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): March 21, 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 March 21, 2022, the Company issued a press release announcing the modification of its contract with the Biomedical Advanced Research and Development Authority ("BARDA"). The modification aims to support the Company's RECELL® System clinical trial in soft tissue reconstruction. A copy of the press release is attached hereto as Exhibit 99.1.

On March 22, 2022, the Company issued a press release announcing an Investor Webinar led by Dr. Mike Perry, the Company's CEO, and Michael Holder, the Company's CFO, on Thursday 24 March 2022 at 11am (AEDT). A copy of the press release is attached hereto as Exhibit 99.2.

On March 23, 2022, the Company issued a press release announcing that an abstract highlighting the clinical trial protocol utilizing the RECELL® Autologous Cell Harvesting Device (RECELL® System) to treat vitiligo will be presented at the Global Vitiligo Foundation Annual Scientific Symposium on March 24, 2022 at 9:38am EDT. A copy of the press release is attached hereto as Exhibit 99.3.

The information under these 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 Announces Modification of BARDA Contract to Advance Development of RECELL® System in Soft Tissue Reconstruction**
99.2	**Investor Webinar Release**
99.3	**RECELL® System Vitiligo Clinical Trial Protocol to be Presented at the Global Vitiligo Foundation Annual Scientific Symposium**
EXHIBIT 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: March 24, 2022

AVITA MEDICAL, INC.

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

Exhibit 99.1

AVITA Medical Announces Modification of BARDA Contract to Advance Development of RECELL® System in Soft Tissue Reconstruction

March 21, 2022

Funds will support completion of the ongoing pivotal clinical trial

VALENCIA, Calif. and MELBOURNE, Australia, March 21, 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 the Biomedical Advanced Research and Development Authority (BARDA) has modified its existing contract with the Company to support AVITA Medical's clinical trial in soft tissue reconstruction. BARDA is a part of the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS).

"We are extremely pleased that BARDA is supporting advanced treatment options for soft tissue reconstruction," said Dr. Mike Perry, Chief Executive Officer of AVITA Medical. "The RECELL System has already proven itself as a safe and effective tool for those with burns, and we are committed to expanding its use to include all acute wounds. We are pleased BARDA recognizes the potential it holds for a broader group of patients experiencing trauma. BARDA has been an outstanding partner, and we are excited to continue our work to expand the indication for the RECELL System with their support."

Soft tissue reconstruction is of particular concern to BARDA and AVITA Medical, as skin grafting, the current standard of care for soft tissue reconstruction, requires the harvesting of donor skin which can result in an additional wound to the patient. Significant pain, delayed healing, risk of infection, the need for multiple procedures, discoloration and scarring are associated with donor site wounds. While skin grafting is commonly associated with burn treatment, in 2017, approximately 80% of acute wounds that required skin grafting were non-burn related injuries accounting for more than 200,000 procedures in the U.S.i

AVITA Medical is currently completing a pivotal trial for the use of the RECELL System for soft tissue reconstruction. Currently, the RECELL System is indicated in the U.S. for treatment of acute thermal burns. The clinical trial will compare the clinical performance of conventional autografting to that of widely meshed autografting with the RECELL System on acute non-burn full-thickness skin defects, with the goal of demonstrating that less donor skin is needed without compromising healing outcomes. Topline data from the trial will be shared later this year.

AVITA Medical has had a long-term positive relationship with BARDA since September 2015 and was of fundamental importance to the Company being able to achieve premarket approval for the RECELL System in late 2018.

This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201500028C

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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[i] 2017 Procedural Data. © 2019 DR/Decision Resources, LLC

Exhibit 99.2

Investor Webinar

VALENCIA, Calif. and MELBOURNE, Australia, 22 March 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, invites shareholders and prospective investors to attend its investor webinar and presentation by Dr. Mike Perry, CEO, and Michael Holder, CFO, on Thursday at 11am (AEDT) 24 March 2022.

The webinar will cover highlights from AVITA Medical's successful 2021 calendar year, multiple key accomplishments as previously announced over the past quarter and to date, and planned upcoming company milestones.

Interested parties can register for the webinar using this link: https://zoom.us/webinar/register/WN_LgAAB_tyQGS6vyEPG1yAgw

Participants may submit questions during registration or during the session. A replay will be available on the AVITA Medical website, www.avitamedical.com following the presentation.

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RECELL® System Vitiligo Clinical Trial Protocol to be Presented at the Global Vitiligo Foundation Annual Scientific Symposium

VALENCIA, Calif. and MELBOURNE, Australia, 23 March 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 an abstract highlighting the clinical trial protocol utilizing the RECELL® Autologous Cell Harvesting Device (RECELL® System) to treat vitiligo will be presented at the Global Vitiligo Foundation Annual Scientific Symposium. The conference is being held in Boston and will highlight research and knowledge of both up and coming vitiligo researchers and those who have and continue to build the foundational knowledge about vitiligo.

“We are pleased to share our clinical study protocol, which aims to establish safety and effectiveness for repigmentation of stable vitiligo lesions utilizing the RECELL System, with leaders of the vitiligo community,” said Dr. Mike Perry, Chief Executive Officer of AVITA Medical. “With enrollment of our vitiligo pivotal trial complete, we look forward to sharing results of our blinded, randomized study in the near future and working with the FDA to bring our novel treatment option to patients.”

RECELL System Abstract

- March 24 at 9:38am, Abstract #4: RECELL Autologous Cell Harvesting Device: A Review of the Science of Autologous Skin Cell Suspension and Clinical Protocol Aimed in Establishing Safety and Effectiveness for Repigmentation of Stable Vitiligo Lesions. Authors: K. Bush, A. Hopkin, E. Kirshner, A. Quick

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] [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.

# # #

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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