

# **AVITA Therapeutics Provides Company Update and Revised Corporate Presentation**

August 26, 2020

VALENCIA, Calif. & MELBOURNE, Australia--(BUSINESS WIRE)--Aug. 26, 2020-- AVITA Therapeutics, Inc. (NASDAQ: RCEL, ASX: AVH), 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 provided an update on corporate developments.

### • U.S. RECELL® System Sales:

- o July represented the highest monthly sales for RECELL Systems in the United States since launch in January
- Unaudited sales for the RECELL System in July were U.S.\$1.83 million.
- July also witnessed very broad utilization of the RECELL System with 57 unique account orders, and more than 90 physicians using the RECELL System.
- AVITA expects quarterly revenue in the September quarter to resume growth, and for sales to exceed the U.S.\$3.9 million previously reported for the three (3) months ended June 30, 2020.
  - Recall that in the quarter ended June 30, 2020 revenue was deeply impacted by COVID in the United States with sales in the month of April down approximately 25% (versus the previous month).
  - Revenue then recovered in both May and June to deliver a flat sequential quarterly revenue result from the March quarter to the June quarter.

#### · Clinical Studies:

- As previously advised, the U.S. Food & Drug Administration (FDA) granted an investigational device exemption (IDE) to support a vitiligo pivotal study on July 2<sup>nd</sup>, 2020.
- Since receipt of the IDE, the Company has worked aggressively to obtain investigational review board approval (IRB) to support initiation of this study, together with commencing contracting discussions with potential clinical sites.
- AVITA expects to treat our first vitiligo patient during September 2020.
- There is a very high degree of both patient and clinical site enthusiasm in participating in our vitiligo pivotal study. Further, the Company continues to believe that the RECELL System is uniquely positioned to offer vitiligo patients a single curative therapy given that the RECELL System has been used to treat over 1,000 vitiligo patients internationally, and has been shown to provide patient benefits to vitiligo patients in eight (8) peer-reviewed publications.
- AVITA is also actively endeavoring to increase the number of clinical studies participating in each of our clinical studies. Additional clinical study sites have recently been added to both the pediatric scald and the soft tissue pivotal studies, and more sites are expected to be onboarded over the next few months.

#### Corporate:

- The Company expects to release its Annual Report for the twelve (12) months ended June 30, 2020 on August 28<sup>th</sup>.
- The Company will participate both in the Morgan Stanley Virtual 18th Annual Global Healthcare Conference and the Cantor Global Healthcare Conference, which are both scheduled to take place in September.
- A copy of the Company's revised corporate presentation is available on the Company's website.

For more detailed information on the Company's recent developments, please see our press release dated July 10, 2020 (which is available on both the Company's and ASX's website).

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

## 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 <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.

AVITA Therapeutics' 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™ 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 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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