# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 6–K	
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# REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

**November 13, 2019** 

Commission File Number 001-39059

# **AVITA MEDICAL LIMITED**

(Name of Registrant)

Level 7, 330 Collins Street Melbourne VIC 3000 Australia Tel: +61 (0) 3 8689 9997 Fax: +61 (0) 8 9474 7742 (Address of principal executive office)

ndicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.
Form 20-F $\boxtimes$ Form 40-F $\square$
ndicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): $\Box$
ndicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): $\Box$
ndicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934. Yes $\square$ No $\boxtimes$
f "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82

# AVITA MEDICAL LIMITED

# Form 6-K

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# **EXPLANATORY NOTE**

Avita Medical Limited (the "Company") published an announcement (the "Public Notice") to the Australian Securities Exchange on November 13, 2019 titled "AVITA Medical Announces Institutional Placement of A\$120.0 Million to Support Commercial Growth and Pipeline Development". A copy of the Public Notice is attached as an exhibit to this report on Form 6-K.

This report on Form 6-K (including the exhibit hereto) shall not be deemed to be "filed" for purposes of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and shall not be incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

# **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, thereunto duly authorized.

# **Avita Medical Limited**

By: /s/ Michael Perry

Name: Michael Perry

Title: Chief Executive Officer

Date: November 13, 2019



ASX/News Release

#### AVITA Medical Announces Institutional Placement of A\$120.0 Million to Support Commercial Growth and Pipeline Development

**Valencia, Calif., USA, and Melbourne, Australia, 13 November 2019** — AVITA Medical (ASX: AVH, NASDAQ: RCEL), a regenerative medicine company with a technology platform positioned to address unmet medical needs in therapeutic skin restoration, announced today an institutional placement of A\$120.0 million (Institutional Placement) to fund pipeline development of new indications, including optimizing support for clinical trials and development projects, as well as the Company's continued U.S. commercial growth strategy.

The Institutional Placement was managed by Bell Potter as sole lead manager. Cowen served as financial advisor to the Company in connection with the Institutional Placement. Lake Street Capital Markets also acted as a financial advisor to Avita Medical. The Company has received commitments for A\$120.0 million at an issue price of A\$0.59 per fully paid ordinary share, representing a 7.2 percent discount to the 30-day VWAP, and a 14.5 percent discount to the last closing price on 8 November 2019. The new AVITA shares to be issued under the Institutional Placement will rank equally with existing AVITA shares on issue. The Institutional Placement will occur in a single tranche, and issue 203,389,831 shares to international and Australian sophisticated investors under its 15 percent placement capacity (under ASX Listing Rule 7.1).

"We are grateful for the confidence and conviction of the investors who have joined us in our mission to transform burn care with our revolutionary RECELL® System and to promptly execute on our pipeline of add-on indications," said Dr. Mike Perry, Chief Executive Officer. "This financing reflects our shared excitement for, and strong confidence in, AVITA Medical's myriad near-term growth opportunities. These include trauma/soft tissue reconstruction, vitiligo, our next generation RECELL device to facilitate use of the RECELL System in the outpatient setting, and pediatric scald wounds, as well as efforts to enable research programs to support the advancement and extension of our existing intellectual property. Through diligent and focused execution on our highly de-risked pipeline of new indications, we have the opportunity to access the full potential of our innovative regenerative medicine platform to advance patient care that addresses unmet medical needs, while aggressively growing our top line revenues and ultimately building a robust self-sustaining business."

# Accelerating pipeline development

The funds from the Institutional Placement will enable AVITA Medical to fast-track progression of clinical development programs and to accelerate its broader commercialization strategy. Key initiatives include:

- Initiating U.S. pivotal trials to establish the safety and efficacy of the RECELL System in soft tissue reconstruction and traumatic wounds, as well as early intervention in the treatment of pediatric scald wounds
- Further development and submission to the FDA of a next generation RECELL System to facilitate access to the large outpatient market
- Pilot studies with the RECELL System for the treatment of vitiligo, and subsequent rapid advancement into a pivotal clinical trial to secure
  this indication in the U.S.

- Conducting research and preclinical studies to augment our existing IP portfolio
- Securing marketing approval and reimbursement for the RECELL System in Japan in collaboration with our partner, COSMOTEC, an M3
  Group company targeting patients with burn injuries, soft tissue wounds, chronic wounds (DFUs/VLUs), and vitiligo
- Early phase research into cell and cell-based gene therapy for skin regeneration that either corrects inborn genetic defects of the skin or contributes materially to rejuvenation

In addition to the successful Institutional Placement, the Company's CEO Dr Michael Perry has sold 23,470,000 shares to enable him to meet his tax obligations relating to previously issued Restricted Stock Units (RSU's).

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#### ABOUT AVITA MEDICAL LIMITED

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 REGENERATIVE EPIDERMAL SUSPENSION™ (RES™), 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 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.

# FOR FURTHER INFORMATION:

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