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 12, 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 8.01. Other Events.

On September 12, 2022, AVITA Medical, Inc. issued a press release announcing positive topline results from a pivotal randomized, controlled trial evaluating the safety and effectiveness of the RECELL® System for repigmentation of stable vitiligo lesions. A copy of the press release is attached hereto as Exhibit 99.1.

The information under Items 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.

Exhibit No.	Description
99.1	**AVITA Medical Achieves Positive Topline Pivotal Trial Results for Treatment of Stable Vitiligo Using the RECELL® System**
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 13, 2022

AVITA MEDICAL, INC.

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

AVITA Medical Achieves Positive Topline Pivotal Trial Results for Treatment of Stable Vitiligo Using the RECELL® System

- *The study achieved its primary effectiveness endpoint of super-superiority*
- *AVITA Medical continues to plan for submission to FDA by the end of 2022*

VALENCIA, Calif. 12 SEPTEMBER 2022 and MELBOURNE, Australia, 13 SEPTEMBER 2022 — AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH) (Company), a regenerative medicine company leading the development and commercialization of first-in-class devices and autologous cellular therapies for skin restoration, today announced positive topline results from a pivotal randomized, controlled trial evaluating the safety and effectiveness of the RECELL® System for repigmentation of stable vitiligo lesions.

The study compared repigmentation success rates, in a design where each patient randomly received RECELL treatment in one portion of depigmented area and treatment with the study control in another portion of depigmented area. The study control treatment was the standard of care narrowband ultraviolet-B phototherapy, which is typical first-line treatment for vitiligo. Repigmentation was evaluated 6 months after treatment by an expert central review committee (CRC).

The CRC reported the following:

- Fifty-six percent (56%) of RECELL treatments (versus 12% of control treatments) resulted in repigmentation of more than 50% of the treated area
- Thirty-six percent (36%) of RECELL treatments (versus 0% of control treatments) resulted in repigmentation of at least 80% of the treated area, establishing super-superiority for the primary endpoint ($p<0.025$)

RECELL's compelling safety profile to date is reflected in preliminary review of adverse events in this study.

These are the first results from a U.S. randomized, controlled trial of the RECELL System in treating patients with segmental and nonsegmental stable vitiligo and provide a foundation for communicating favorable clinical benefit in pursuit of FDA approval via submission of a PMA supplement for this indication later this year.

“Vitiligo often has a severe impact on quality of life and is a therapeutic area within which there have been very limited treatment options. We are excited by our topline data, as we are now closer to our goal of providing patients with a durable, clinically meaningful, one-time treatment for repigmentation,” said Dr. Mike Perry, Chief Executive Officer of AVITA Medical. “RECELL has the potential to address the unmet medical need for an estimated 1.3 million people in the U.S. who suffer from stable vitiligo, and further, we envision a potential opportunity for RECELL as part of a multi-modal treatment plan for patients achieving stability with JAK inhibitor treatment.”

“Repigmentation is challenging to manage and burdensome for patients with vitiligo,” said Iltefat Hamzavi, MD, of Henry Ford Hospital (Detroit, MI), lead investigator of the trial. “These are encouraging results that underscore the potential for RECELL to address repigmentation in patients with stable vitiligo in a rapid and sustained fashion which is distinct from existing therapies.”

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 up to 6.5 million Americans,[ii] with an estimated 1.3 million suffering from stable vitiligo. Vitiligo has a comparable psychosocial impact to other major dermatology diseases including psoriasis (thick, scaly skin) and atopic dermatitis (red, cracked skin).[iii, iv, v] 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]

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ABOUT AVITA MEDICAL, INC. AVITA Medical is a regenerative medicine company leading the development and commercialization of devices and autologous cellular therapies for skin restoration. The RECELL® System technology platform, approved by the FDA for the treatment of acute thermal burns in both adults and children, harnesses the regenerative properties of a patient’s own skin to create Spray-On Skin™ cells. Delivered at the point-of-care, RECELL enables improved clinical outcomes and validated cost savings. RECELL is the catalyst of a new treatment paradigm and AVITA Medical is leveraging its proven and differentiated capabilities to develop first-in-class cellular therapies for multiple indications, including acute traumatic wounds and repigmentation of stable vitiligo lesions.

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 approved for 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. In February 2022, the FDA reviewed and approved the PMA supplement for RECELL Autologous Cell Harvesting Device, an enhanced RECELL System aimed at providing clinicians a more efficient user experience and simplified workflow.

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 15,000 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 approved under the RECELL System brand to promote skin healing in a wide range of applications including burns, acute traumatic wounds, vitiligo, and aesthetics. The RECELL System is TGA-registered in Australia, received CE-mark approval in Europe and has PMDA approval in Japan. 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.

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

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