
**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): November 9, 2020

Avita Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39059
(Commission
File Number)

85-1021707
(IRS Employer
Identification No.)

28159 Avenue Stanford, Suite 220, Valencia, CA 91355
(Address of principal executive offices, including Zip Code)

661.367.9170
(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 November 9, 2020, AVITA Therapeutics, Inc. (the “Company”), announced a preclinical research collaboration pairing the Company’s proprietary Spray-On Skin™ Cells with Houston Methodist Research Institute’s expertise in reversing cellular aging. The project seeks to establish proof-of-concept for the development of a novel approach to reverse aging and rejuvenate skin, with the potential for broader applicability, such as scar revision and wound healing. The Company has also entered into an Option Agreement to negotiate an exclusive, worldwide license to this patented technology for skin applications, as well as first right of negotiation to technologies emerging from the collaboration for potential further development and commercialization.

Under the Sponsored Research Agreement, the Company will gain access to Houston Methodist Research Institute’s innovative technologies, including an RNA-based approach to rejuvenate human cells. Houston Methodist Research Institute has studied the use of telomerase to lengthen the ends of chromosomes (“telomeres”), which act as molecular clocks in cells and progressively shorten with age. Through that research, the Houston Methodist Research Institute’s team has established a proof-of-concept that their RNA technology reverses aging of cells, including those derived from patients with progeria (a model of accelerated aging). During the research collaboration, the Company and Houston Methodist Research Institute will explore applications of this RNA technology to rejuvenate skin by reversing aging mechanisms. The initial research program is expected to run 18 months, followed by further work to develop a data package enabling regulatory submission, targeting an Investigational New Drug application.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	<u>Press release of AVITA Therapeutics, Inc. dated November 9, 2020 (“AVITA Therapeutics and the Houston Methodist Research Institute Enter into Collaboration to Explore Novel Approaches for Skin Rejuvenation”).</u>

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: November 9, 2020

AVITA THERAPEUTICS, INC.

By: /s/ Donna Shiroma

Name: Donna Shiroma

Title: General Counsel



AVITA Therapeutics and the Houston Methodist Research Institute Enter into Collaboration to Explore Novel Approaches for Skin Rejuvenation

November 9, 2020

Preclinical research will pair AVITA Therapeutics' Spray-On Skin™ Cells with Houston Methodist Research Institute's technologies to reverse cellular aging

AVITA Therapeutics secures exclusive licensing option

VALENCIA, Calif. and MELBOURNE, Australia, Nov. 09, 2020 (GLOBE NEWSWIRE) — AVITA Therapeutics, 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 a preclinical research collaboration pairing AVITA Therapeutics' proprietary Spray-On Skin™ Cells with Houston Methodist Research Institute's expertise in reversing cellular aging. The project seeks to establish proof-of-concept for the development of a novel approach to reverse aging and rejuvenate skin, with the potential for broader applicability, such as scar revision and wound healing. AVITA Therapeutics has also entered into an Option Agreement to negotiate an exclusive, worldwide license to this patented technology for skin applications, as well as first right of negotiation to technologies emerging from the collaboration for potential further development and commercialization.

"The Houston Methodist Research Institute is at the forefront of developing cutting-edge approaches for reversing cellular aging, and we look forward to working together on the exploration of combining their technology with AVITA Therapeutics' proprietary Spray-on Skin™ Cells to rejuvenate aging skin," said Dr. Mike Perry, Chief Executive Officer of AVITA Therapeutics. "This collaboration expands our pipeline to include exploration of modified-cells delivery and is another milestone in our commitment to harnessing the promise of regenerative medicine and unlocking the full potential of our technology platform to improve patients' lives through skin restoration."

Under the Sponsored Research Agreement (SRA), AVITA Therapeutics will gain access to Houston Methodist's innovative technologies, including an RNA-based approach to rejuvenate human cells. Houston Methodist has studied the use of telomerase to lengthen the ends of chromosomes ("telomeres"), which act as molecular clocks in cells and progressively shorten with age. Through that research, the Houston Methodist team has established a proof-of-concept that their RNA technology reverses aging of cells, including those derived from patients with progeria (a model of accelerated aging). During the research collaboration, AVITA Therapeutics and Houston Methodist Research Institute will explore applications of this RNA technology to rejuvenate skin by reversing aging mechanisms. The initial research program is expected to run 18 months, followed by further work to develop a data package enabling regulatory submission, targeting an Investigational New Drug application.

"AVITA Therapeutics' innovative platform has advanced care for burn patients, and we are encouraged by the progress we have seen with our technology in improving cell function through our progeria research," said John Cooke, M.D., Ph.D., Chair of the Department of Cardiovascular Sciences at Houston Methodist Research Institute. "We look forward to collaborating with AVITA to combine our respective technology platforms to explore a potential new approach to reverse aging and improve functionality of skin. Our experience in RNA-based methods to regenerate blood vessels and reverse age-related endotheliopathy is directly relevant to skin repair and rejuvenation."

Americans spend \$16.5 billion in aesthetic procedures annually, and facial rejuvenation is an area of growth. More than three million aesthetic procedures have been performed annually in the U.S. aimed to improve skin tightness, texture and evenness in skin toneⁱ. Personalized, cellular-level approaches to skin rejuvenation, developed with robust evidence, are an area of significant interestⁱⁱ.

Authorized for release by the Chief Executive Officer of AVITA Therapeutics, Inc.

ABOUT AVITA THERAPEUTICS, INC.

AVITA Therapeutics is a regenerative medicine company with a technology platform positioned to address unmet medical needs in burns, chronic wounds, and aesthetics indications. AVITA Therapeutics' 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 Therapeutics' 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 in patients 18 years and older. 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 8,000 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.

FOR FURTHER INFORMATION:

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Source: AVITA Therapeutics, Inc.

i Estimates and data based on information on file at Avita Medical Limited

ii Goddard et al. Aesthetic Surgery Journal, Volume 40, Issue 4, April 2020, Pages 460–465.