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): April 4, 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 April 4, 2022, AVITA Medical, Inc. issued a press release announcing that fifteen presentations highlighting the clinical and cost-savings benefits of the RECELL® Autologous Cell Harvesting Device for the treatment of burn wounds will be shared at the American Burn Association (ABA) Annual Meeting in Las Vegas, Nevada, which is being held on April 5-8, 2022. 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.

Exhibit No.	Description
99.1	RECELL® System Data to be Presented at the American Burn Association Annual Meeting
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: April 5, 2022

AVITA MEDICAL, INC.

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

RECELL® System Data to be Presented at the American Burn Association Annual Meeting

April 4, 2022

Data from 15 presentations will highlight the use of the platform for the treatment of pediatric and adult burn wounds

VALENCIA, Calif. and MELBOURNE, Australia, April 04, 2022 (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 fifteen presentations highlighting the clinical and cost-savings benefits of the RECELL® Autologous Cell Harvesting Device (RECELL® System) for the treatment of burn wounds will be shared at the American Burn Association (ABA) Annual Meeting. The conference will be held in Las Vegas, April 5-8, and will bring together more than 2,000 multi-disciplinary burn care professionals from across the globe to discuss burn care and the latest research related to burn injuries.

“The depth and breadth of the RECELL System data being presented at the American Burn Association Annual Meeting highlights the impact this platform is having on the treatment protocol for burn injuries,” said Dr. Mike Perry, Chief Executive Officer of AVITA Medical. “Given the substantial and growing body of data supporting the efficacy of the RECELL System for treatment of burn wounds, coupled with the real-world treatment of more than 15,000 patients globally, we look forward to building on this strong track record to expand use of the RECELL System to encompass broader indications, including soft-tissue repair and vitiligo, following the completion of our clinical trials and approval by the FDA.”

RECELL® System Presentations

In the U.S., the RECELL® System is indicated for the treatment of acute 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. Physician-initiated research beyond the FDA approved indication is not sponsored by AVITA Medical and contains independent data.

- Decreasing Preparation Time of Full-thickness Engineered Constructs: Seeding Dermal Allografts with Non-cultured Keratinocytes. Authors: Gallentine, Powell
- Early Post-operative Mobilization after treatment of burn wounds with Autologous Skin Cell Suspension. Authors: Kelly, Kahn
- Outcomes for 43 hand burns treated with 2:1 meshed and epidermal autografts with abundant donors. Authors: Yoo, Carter
- ASCS Treatment impact on length of stay data and costs for patients with small burn. Authors: Carter, Carson, Rae, Saquib Wibbenmeyer, Hickerson
- Partial thickness pediatric burn injuries treated with autologous skin cell suspension. Author: Kopari
- Bromelain based enzymatic debridement followed by application of autologous skin cell suspension for treatment of burns. Authors: Williams, Bright
- Timing of autologous spray cell suspension: better early than late. Author: Komak
- Use of autologous skin cell suspension (ASCS) for full-thickness burn injuries reduces autograft procedures. Author: Holmes
- Minimally invasive skin grafting with enzymatic debridement and autologous skin cell suspension. Author: Kahn
- Autologous skin cell suspension application for toxic epidermal necrolysis: a case report. Author: Pang
- Single stage application of autologous skin cell suspension in deep partial thickness pediatric facial burns. Author: Lou
- Autologous skin cell suspension versus standard split thickness autografting: a comparison of operative efficiency. Authors: Sweitzer, Bell
- Catastrophic burn management: A case series using autologous skin cell suspension. Author: Deeter
- Evaluation of dermal and epidermal replacement strategies for the treatment of full-thickness wounds. Author: Hickerson
- Histologic changes of skin biopsies after autologous skin cell suspension. Author: Lennard

The RECELL System is indicated in the U.S. for treatment of acute thermal burns. The frequency of burn-related injuries and the cost of treatment are high. The Centers for Disease Control and Prevention (CDC) reported that 486,000 patients receive emergency medical treatment for burns annually. Burn injuries result in approximately 3,400 deaths each year, the third-leading cause of accidental home injury deaths. Burns covering up to 90 percent of a person’s body surface area, once considered fatal injuries, have become survivable with appropriate treatment. Although split-thickness autografts are the current standard treatment, grafting is often associated with significant donor site pain, delayed healing and scarring.

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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