURTHER INFORMATION:**

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**FDA Approves IDE Amendment to a Single-Arm Design for AVITA Medical's Pivotal Study of the RECELL® System for Vitiligo Treatment**

August 16, 2021

- *New single-arm design to evaluate 23 subjects at 15 clinical sites, versus previously approved 3-arm study of 84 subjects*
- *The 1:20 expansion ratio to be used is the best-case scenario for patients as it requires the least amount of donor skin*

VALENCIA, Calif. and MELBOURNE, Australia, Aug. 16, 2021 (GLOBE NEWSWIRE) — AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH), 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 the U.S. Food and Drug Administration (FDA) has approved the company's request to amend its pivotal clinical trial evaluating the safety and effectiveness of the RECELL® System for the repigmentation of stable vitiligo lesions to a streamlined single-arm trial design. The Company's strategic decision to pursue a single cell suspension formulation (1:20 expansion ratio) is based on data from other research efforts that suggest the improbability of meaningful clinical performance differences amongst the three cell suspensions in the initial pivotal clinical trial design.

"The simplified study design and reduced number of study subjects reflects confidence both in the exceptional safety profile of RECELL and in the anticipated high incidence of repigmentation with RECELL treatment, as we have seen in 11 peer-reviewed publications and in the treatment of more than 1,000 patients outside the U.S.," said Dr. Mike Perry, Chief Executive Officer of AVITA Medical. "The design change allows this program to progress in a timely and cost-effective manner toward bringing a novel therapeutic option to an underserved population. Our ongoing multi-media outreach and clinical and advocacy group referral programs are generating significant interest in the trial. The program is on track, and we continue to believe we could be in a position to enter the U.S. market with the vitiligo indication, following successful completion of the clinical trial, as early as the second half of calendar year 2023."

**Pivotal Trial Design**

The multi-center pivotal study includes 15 clinical sites to assess the safety and effectiveness of the RECELL System in treatment of depigmented vitiligo lesions in patients whose vitiligo is stable, meaning they have not had new vitiligo lesions or lesions that have expanded for at least one year. The primary effectiveness evaluation is based on a comparison of the incidence of successful repigmentation with RECELL versus that of a standard of care control. Long-term durability data (assessing sustained repigmentation over 52 weeks) will be collected.

Each site is required to complete a run-in treatment as part of study initiation. Subjects treated in the earlier version of the pivotal clinical trial will be counted as part of the run-in cohort. After run-in, 23 subjects will be treated and evaluated in the final pivotal cohort. As with the previous design, an interim analysis will be conducted on 24-week data for approximately half of the subjects to evaluate sufficiency of the sample size, with a possible increase to sample size as needed (up to 46 subjects).

**About Vitiligo**

Vitiligo is a disease resulting in loss of color, or pigmentation, in patches of skin, negatively impacting the quality of life for those living with the condition.(i) Vitiligo affects approximately 6.5 million people in the United States(ii), rivalling the prevalence of psoriasis.(iiii) There is currently no cure for vitiligo, nor a universally accepted method for limiting the spread of the disease. Although many treatments are being used for the management of vitiligo, they are often temporary with a high rate of recurrence.(iv)

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(i) Willingness-to-pay and quality of life in patients with vitiligo. Radtke, et al. BJD. 2009
(ii) Advances in Vitiligo: An Update on Medical and Surgical Treatments. A. Dillon, et al. J Clin Aesth Derm. 2017
(iii) National Psoriasis Foundation – Statistics, https://www.psoriasis.org/content/statistics Accessed 12/28/19
(iv) Vitiligo Research Foundation – Treatment Guidelines. https://vrfoundation.org/treatment_guidelines Accessed 12/28/19