

30 September 2011

VitroGro® Sales to Start Second Quarter 2012

Key Points:

- **Commercial negotiations** are proceeding well. The Company is confident that an announcement will be made during November 2011 and sales of VitroGro® to treat chronic wounds are expected to start in the UK and Europe during the 2nd quarter of calendar 2012, as planned.
- **EU Approval for Sale:** The EU human trial of VitroGro® has been completed and the final report is expected during October 2011. The EU regulatory consultant is confident that the results already achieved (**ASX:TIS** Strong New Clinical Trial Data, 14 July 2011) are sufficient for EU approval for sale. On track for start of sales during the 2nd quarter 2012.
- **Manufacturing:** VitroGro® has been produced with the larger scale manufacturing system and final packaging of ready-to-sell VitroGro® is about to start.
- **FDA:** Request for Designation result is expected by the end of October 2011. Expert regulatory consultants are confident of device classification. Recruitment for the FDA venous ulcer trial of VitroGro® is planned to start during December 2011.

Biomedical company, **Tissue Therapies Limited (ASX: TIS)** has released an update on the key commercial activities associated with the commencement of sales of VitroGro® for the treatment of chronic wounds in the EU (including the UK) and preparation for US FDA approval.

Current global economic conditions have made establishing an attractive commercial arrangement more difficult but negotiations are now well advanced and an announcement is planned during November 2011. This will allow sufficient preparation time for the planned sales launch in the UK and Europe during the second quarter of 2012.

The clinical trial required for EU approval for sale is now complete. The internationally respected wound healing clinician and researcher Professor Keith Harding is performing the analysis of the results and the final report will be provided to Tissue Therapies during October 2011. The EU regulatory consultant working with Tissue Therapies is confident that the human trial data already announced is sufficient for approval for sale.

Preparation for reimbursement approvals in the UK and European countries are also well advanced. The ideal initial customers are specialist hospital and wound care clinics and sales to these centres do not require reimbursement approvals.

Manufacturing of VitroGro® to the desired larger scale has been successfully completed to the Good Manufacturing Practice (GMP) standard required for human use. Final packaging design consistent with regulatory and commercial requirements is complete and packaging of ready-for-sale VitroGro® is about to start.

The Company took advantage of the opportunity for an expert consulting review of the USA FDA Request for Designation (RFD) application prior to its submission. This regulatory consulting group includes two former Directors of the FDA. These consultants are confident that the RFD will result in a successful device classification.

Preparations for the FDA clinical trial of VitroGro® for the treatment of venous ulcers are almost complete. The Chief Clinical Investigator and Clinical Research Organisation have been appointed, the protocol has been finalised, site selection is underway and patient recruitment is planned to start during December 2011.

The CEO of Tissue Therapies, Dr Steven Mercer said, "We are delighted to now be so close to the start of sales of VitroGro® for the treatment of chronic wounds."

"As part of our preparation for sales, the Tissue Therapies Chief Scientist Professor Zee Upton and I recently met with more than twenty key wound care opinion leaders in the UK and Europe. They were unanimous in their praise of the careful, scientific approach we have taken in the development of VitroGro® and are impatient to start using VitroGro® to treat their patients."

He went on to say, "I am looking forward to our launch in the UK and Europe and am confident of a strong market acceptance of VitroGro®."

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About Tissue Therapies Limited

Tissue Therapies Limited is an Australian company developing biomedical technologies for wound healing, tissue repair, cell culture and other applications.

The Company has worldwide exclusive rights to commercialise VitroGro®, a technology developed by cell biology, tissue engineering and protein engineering experts at the Institute of Health and Biomedical Innovation (IHBI) at the Queensland University of Technology (QUT) for enhancing cell growth and migration. VitroGro® has particular commercial applications in wound healing, tissue regeneration, cell-based therapies and cell culture.

Based on its VitroGro® technology, Tissue Therapies is developing more effective treatments for acute and chronic wound healing applications including chronic skin ulcers and burns.

Tissue Therapies is also proceeding with the development of other commercial applications for VitroGro® and other technologies for the treatment of psoriasis, scar prevention and treatment and potential treatments for various cancers including those of the breast, colon and prostate.

VitroGro® also provides a fundamental, transforming technology for completely defined cell culture reagents (ie. containing no purified animal or human proteins) to sustain and enhance the growth of live cells for emerging cell-based therapies, along with research and industrial cell culture markets internationally.

More information: www.tissuetherapies.com