MEDIA RELEASE



ASX ANNOUNCEMENT

RECEIPT OF US\$400K TO COMMENCE AFIRM STUDY

- Receipt of initial US\$400K pre- payment from AFIRM
- Investigational Sites confirmed
- Initial training
- Preliminary data from pilot trial extremely positive to be presented at EBA

13 August 2009: Avita Medical Ltd (ASX: AVH) has received an initial US\$400k (AU\$480K) payment as part of the US\$1.45 million grant awarded by the US Department of Defense. In May the company announced award of the grant through the newly established US Armed Forces Institute of Regenerative Medicine (AFIRM). The start date for the award was 3 June 2009.

Ten US clinical investigational sites will participate in the study. The Company has completed the screening and selection of participating sites which includes major armed forces, private and university hospitals and burns centres.

Investigators include many high profile burns specialist including, among others, the President of the American Burns Association, the Editor-in-Chief for the prestigious professional journal *Burns*, the Dean of the Loyola University School of Medicine, the Director of the United States Army Institute of Surgical Research Center, and the Vice-Chairman, Department of Surgery, University of Texas Health Science Center.

A meeting of investigators and key support staff was held in early July at Wake Forest University Baptist Medical Center in North Carolina, US. Initial training of investigators was also conducted at this 2-day meeting. The company is completing negotiations on final contracts with investigational sites.

Although over 2,500 patients have been treated with ReCell outside of the US to date, data from a small pilot trial conducted at 2 of the participating sites (Wishard Hospital Burn Center, Indiana, and Wake Forest University Baptist Medical Center, North Carolina) has been collected and analysed to support substantial claims regarding the performance of the ReCell regenerative technology.

Avita Medical CEO Dr William Dolphin said, "The pilot data obtained at the US sites are extremely encouraging – not unexpected and in keeping with previously published results on the use of ReCell in the treatment of burns, but confirmatory data is always welcome." The pilot study compared healing rates in burn victims treated with split thickness skin grafts (STSG, the current standard of care) and ReCell. The ReCell technology performed extremely well, with 10 of 14 patients displaying 'full healing' within 2 weeks and 13/14 within 3 weeks. Average healing time for STSG is 4-5 weeks.

The results from the pilot study will be presented at the European Burns Association Meeting in Lausanne, Switzerland 3-5 September 2009; results of additional, unrelated clinical studies with ReCell incorporating data from clinics in the United Kingdom and France will be presented separately at the conference.

Dr. James Holmes, Director, Burn Center, Wake Forest University Baptist Medical Center said, "ReCell is a game-changing technology that I believe will offer tremendous benefits to



the military and civilian populations, reducing morbidity, mortality and length of hospital stay."

Avita Medical CEO Dr William Dolphin said, "Laying of the necessary groundwork for the AFIRM study is progressing rapidly to plan. We have an outstanding, highly influential and highly supportive group of surgeons participating in the study and we are looking forward to initiating recruitment into the study."

In addition to developing clinical treatments, AFIRM will serve as a training facility to develop experts in treating trauma using regenerative medicine, likely to positively impact the uptake of ReCell as a new standard of care for burns and wounds treatment in the future.

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ABOUT AVITA MEDICAL LIMITED

Avita Medical Limited (<u>www.avitamedical.com</u>) is a publicly listed, global medical technology company that develops and distributes regenerative and tissue-engineered products for the treatment of a wide range of wounds, scars and skin defects. Using proprietary tissue-culture/collection technology, the company is able to provide innovative treatment solutions derived from the patient's own skin, to enhance healing rates, reduce scar formation and reintroduce pigmentation into the skin.

ReCell[®] is a stand-alone, rapid cell harvesting device that enables surgeons to treat skin defects using the patient's own cells. The surgeon can prepare a small quantity of cells within 30 minutes on site, replacing the need for skin grafts and obviating the requirement for culturing laboratories. ReCell[®] has been designed for use in a wide variety of burns, plastic, reconstructive and cosmetic procedures. ReCell[®] is gaining acceptance in a number of indications including Vitiligo, a common skin pigmentation disease.

ReCell[®] is patented, CE marked for the EU and TGA registered in Australia

ABOUT AFIRM

The US Army Medical Research and Materiel Command has established the Armed Forces Institute of Regenerative Medicine (AFIRM) dedicated to repairing battlefield injuries through the use of regenerative medicine. The AFIRM program was established in April 2008 in conjunction with the Office of Naval Research, the National Institutes of Health, the Air Force, Office of the Surgeon General and the Department of Veterans Affairs.

AFIRM is made up of two multi-institutional consortia comprised of over 20 academic and commercial entities spearheaded by the Institute for Regenerative Medicine at Wake Forest



University Baptist Medical Center in North Carolina, United States and Rutgers University in New Jersey working closely with the U.S. Army Institute of Surgical Research in San Antonio, Texas.

AFIRM is dedicated to developing the science of regenerative medicine and bringing transformational technologies to wounded soldiers. Regenerative medicine takes advantage of the body's natural healing powers to restore or replace damaged tissue and organs. Regenerative medicine encompasses many novel approaches for the treatment of damaged tissues and organs by using therapies that prompt the body to autonomously regenerate, and by using the patient's own cells, for the creation of engineered tissues or organs for therapy.

Therapies developed by AFIRM will also benefit people in the civilian population with burns or severe trauma.