# 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): January 12, 2021**

# 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 2.02. Results of Operations and Financial Condition.**

On January 12, 2021, AVITA Medical, Inc. (the "Company") issued a press release announcing its preliminary unaudited estimates of its top line results for the three months ended December 31, 2020. A copy of the Company's press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information under Item 2.02 in this current report on Form 8-K and the related information in the exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description of Exhibit |
|---|---|
| 99.1 | Press release, titled "AVITA Medical Announces Preliminary Fiscal Second Quarter 2021 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: January 12, 2021

**AVITA MEDICAL, INC.**

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

**ASX/News Release**

## AVITA Medical Announces Preliminary Fiscal Second Quarter 2021 Results

**Valencia, Calif. and MELBOURNE, Australia, January 12, 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 estimates of its top line results for the three months ended December 31, 2020.

**Preliminary Fiscal Second Quarter Estimates**

- U.S based RECELL® revenue is expected to be $5.0 million in the second quarter of 2021 ended December 31, 2020, compared to $5.0 million in the previous quarter. U.S based RECELL revenue increased $1.9 million or 62% over the same quarter in the prior year.
- Total global revenue is expected to be $5.1 million in the second quarter of 2021, compared to $5.1 million in the previous quarter. Total global revenue increased $1.8 million in the current quarter or 57% over the same quarter in the prior year.
- The Company had cash of approximately $59.8 million, a decrease of $6.0 million or 9% over the $65.8 million held at the end of the previous quarter.

**Commercial Metrics:**

- Enrolled 9 additional patients in the pivotal study assessing the use of the RECELL System to treat stable vitiligo.
- Added 7 new accounts in the second quarter 2021 for a total of 93 accounts.
- Estimated procedural volumes were 485 in the second quarter of 2021, compared to 496 in the previous quarter.

“I’m pleased with our team’s commercial execution during these challenging times,” said Dr. Mike Perry, AVITA Medical Chief Executive Officer. “We continue to make solid progress on our pipeline initiatives, and I look forward to updating you further during our quarterly earnings call.”

The Company is providing the above information in advance of its participation in the 39th Annual J.P. Morgan Health Conference, which begins on Monday, January 11, 2021. The Company will post its conference presentation to the ASX Market Announcements Platform and will also make that presentation available on its website at www.avitamedical.com/investors.

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

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Financial Measures and other Items

The foregoing information and estimates are preliminary in nature and are subject to revisions as we prepare our Form 10-Q Quarterly Report for the second quarter ended December 31, 2020. Because we have not completed our normal quarterly closing and review procedures for the six months ended December 31, 2020, and subsequent events may occur that require material adjustments to these results, the final results and other disclosures for the period may differ materially from these estimates. These estimates should not be viewed as a substitute for the full disclosure of our Form 10-Q Quarterly Report. These estimated results should be read together with subsequent filings and announcements, including any subsequent press release announcing the Company's earnings for the second quarter ended December 31, 2020.

*Non-U.S. GAAP Financial Measures and Other Items*

We use the following measures of financial performance which are not presented in accordance with U.S. GAAP:

- "U.S. based RECELL Sales", which is the amount of revenue denominated in United States dollars, we generate from our commercial efforts in relation to the sale of RECELL Systems within the United states. Management believes that this measurement is useful for comparing period to period sales performance, and product acceptance of the Company's lead product, the RECELL System, within the United States burn market.

U.S. base RECELL Sales is a non-GAAP financial measure used by management in evaluating sales performance, and product acceptance, within the United States and for the purposes of making strategic decisions. Management believes that the presentation of U.S. base RECELL sales provides useful information to investors regarding our revenue results because they assist both investors and management in analyzing and benchmarking the performance and value of our business. U.S. RECELL Sales provides indicators of product performance that are not affected by currency fluctuations. Accordingly, management believes that this measurement is useful for comparing general sales performance from period to period in the Company's largest market.

**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 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 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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