

## Avita Medical and BARDA Execute a US\$24.3m Contract Option

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**Valencia, CA, USA, Perth, Australia and London, United Kingdom, 21 September 2017** — Avita Medical (ASX: [AVH](#)), (OTCQX: [AVMXY](#)), a regenerative medicine company specializing in the treatment of wounds and skin defects, today announced the execution of an expanded contract option valued at approximately US\$24.3 million. This newly executed contract option establishes funding for key clinical and health economics research in U.S. pediatric burn care and extends Avita's [Project Bioshield](#) contract through to September 2022.

The option execution relates to an original contract between Avita Medical and the [Biomedical Advanced Research and Development Authority](#) (BARDA), a division of the U.S. Department of Health and Human Services, [Office of the Assistant Secretary for Preparedness and Response](#) (ASPR).

Avita Medical has had a strong relationship with BARDA since the execution of a five-year contract in September 2015. Under the base contract BARDA made an initial investment of US\$16.9 million to support Avita's ongoing U.S. clinical regulatory program towards FDA Premarket Approval (PMA), and to procure 5,000-plus ReCell® devices. The contract also allowed BARDA to exercise future options to support additional clinical trials, and provide surge capacity for up to another 20,000 ReCell® devices. Supplemental funding worth up to US\$7.96 million was also provided to Avita under the contract in June of 2016, to provide further operational support to Avita's PMA preparation and Compassionate Use program. Both objectives support BARDA's overarching goal of building burn care preparedness, by securing effective medical countermeasures for burn injuries for use in case of a mass casualty.

The base contract between BARDA and Avita Medical has provided substantial support to the shared primary goals of achieving U.S. regulatory approval for the Company's ReCell® Autologous Cell Harvesting Device thus establishing preparedness for a potential U.S. mass casualty event involving thermal burn injuries.

Pediatric burn care is of particular concern to BARDA and Avita, as the primary modality for treatment continues to involve harvesting the patient's own skin for autografts. Thirty percent of burns in the U.S. occur in patients under 16 years of age.<sup>i</sup> In the pediatric population, donor skin comes at a high premium due to limited availability and distinct increases in morbidity associated with harvesting skin for conventional autografts. Pediatric use is of interest to BARDA because MCM development must include at-risk, vulnerable populations such as children.

Two randomized control trials (RCTs), powered to demonstrate statistical significance, have been presented to the FDA via the pre-submission process. One trial focuses on characterizing benefit derived from use of Regenerative Epithelial Suspension prepared using the ReCell® device to treat donor sites in patients aged 1 to 16 years. The other trial, planned to run in parallel, will aim to show decreases both in time to healing and in the frequency of conventional autografting in patients of the same age range who have suffered second-degree burn injuries. Second-degree burns often result from scald injuries, accounting for approximately 60% of burns in the U.S. in the study population.<sup>i</sup> The two-cohort study design, planned to include collection of costing data in addition to clinical data, will further inform both clinical and health economic benefits of using ReCell®. Both studies will compare treatment using the ReCell® device versus current standard approaches. Up to twenty U.S. burn centers may be involved in

recruiting patients into these studies.

“Continued development of the foundation of evidence supporting the use of ReCell® is essential for elevating the standard of care in pediatric burns. These studies will contribute substantially toward rounding out the story and enabling changes to burn care in everyday clinical practice,” said Andrew Quick, Sr. VP of Clinical Development.

<sup>i</sup> [2016 National Burn Repository Report of Data from 2006-2015, The American Burn Association](#)

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## **ABOUT AVITA MEDICAL LIMITED**

Avita’s patented and proprietary collection and application technology provides innovative treatment solutions derived from the regenerative properties of a patient’s own skin. Our medical devices work by preparing a Regenerative Epithelial Suspension (RES™), an autologous suspension comprised of the patients’ own skin cells and wound healing factors that are necessary to regenerate natural healthy skin. This is then applied to the area to be treated.

In all countries outside of Europe, our portfolio is marketed under the ReCell® brand to promote skin healing in a wide range of applications including burns, chronic wounds and aesthetics.

ReCell® is TGA-registered in Australia, and CFDA-cleared in China. In the United States, ReCell® is an investigational device limited by federal law to investigational use.

In Europe, our portfolio of medical device products received CE-mark approval as three tailored product presentations, with three individual brand names. ReCell® is designed for the treatment of burns and plastic reconstructive procedures; ReGenerCell™ has been formulated for chronic wounds including leg and foot ulcers; and ReNovaCell™ is tailored for aesthetic applications including the restoration of pigmentation.

To learn more, visit [www.avitamedical.com](http://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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**FOR FURTHER INFORMATION:**

<p><b>Australia</b> <b>Monsoon Communications</b> Sarah Kemter Phone: +61 (0)3 9620 3333 Mobile: +61 (0)407 162 530 <a href="mailto:sarahk@monsoon.com.au">sarahk@monsoon.com.au</a></p>	<p><b>USA</b> <b>Westwicke Partners</b> Jamar Ismail Phone +1 (415) 513-1282 <a href="mailto:jamar.ismail@westwicke.com">jamar.ismail@westwicke.com</a></p>
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