
**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): June 15, 2021

Avita Medical, 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 2.02. Results of Operations and Financial Condition.

On June 15, 2021, Avita Medical, Inc. (the “Company”), issued a press release announcing preliminary unaudited results for the fourth quarter ended June 30, 2021 and certain other business updates (the “Business Update Press Release”). A copy of the press release is furnished herewith as Exhibit 99.1 to this report.

The information under this Item 2.02 and in Exhibit 99.1 is preliminary, has not been audited and is subject to change upon completion of the Company’s closing procedures. The information disclosed under this Item 2.02, including Exhibit 99.1 hereto, 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

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	AVITA Medical Announces Preliminary Fourth Quarter 2021 Financial Results

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: June 17, 2021

AVITA THERAPEUTICS, INC.

By: /s/ Donna Shiroma

Name: Donna Shiroma

Title: General Counsel



AVITA Medical Announces Preliminary Fourth Quarter 2021 Financial Results

VALENCIA, Calif., USA, June 15, 2021, and MELBOURNE, Australia, June 16, 2021 (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, today announced preliminary, unaudited financial results for the fiscal fourth quarter 2021.

For the fiscal quarter ending June 30, 2021, AVITA Medical has to date realized total revenue in excess of its fiscal fourth quarter guidance range of \$8.2 million to \$8.6 million. Based on the strength of both RECELL[®] commercial revenue and BARDA related revenue, the Company is raising fiscal Q4 guidance to be in the range of \$9.5 - \$9.7 million, consisting of \$6.0 - \$6.2 million of RECELL[®] commercial revenue and \$3.5 million of RECELL[®] revenue associated with BARDA, the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority within the Office of the Assistance Secretary for Preparedness and Response. RECELL[®] commercial revenue as revised in the guidance reflects a 55% to 60% increase over the prior year period and 30% to 34% increase over the third quarter of 2021.

“As people begin to return to normal activities after the confines of the COVID-19 pandemic, we have seen an increase in burn accidents requiring treatment with the RECELL[®] System in burn centers across the country,” said Dr. Mike Perry, AVITA Medical’s Chief Executive Officer.

The Company expects to announce fourth quarter financial and operating results on August 25, 2021. More details about the upcoming earnings announcement, including the time and webcast details, will be provided at a later date.

The preliminary unaudited revenue results described in this press release are estimates only and subject to revision until we report our Q4 2021 financial results in our Annual Report on Form 10-K.

For more information about the RECELL System, please visit <https://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. The RECELL System is indicated for use in the treatment of

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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 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.

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

FOR FURTHER INFORMATION:

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