

**AVITA MEDICAL, INC. (ASX:AVH)****Form 10-K/A filed with the Securities and Exchange Commission**

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**Valencia, Calif., USA 11 March 2021 and Melbourne, Australia, 12 March 2021:** On 10 March 2021 (United States) / 11 March 2021 (Australia), AVITA Medical, Inc. (**Company**) filed the attached report on Form 10-K/A (**Amendment Filing**) with the Securities and Exchange Commission (**SEC**) for the purpose of amending the Company's Form 10-K for the year ended 30 June 2020 that was filed with the SEC on 27 August 2020 (United States) and with the Australian Securities Exchange on 28 August 2020 (Australia) (**Form 10-K**).

The purpose of the Amendment Filing is to update the Company's disclosure in the Form 10-K in Item 9.A "Controls and Procedures" to include a statement on whether or not internal control over financial reporting was effective as of 30 June 2020. In addition, the Amendment Filing also amends Item 15 of Part IV of the Form 10-K to include as exhibits the new certifications required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended.

Authorised for release by the General Counsel of the Company.

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**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<sup>®</sup> 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<sup>®</sup> 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<sup>™</sup> 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<sup>®</sup> 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](http://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 announcement 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 goals. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Each forward- looking statement contained in this announcement 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 announcement. 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 announcement speak only as of the date of this announcement, and we undertake no obligation to update or revise any of these statements.*

### FOR FURTHER INFORMATION:

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 10-K/A**

(Amendment No. 1)

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☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended June 30, 2020

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-39059



**AVITA MEDICAL, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**85-1021707**  
(IRS Employer  
Identification No.)

28159 Avenue Stanford  
Suite 220  
Valencia, CA 91355  
(Address of principal executive offices and Zip Code)

Registrant's telephone number, including area code: (661) 367-9170

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	RCEL	The NASDAQ Stock Market LLC

Securities registered pursuant to section 12(g) of the Act:  
None

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer”, “accelerated filer”, “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☒

Smaller reporting company ☐

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has selected 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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and nonvoting common equity held by non-affiliates of the registrant was approximately \$963,450,796 on December 31, 2019, using the closing price on that day of \$45.5

The number of shares of the registrant’s \$0.0001 par value common stock outstanding as of August 20, 2020 was 21,468,494.

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## EXPLANATORY NOTE

This amended report on Form 10-K/A (the “Amendment Filing”) amends the annual report on Form 10-K of Avita Medical, Inc. (formerly Avita Therapeutics, Inc.) (the “Registrant”) for the year ended June 30, 2020 initially filed with the Securities and Exchange Commission on August 27, 2020 (the “Original Filing”) for the purpose of updating the disclosure in Item 9.A, Controls and Procedures. Management’s Annual Report on Internal Controls over Financial Reporting contained in Item 9.A of the Original Filing inadvertently omitted a statement on whether or not internal control over financial reporting was effective as of June 30, 2020. This Amendment Filing corrects such omission.

This Amendment Filing also amends Item 15 of Part IV of the Form 10-K solely to include as exhibits the new certifications required by Rule 13a-14(a) under the Securities Exchange Act of 1934, as amended. Because no financial statements have been included in this Amendment Filing, paragraph 3 of the certifications have been omitted. We are not including the certifications under Section 906 of the Sarbanes-Oxley Act of 2002 as no financial statements are being filed with this Amendment Filing. Except as expressly stated, this Amendment does not reflect events occurring after the filing of the Original Filing or modify or update in any way any of the other items or disclosures contained in the Original Filing, including, without limitation, the consolidated financial statements and the related footnotes. Accordingly, this Amendment Filing should be read in conjunction with the Original Filing and the Registrant’s other filings with the SEC subsequent to the filing of the Original Filing.

## PART II

### Item 9A. CONTROLS AND PROCEDURES

#### Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its chief executive officer and chief financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. As required by Rules 13a-15(b) and 15d-15(b) under the Exchange Act, our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of June 30, 2020. Based on this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective as of June 30, 2020.

#### Management’s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for our company, as this term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. As required by Rules 13a-15(e) and 15d-15(e) under the Exchange Act, our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of June 30, 2020, based on the criteria set forth in the Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of June 30, 2020.

This report does not include an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting, in accordance with applicable SEC rules that permit us to provide only management’s report in this report.

#### Changes in Internal Control over Financial Reporting

##### *Remediation of Material Weakness*

Throughout the year ended June 30, 2020, the Company undertook remediation measures related to the previously reported material weaknesses in internal control over financial reporting. We completed these remediation measures during the year ended June 30, 2020, including testing of the design and implementation of the related controls. Specifically, we implemented a more rigorous process to track and monitor our accumulated tax losses and we have hired an external income tax specialist to review our application of tax legislation across jurisdictions. Based on these procedures, we believe that the previously reported material weakness has been remediated.

Other than described above, there was no change in our internal control over financial reporting during the year ended June 30, 2020, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### **Inherent Limitations on Disclosure Controls and Procedures**

Management recognizes that any controls and procedures, no matter how well-designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Because of these inherent limitations, our disclosure controls and procedures may not prevent or detect all instances of fraud, misstatements, or other control issues. In addition, projections of any evaluation of the effectiveness of disclosure or internal controls to future periods are subject to risks, including, among others, that controls may become inadequate because of changes in conditions or that the degree of compliance with policies or procedures may deteriorate.

## PART IV

### Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

#### EXHIBITS

<u>Exhibit Number</u>	<u>Exhibit Description</u>
31.1	<a href="#"><u>Certification of CEO pursuant to Section 302 of The Sarbanes-Oxley Act of 2002</u></a>
31.2	<a href="#"><u>Certification of CFO pursuant to Section 302 of The Sarbanes-Oxley Act of 2002</u></a>



## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### AVITA Medical, Inc.

(Registrant)

Date: March 10, 2021

/s/ Dr. Michael Perry

Dr. Michael Perry  
Chief Executive Officer (Principal Executive Officer)

Date: March 10, 2021

/s/ Sean Ekins

Sean Ekins  
Sr. VP of Finance  
(Interim Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Dr. Michael Perry</u> Dr. Michael Perry	Chief Executive Officer and Director (Principal Executive Officer)	March 10, 2021
<u>/s/ Sean Ekins</u> Sean Ekins	Sr. VP of Finance (Interim Principal Financial and Accounting Officer)	March 10, 2021
<u>/s/ Lou Panaccio</u> Lou Panaccio	Director	March 10, 2021
<u>Jeremy Curnock Cook</u>	Director	
<u>/s/ Louis Drapeau</u> Louis Drapeau	Director	March 10, 2021
<u>/s/ Suzanne Crowe</u> Suzanne Crowe	Director	March 10, 2021

**CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael Perry, certify that:

1. I have reviewed this Amendment No. 1 to the annual report on Form 10-K of Avita Medical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15I and 15d-15I) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: March 10, 2021

/s/ Michael Perry

Name: Michael Perry

Title: President and Chief Executive Officer

**CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Sean Ekins, certify that:

1. I have reviewed this Amendment No. 1 to the annual report on Form 10-K of Avita Medical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15I and 15d-15I) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: March 10, 2021

/s/ Sean Ekins

Name: Sean Ekins

Title: Sr. VP of Finance

(Interim Principal Financial and Accounting Officer)