AVITA Medical Updates Full Year 2023 Guidance

November 20, 2023

VALENCIA, Calif., Nov. 20, 2023 (GLOBE NEWSWIRE) -- AVITA Medical, Inc. (NASDAQ: RCEL, ASX: AVH) (the "Company"), a regenerative medicine company leading the development and commercialization of first-in-class devices and autologous cellular therapies for skin restoration, today announced an update to its full year 2023 guidance. This update is a result of slower-than-anticipated progression through the customer's Value Analysis Committee (VAC) processes, driven by the expanded label applications of its newest indication, full-thickness skin defects.

"Our expanded label for full-thickness skin defects opens up an abundance of exciting applications," Jim Corbett, Chief Executive Officer of AVITA Medical. "With a wider range of potential uses, more clinicians within the hospital are engaged in the VAC process, leading to longer hospital approval timelines. Although the VAC processes are taking longer than anticipated, we expect that once completed, the process will yield positive approvals and an expanded market opportunity. The broader clinical involvement validates the substantial market opportunity this expanded label represents, which is greater than 10 times the size of the burn market."

As a result of these dynamics, the Company is revising its expected full year 2023 commercial revenue from the previously disclosed range of $51 million to $53 million to a range of approximately $49.5 million to $50.5 million, with lower and upper bounds reflecting growth rates of approximately 45% and 48%, respectively, over the same period in 2022.

About AVITA Medical, Inc.
AVITA Medical® is a regenerative medicine company leading the development and commercialization of devices and autologous cellular therapies for skin restoration. The RECELL® System technology platform, approved by the Food and Drug Administration for the treatment of thermal burn wounds and full-thickness skin defects and for repigmentation of stable depigmented vitiligo lesions, harnesses the regenerative properties of a patient's own skin to create Spray-On Skin ™ cells. Delivered at the point-of-care, RECELL enables improved clinical outcomes. RECELL is the catalyst of a new treatment paradigm and AVITA Medical is leveraging its proven and differentiated capabilities to develop first-in-class cellular therapies for multiple indications.

In international markets, our products are approved under the RECELL System brand to promote skin healing in a wide range of applications including burns, full-thickness skin defects, and vitiligo. The RECELL System is TGA-registered in Australia, received CE-mark approval in Europe and has PMDA approval in Japan.

To learn more, visit www.avitamedical.com.

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," "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 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 goal. 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 statements. Applicable risks and uncertainties include, among others, the timing and realization 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 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.

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