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## Avita Medical Awarded US\$7.96m in BARDA Extension Deal

- *Additional non-dilutive funds to accelerate US market approval and product launch*
- *Support aims to increase familiarity/acceptance in US burn centers, demonstrate economic benefits and increase acceptance of ReCell® in US Burns Centers*
- *Funds will be deployed to support recruitment of additional US operational staff*

**Northridge, CA, Perth, Australia and Cambridge, United Kingdom, 27 June 2016** — A US Federal authority charged with supporting development of medical countermeasures for possible mass casualty events has agreed to fund Avita Medical a further \$US7.96 million to support the regenerative medicine company in its plans for US market approval and product launch of ReCell®, the Company said today.

Avita Medical Limited, (ASX:AVH; OTCQX:AVMXY) which makes Autologous Cell Harvesting Devices for treatment of burns, chronic wounds and certain aesthetic conditions, said the award supplements the contract executed last September with the Biomedical Advanced Research and Development Authority (BARDA), worth up to \$US53.9m. The initial contract with BARDA, an authority under the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services, includes procurement and various elements of support for late-stage development of ReCell®. The new contract addendum, worth up to \$US7.96 million (AUD \$11m), commences immediately, giving further operational support to facilitate the overarching objective of BARDA for preparedness via securing effective treatment of burn injuries secondary to detonation of a nuclear device.

The additional funds will bolster ongoing work toward the Company's filing of a PMA application, along with funding new initiatives toward gaining familiarity and acceptance of ReCell® within US Burn Centers, including health economic modelling of the benefits associated with ReCell® for burns treatment and continuing engagement with US Burn Centers for use of ReCell® under the Company's open Investigational Device Exemptions (IDEs) for treatment of a range of burn injuries including the particularly extensive burns associated with Compassionate Use. Towards this, Avita will utilize these funds towards recruitment of new personnel at the Company's office in Northridge, California. The new staff will be focused on such operational areas as regulatory, supply chain, quality systems, clinical support and reimbursement.

"This welcome infusion of significant non-dilutive capital to fund our activities in the US, which we would otherwise have had to fund ourselves, greatly supports Avita Medical on its commercial journey," said Avita CEO Adam Kelliher. "We are particularly excited about the health economics support, which we hope will enable us to show how innovative approaches such as ours can both help burn victims and save money as these are the key drivers to support our reimbursement efforts."

BARDA's initial contract funds the completion of Avita's FDA approval trial, for which all treatments have now been completed, and the cohort is currently being observed over a 52-week safety period. As well as an initial procurement of some 5,000 devices, the contract also funds an education programme, so that burns surgeons across the US will be trained as well as supplied with the medical devices, should there be a mass casualty event involving numerous burn injuries. The procurement order could be

placed prior to FDA approval based on the possibility for deployment of ReCell® devices under an Emergency Use Authorisation. The Company said it is in close communication with BARDA on the progress of its FDA approval pathway, which is scheduled to complete in calendar Q3 2017.

#### **ABOUT RECELL® AND RES™**

ReCell® is Avita Medical's unique proprietary technology that enables a clinician to rapidly create, at point of care in approximately 30 minutes, Regenerative Epithelial Suspension (RES™) using a small sample of the patient's skin. RES™ is an autologous suspension comprising the cells and wound healing factors necessary to regenerate natural, healthy skin. RES™ has a broad range of applications and can be used to restart healing in unresponsive wounds, to repair burns using less donor skin, yet with improved functional and aesthetic outcomes, and to restore pigmentation and improve cosmesis of damaged skin.

#### **ABOUT AVITA MEDICAL LTD**

Avita Medical develops and distributes regenerative products for the treatment of a broad range of wounds, scars and skin defects. Avita's patented and proprietary collection and application technology provides innovative treatment solutions derived from a patient's own skin. The company's lead product, ReCell®, is used in the treatment of a wide variety of burns, plastic, reconstructive and cosmetic procedures. ReCell® is patented, CE-marked for Europe, 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. To learn more, visit [www.avitamedical.com](http://www.avitamedical.com).

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#### **FOR FURTHER INFORMATION**

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