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): July 22, 2022

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:

	Trading	Name of each exchange
Title of each class	Symbol(s)	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. \Box

Item 8.01. Other Events.

On July 22, 2022, AVITA Medical, Inc. ("the Company") issued an ASX News Release announcing that it is aware of changes to its substantial holders that were previously disclosed to the market. To the best of the Company's knowledge, Redmile Group, LLC ceased to be a substantial holder of the Company within the meaning of section 671B of the *Corporations Act 2001* (Cth), per the below details.

	Previous number of equity securities in which the	Previous	Current number of equity	
	shareholder had a relevant	% of	securities in which the	Current %
	interest ⁽²⁾	voting	shareholder has a relevant	of voting
Name	as disclosed to ASX	power	interest ⁽²⁾	power
Redmile Group, LLC ⁽¹⁾	1,346,217 shares of common stock in the Company	5.40%	Nil	Nil

- (1) Redmile Group, LLC has previously advised that the equity securities held by it in the Company are comprised of equity securities in the Company that are owned by certain private investment vehicles and / or separately managed accounts managed by Redmile Group, LLC, which equity securities may be deemed to be beneficially owned by Redmile Group, LLC as investment manager of such private investment vehicles and / or separately managed accounts. The Company is not able to confirm whether this is still the case.
- (2) To the best of the Company's knowledge.

A copy of the ASX News Release is attached hereto as Exhibit 99.1.

The information under this Item 8.01 and in Item 9.01 below are 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.

No.	Description
99.1	Substantial Holder Notice
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: July 22, 2022

AVITA MEDICAL, INC.

By: /s/ Donna Shiroma

Name: Donna Shiroma Title: General Counsel



AVITA MEDICAL, INC.

Substantial holder notice

VALENCIA, Calif., USA, and MELBOURNE, Australia 22 July 2022: AVITA Medical, Inc. (NASDAQ: RCEL, ASX:AVH) (Company) advises that it is aware of changes to its substantial holders that were previously disclosed to the market.

Set out below are details, to the best of the Company's knowledge, of a person who has ceased to be a substantial holder of the Company within the meaning of section 671B of the *Corporations Act 2001* (Cth).

Name	Previous number of equity securities in which the shareholder had a relevant interest ⁽²⁾ as disclosed to ASX		Previous % of voting power	Current number of equity securities in which the shareholder has a relevant interest ⁽²⁾	Current % of voting power	
Redmile Group, LLC(1)	1,346,217 shares of common stock in the Company	5.40%		Nil	Nil	_

(1) Redmile Group, LLC has previously advised that the equity securities held by it in the Company are comprised of equity securities in the Company that are owned by certain private investment vehicles and / or separately managed accounts managed by Redmile Group, LLC, which equity securities may be deemed to be beneficially owned by Redmile Group, LLC as investment manager of such private investment vehicles and / or separately managed accounts. The Company is not able to confirm whether this is still the case.

(2) To the best of the Company's knowledge.

Authorised for release by the Chief Financial Officer of the Company.

###

ABOUT THE AVITA GROUP

The AVITA group is a regenerative medicine group of companies with a technology platform positioned to address unmet medical needs in burns, chronic wounds, and aesthetics indications. The AVITA group'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.

The AVITA group'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 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 (<u>https://recellsystem.com/</u>) for a full description of indications for use and important safety information including contraindications, warnings and precautions.

AVITA Medical, Inc. Suite 220, 28159 Avenue Stanford, Valencia, California 91355, United States of America

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 announcement 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. Applicable 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 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:

U.S. Media Sam Brown, Inc. Christy Curran Phone +1 615 414 8668 christycurran@sambrown.com

O.U.S Media Monsoon Communications Rudi Michelson Phone +61 (0)3 9620 3333 Mobile +61 (0) 411 402 737 rudim@monsoon.com.au Investors: Westwicke Partners Caroline Corner Phone +1 415 202 5678 caroline.corner@westwicke.com

AVITA Medical, Inc. Suite 220, 28159 Avenue Stanford, Valencia, California 91355, United States of America