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): October 02, 2023

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, California**	**91355**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 661 367-9170

(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 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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.

As previously disclosed, on June 30, 2023, AVITA Medical, Inc. (the “Company”) submitted a premarket approval supplement application (the “PMA”) to the U.S. Food and Drug Administration (the “FDA”) for its latest device, RECELL GO™. The submission initiated a prioritized, interactive review of the PMA under the FDA’s Breakthrough Device program, which follows a 180-day review cycle.

At the halfway point of the process, the Company received notice from the FDA that additional information regarding the PMA is required for the continuation of a substantive review. This request, which is not unique to the Breakthrough Device Program, places the application file on hold for approximately 4 to 6 months while the Company addresses the FDA's questions. Upon the Company’s submission of a complete response to the FDA’s request, the application will reenter the 180-day cycle, with 90 days remaining in the review period. This timing would imply a product launch between May 1 and July 1, 2024.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Current Report on Form 8-K (the "filing") contains 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 filing include, but are not limited to, statements concerning our product development activities, regulatory approval of our products, and our ability to achieve our key strategic, operational, and financial goals. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Each forward-looking statement contained in this filing is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Applicable risks and uncertainties include, among others, the timing and realization of regulatory approvals of our products; failure to achieve the anticipated benefits from approval of our products; the effect of regulatory actions; 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 filing. Investors are encouraged to read our publicly available filings for a discussion of these and other risks and uncertainties. All information provided in this Current Report on Form 8-K is as of October 2, 2023, and the Company undertakes no duty to update this information unless required by law.

SIGNATURES

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.

AVITA Medical, Inc.

Date: October 02, 2023

By: /s/ Donna Shiroma

Donna Shiroma, General Counsel