ASX | News Release

Avita Medical Awarded US Government Contract valued at up to $53.9m USD

Avita's ReCell® device receives support for FDA approval and to be procured by US Biomedical Advanced Research and Development Authority (BARDA) under federal preparedness plan for mass casualty events

Highlights

- BARDA contract commits initial USD$16.9m to support Avita's FDA approval trial for treatment of thermal burn injuries and procure 5000-plus ReCell® devices
- Contract also establishes a strategic, Avita-managed stockpile for ReCell® devices to supply nationally
- A further potential to receive USD$37m in contract options to support additional clinical trials and provide surge capacity for up to 20,000 ReCell® devices
- Contract aim is to address BARDA's stated requirement for autograft-sparing products intended to bolster the government's ability to respond to potential sudden surges in burn care, and improve the standard of US burn care

Australia, 30 September 2015 — Avita Medical Ltd. (ASX: AVH), (OTCQX: AVMXY), a medical device company specializing in the treatment of wounds and skin defects, has been awarded a contract with the Biomedical Advanced Research and Development Authority (BARDA) worth up to USD$53.9 million for late-stage clinical development and procurement of its ReCell® Autologous Cell Harvesting Device under a US mass casualty preparedness program.

The contract, which will run for five years, commits funding of USD$16.9m to support Avita's ongoing US clinical regulatory programme towards FDA Premarket Approval (PMA) and to procure more than 5,000 ReCell® devices to establish an inventory so that ReCell can be deployed to help deal with a mass casualty scenario involving burn injuries. Under the contract, Avita also has the potential to receive up to USD$37m when contract options are executed which provide support for further clinical studies potentially required by the FDA as part of post-market surveillance, or as needed to expand the use of ReCell® to the paediatric population. Lastly, additional contract options provide the US government with surge capacity, supplementing a national stockpile of ReCell® devices. Total procurement under the contract would cover more than 25,000 devices.

BARDA is a US federal agency assigned to ensure the United States is well prepared for public health emergencies. The agency is within the Office of the Assistant Secretary for Preparedness and Response in the US Department of Health and Human Services, and one of its core aims is to develop medical countermeasures to mitigate the medical consequences from potential chemical, biological, radiation and nuclear threats.

ReCell® first gained prominence as a treatment for burns victims following the 2002 bombing in Bali, Indonesia, and was deployed in recent months in another mass casualty event: the Taiwan waterpark disaster. The single-use device is simple to use, and allows medical professionals to quickly make a Regenerative Epithelial Suspension™, which can be immediately applied to a burn. Clinical data have shown that the method can improve short-term healing and provide superior long-term outcomes. In terms of autograft-sparing capability, RES™ can be created using only small skin samples, significantly reducing the need for skin donor sites.

Avita Chief Executive Officer Mr Adam Kelliher said the BARDA agreement was a "transformational opportunity" for the company.

"Securing this contract from a US federal agency is a momentous milestone. US authorities have conducted a detailed evaluation of our technology and this contract further validates the opportunity afforded by our unique regenerative medicine," he said.

"Further, this deal highlights the importance of preparedness for mass casualties. We look forward to meeting BARDA's criteria for large-scale product delivery."

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 LIMITED

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. A pivotal US trial is underway, with patient enrollment completion anticipated by the end of 2015. To learn more, visit www.avitamedical.com.

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FOR FURTHER INFORMATION

Avita Medical Ltd
Adam Kelliher
Chief Executive Officer
Phone: +44 (0) 1763 269 772
akelliher@avitamedical.com

Avita Medical Ltd
Tim Rooney
Chief Financial Officer
Phone: + 1 (818) 356-9400
trooney@avitamedical.com

Avita Medical Ltd
Gabriel Chiappini
Company Secretary
Phone: +61(0) 8 9474 7738
gabriel@laurus.net.au

The Ruth Group
Lee Roth, Investor Relations
Kirsten Thomas, Public Relations
Phone: +1 (646) 536-7012 / +1 (508) 280-6592
lroth@theruthgroup.com/ kthomas@theruthgroup.com