

**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 11, 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 October 11, 2020 (October 12, 2020 Australian Eastern Standard Time), Avita Therapeutics, Inc. (the “Company”), made a required announcement on the Australian Securities Exchange (the “ASX”) announcing the filing of a shelf registration statement on Form S-3 (the “S-3”) with the United States Securities and Exchange Commission (the “SEC”). A copy of the Company’s ASX announcement is included as Exhibit 99.1 to this report.

The information included in this current report on Form 8-K under Item 8.01 and Exhibit 99.1 is being furnished and 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 liabilities of that Section, unless the registrant specifically states that the information is to be considered “filed” under the Exchange Act, or incorporates it by reference into a filing under the Exchange Act or the Securities Act of 1933, as amended.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	<u>ASX Announcement - Shelf Registration Statement Filed with SEC</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: October 12, 2020

AVITA THERAPEUTICS, INC.

By: /s/ David McIntyre

Name: David McIntyre

Title: Chief Financial Officer



Shelf Registration Statement Filed with SEC

Valencia, Calif, USA, and Melbourne, Australia, October 12, 2020 — AVITA Therapeutics, Inc. (NASDAQ: RCEL, ASX:AVH) (the “Company”) advises that it has filed a shelf registration statement on Form S-3 with the United States Securities and Exchange Commission (the “SEC”) (a copy of which is attached to this announcement).

On the recent one-year anniversary of AVITA’s listing on NASDAQ, the Company has for the first-time become eligible to file the attached S-3 registration statement with the SEC. Under the S-3 registration statement (once it is declared effective by the SEC), the Company may, in one or more offerings, issue various types of securities, including its common stock, newly designated preferred stock, warrants or units, from time to time over a maximum period of three years.

Filing a S-3 registration statement is common practice for public companies in the United States and it should be noted that:

- (a) the Company currently has no definitive plans to issue securities under the S-3 registration statement;
- (b) the S-3 registration statement is subject to review by the SEC and will not be effective until such time as the SEC declares it to be effective (at which time the S-3 registration statement will have a “3-year life”);
- (c) the attached S-3 registration statement and this announcement shall not constitute an offer to sell or the solicitation of an offer to buy any of the Company’s securities; and
- (d) the Company has not engaged any party (including investment banks or other professional advisers) in relation to a potential offering of securities.

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

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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, Inc. (ARBN 641 28 155) c/o Mertons Corporate Services Pty Ltd Level 7, 330 Collins Street, Melbourne Victoria 3000

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.

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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 Therapeutics, Inc.

David McIntyre

Chief Financial Officer Phone +1 661 367 9178

dmcintyre@avitamedical.com

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