



## ASX ANNOUNCEMENT

27 March 2012

### **VitroGro® Sales Planned to Start in June 2012**

Biomedical company Tissue Therapies Limited (**ASX: TIS**) is pleased to confirm that the final submission for CE Mark approval has been lodged.

The Chief Executive, Dr Steven Mercer said, "We are confident that this will result in CE Mark by the end of May 2012, well before the planned start of sales during the last week of June 2012."

He said, "Our recruitment of experienced European sales personnel has been carefully timed to coincide with the start of the new European calendar business year. Sales staff hiring is proceeding well but as expected, it is the time limiting factor that determines the start of sales in June 2012."

"There is strong interest already in VitroGro® from key wound care clinical staff in the UK and Europe and the sales and marketing campaign is ready to proceed immediately following CE Mark approval."

This integrated sales and marketing launch plan includes conference presentations, publications, advertising, key-message marketing materials and a major website revision, including multilingual capabilities.

Dr Mercer explained that historic changes in the wound treatment market are magnifying the competitive advantages of VitroGro® and Tissue Therapies.

"Insurers, reimbursement agencies and governments are increasingly demanding solid science, strong clinical results and convincing health economic data."

"This data has not traditionally been required for the approval and reimbursement of wound care products and Tissue Therapies is one of very few wound care companies that can supply all of this."

The CE approval process is well advanced, with all audits successfully completed. While the final submission to obtain CE Mark for VitroGro® could have been made earlier, there are commercially important benefits to Tissue Therapies in minimising the time between approval and the start of sales, including:

- Deferral of the final CE Mark submission by two months will extend the expiry date of the initial batches of VitroGro by two months. Sales estimates for these last two months prior to initial expiry are significant.
- New analysis work with packaging partner Catalent has revealed that repackaging VitroGro® for expiry date extension will be uneconomic: any unsold stock of VitroGro® finished product with the initial expiry date may have to be destroyed when the expiry date is reached in September 2013.

- Large scale manufacturing of commercial batches of VitroGro® was required for validation and regulatory approval. The difference between supply and demand only applies to the initial batches of VitroGro® because progressive expiry date extension of each subsequent batch and increasing sales will align production and demand.
- Extension of the expiry date of the initial batches of VitroGro® by two months defers the costs of manufacturing the next batch by two months.
- Deferral of the final CE data submission by two months has also delivered the additional benefit of allowing time for completion of the validation data required for US FDA submissions, saving future time and costs for FDA approvals.

The CEO of Tissue Therapies, Dr Steven Mercer said, “It has only become evident recently that repackaging / relabelling to allow for the extension of the VitroGro® final product expiry date is likely to be uneconomic and we have therefore had to carefully analyse our options to maximise Tissue Therapies’ position when the initial batches expire.”

He also said, “Deferring the final CE Mark data submission is commercially logical given that this has no effect on the start of sales and yet delivers significant financial benefits to Tissue Therapies.”

“Based on market feedback to our published science, health economics data and clinical results, we believe that VitroGro® will hold a strong competitive advantage over existing wound treatment products in our target markets.”

“We are convinced this will be one of the most important product launches in the wound care market for many years and are working hard to ensure the maximum impact.”

## What is VitroGro®

- VitroGro® ECM is a biomimetic scaffold that is sterile, acellular and flowable (designed to be applied to the surface of wounds).
- It is an artificially created matrix protein designed from polypeptide sequences that normally provide attachment sites in healthy skin that guide cells during normal wound healing.
- In chronic (non-healing) wounds, skin cells are deprived of these attachment sites because the extracellular matrix (ECM) is degraded.
- VitroGro® ECM restores normal wound healing by replacing the degraded ECM with a scaffold containing the attachment sites that guide skin cell attachment, proliferation and migration (the essential processes of normal wound healing).
- VitroGro® ECM is a temporary matrix that is designed to be replaced through the normal process of tissue restoration and turnover.
- VitroGro® ECM consistently and conveniently restores healing in chronic ulcers that have failed to respond to current expert care.
- Expert health economics modelling indicates that VitroGro® ECM offers the opportunity for substantially more cost effective treatment of wounds compared to the current standard of care.

## 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 to enhance cell growth and migration 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). 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 of various VitroGro® and other technologies for the treatment of psoriasis, scar prevention 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](http://www.tissuetherapies.com)