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 17, 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 February 17, 2022, AVITA Medical, Inc. (“the Company”) issued a press release announcing that it has received U.S. Food and Drug Administration (FDA) Pre-Market Approval of a new Ease-of-Use design for the RECELL Autologous Cell Harvesting 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 are 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 Announces FDA Approval of New RECELL® System with Improved Ease of Use
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: February 18, 2022

AVITA MEDICAL, INC.

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

AVITA Medical Announces FDA Approval of New RECELL® System with Improved Ease of Use

System enhanced in response to clinician workflow and usability feedback; new system simplifies process

United States product launch planned for Q2 2022

VALENCIA, Calif. and MELBOURNE, Australia, 17 February 2022 — 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 United States Food and Drug Administration (FDA) has reviewed and approved the premarket approval application (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 a device that enables healthcare professionals to produce a suspension of Spray-On Skin™ Cells using a small sample of the patient's own skin for the treatment of acute thermal burns.

"To ensure RECELL continues to meet the needs of our customers, we initiated a program to explore how we could improve the device, and then addressed those matters with this new system," said Dr. Mike Perry, Chief Executive Officer of AVITA Medical. "Based upon research and human factors testing, we are confident that the new RECELL System will be positively received by the burn community. The enhancements will provide a range of benefits to clinicians using the device and in turn, patients will benefit as the procedure becomes more efficient."

Until now, the RECELL System – which launched in the United States nearly two years ago – consisted of multiple individually packaged sterile components requiring transfer into the sterile field and required clinicians to rely on multiple people to assist during the process. AVITA Medical researchers spoke with surgeons, physician assistants and registered nurses – both experienced and new users of the device – to study how procedures with the RECELL System are being conducted in real-world scenarios and how they can be improved.

While the intended use of the device as a whole remains unchanged, the RECELL System has been modified to reduce set-up steps by approximately one-third and to enable use of the device with reduced support personnel. In a survey, 94% of users believe that the new RECELL System will allow them to prepare for a procedure faster than with the current RECELL System and more than 80% of users anticipate a faster learning curve for a newly trained user to become proficient with the system.[i]

The launch of the new RECELL System in the United States will begin in Q2 2022. For more information about the RECELL System, please visit www.RECELLSystem.com.

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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 and a new ease-of-use design was approved in 2022. 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.

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

FOR FURTHER INFORMATION:

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