

# AVITA Medical Announces Preliminary Unaudited Results for the Quarter ended December 31, 2021

January 10, 2022

VALENCIA, Calif. and MELBOURNE, Australia., Jan. 10, 2022 (GLOBE NEWSWIRE) -- AVITA Medical, Inc. (NASDAQ: RCEL, ASX:AVH) (the "Company"), a regenerative medicine company that is developing and commercializing a technology platform that enables point-of-care autologous skin restoration for multiple unmet needs, today announced preliminary unaudited estimates of its top line results for the three months ended December 31, 2021.

## Preliminary Results for the Quarter ended December 31 and Recent Updates:

- Total revenue increased 35% to \$6.9 million in the quarter ended December 31, 2021, compared to \$5.1 million over the same quarter in the prior year
- As of December 31, 2021, the Company had approximately \$55.5 million in cash and cash equivalents and \$49.3 million in short-term and long-term marketable securities, and no debt
- Effective December 2021, the Company changed its fiscal year-end to December 31
- Completed enrollment in two clinical trials with the goal of submitting premarket approval (PMA) supplements in 2022
  - In December 2021, completed enrollment of pivotal clinical trial evaluating the safety and effectiveness of the RECELL® System for the repigmentation of stable vitiligo lesions
  - o In January 2022, completed enrollment of pivotal study of RECELL System for soft tissue reconstruction (trauma)
- Successfully established proof of concept with preclinical data in two key areas of cell-based gene therapy skin rejuvenation and epidermolysis bullosa.

"Our recent successes in getting two pivotal clinical trials fully enrolled, and also demonstrating proof of concept in two other potential indications, underscore our commitment to further growing the market opportunities for the RECELL system," said Dr. Mike Perry, AVITA Medical Chief Executive Officer. "Looking ahead, we will be preparing our vitiligo and soft tissue dossiers to submit PMA supplement applications to the FDA in late 2022 for commercial launches for those indications in 2023."

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

## **ABOUT AVITA Medical, Inc.**

AVITA Medical, Inc. is a regenerative medicine company with a technology platform positioned to address unmet medical needs in burns, chronic wounds, and aesthetics indications. AVITA Medical Inc. 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 Medicals' 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 approved for acute partial-thickness thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients. 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 (<a href="https://recellsystem.com/">https://recellsystem.com/</a>) 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 <a href="https://www.avitamedical.com">www.avitamedical.com</a>.

#### **CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This press release 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," "flook 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 press release 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 press release 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 including, but not limited to the ongoing COVID-19 pandemic which are outside of the company's control. Investors should not place considerable reliance on the forward-looking statements contained in this press release. 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 press release 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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