



ASX/MEDIA RELEASE

POSITIVE INTERIM RESULTS FOR CLINICAL TRIAL

- *5 Patients treated with immediate and significant improvement*
- *Rapid path to regulatory approval as a medical device*

SYDNEY 6 DECEMBER, 2010 – Australia’s largest manufacturer of orthopaedic devices, Advanced Surgical Design and Manufacture Limited (ASDM) (ASX: AMT), today announced highly positive interim results for the first 5 patients enrolled in its PAD Clinical Trial.

The PAD Device is a unique implantable medical device for the reperfusion of limbs and in the treatment of patients suffering chronic peripheral artery disease and the pending amputation of a limb.

To date 5 patients have been implanted with the device in this Trial. Importantly, all treated patients have been discharged from hospital with significant improvement in blood flow together with immediate and significant reduction in chronic pain. One patient however returned to hospital at a later date when it was determined that the diseased limb had progressed beyond any reasonable point of recovery due to extensive pre-existing gangrene.

ASDM is both Sponsor of the Clinical Trial and manufacturer of the device. The purpose of the Trial is first and foremost to assist patients in significantly improving their quality of life. Additionally, the Trial will be used to collect clinical evidence as part of national and international regulatory requirements for a Class III device. Nevertheless, as a medical device, ASDM would expect regulatory approvals to be significantly faster than for a pharmaceutical treatment, thereby shortening the time to get this technology to market.

The timing and recruitment of patients for the Trial is under the complete management of Prof. Rod Lane as both principal investigator and inventor of the treatment.

Peripheral artery disease is a major source of morbidity and mortality. Currently over 1,000 limbs are amputated daily in the western world. Approximately 40% of amputees die within 12 months of amputation. The market for a device in the field is currently estimated to be approximately \$1.2B annually and growing rapidly.

ASDM CEO and Managing Director Dr Greg Roger said, “We’re very encouraged by the early results from this Trial. Peripheral Artery Disease is a terribly debilitating, painful disease. We hope to be able to bring this innovative technology quickly to market and to help the many thousands of patients who are currently offered amputation as the only means of ending the shocking pain that these people suffer over a period of years”.

ABOUT PAD

The HELP treatment, is focused on patients who have no alternative other than major limb amputation and was invented by Prof Rod Lane of Macquarie University. Developed at ASDM with Prof Lane, the PAD device returns arterial blood flow to legs which have arteries clogged most often caused by the ravages of smoking and diabetes. More than 1,000 legs each day are amputated in the Western World for this condition. Often patients undergo many previous surgeries to attempt to save affected limbs. Amputation is life-threatening surgery with approximately 40% mortality within 12 months of amputation.

ASDM is the Sponsor of the 40 patient Trial being carried out in Australia. In each of these first five cases the use of ASDM's PAD access device met the primary immediate goals of the Trial for all treatment sessions. The first case, with significantly advanced and complex pathology, subsequently went on to amputation, while the following four patients, also requiring imminent major amputation at the time of admission to the trial, have now been discharged from hospital with their legs intact. The end point of the study, at 6 months after treatment, is yet to be reached for these patients.

Prof. Rod Lane, in his interim report, stated:

“5 patients have been treated with regional hyperperfusion for critical limb ischaemia after enrolment by HELP trial investigators (vascular surgeons). All were facing major amputation and all of the normal standard vascular approaches had been exhausted. All had rest pain, ischaemic ulcers, or gangrene. All patients had given informed consent.

RESULTS:

All patients had implantation of extraction and inflow devices with immediate significant pain relief. All 5 had significant improvement in the non-invasive estimates of blood flow. All patients were discharged with limbs intact. In 3 patients there was no gangrene, the ulcers had healed and there was no rest pain. One had significant residual gangrene and one had a healed ulcer but significant residual gangrene.”

Prof Lane further said, “As a practicing surgeon these results give great hope that we may soon be able to save thousand of patients’ legs, improve their quality of living and cut healthcare costs for this terrible condition. For the patients themselves, each leg saved, along with the relief from pain and ulceration, is a great result.”

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ABOUT ADVANCED SURGICAL DESIGN AND MANUFACTURE

ASDM is Australia's largest manufacturer of orthopaedic devices. Our focus is to deliver exceptional service. Our goal is to build a large and highly profitable medical technology company.

Our principal product is the Active Total Knee, which has significantly improved the quality of life for 4,500 people globally. Our sales and technical support reach covers Australia, US, and Europe.

We also exclusively distribute, Permedica S.p.A., Arthrosurface Inc, Geistlich AG and Parcus Medical LLC implantable orthopaedic devices, accessories and surgical instruments.

ASDM is a high quality organisation which provides a professional and effective integrated service to surgeons. Furthermore, ASDM has a long track record of successfully bring products to market and translating intellectual property into profit.

The company continues to build upon its extensive patent and product development portfolio. We have extensive research relationships with universities, companies and surgeon inventors. Our partnerships are building innovative products, which will deliver significant shareholder wealth.

For more information, please visit www.asdm.com.au