



ASX ANNOUNCEMENT

23 July 2009

Excellent Preclinical Results for New Formulation VitroGro® & Progressive Human Trial Results

Preclinical Results of New Formulation Single-Protein VitroGro®

Biomedical company, **Tissue Therapies Limited (ASX: TIS)** has announced receipt of exceptional preclinical results for two new formulations of VitroGro®, as summarised in the charts at the end of this announcement.

Both new formulations of VitroGro® package into a single-protein, the same wound healing biology as the original multi-protein VitroGro®. As can be seen in the summary charts, New Formulation VitroGro®1 is more efficient than both the original multi-protein formulation and New Formulation VitroGro® 2. These results are consistent with the laboratory data Tissue Therapies already has, including that from the live human skin model developed by scientists at QUT.

Healing (re-epithelialisation) was faster for New Formulation VitroGro® 1 (VG 1) and this is the formulation that Tissue Therapies will proceed to manufacture for clinical trial and regulatory approval for sale, as per the Key Milestones already announced (please see **ASX: TIS Rights Issue Prospectus, 28 January 2009**).

The commercial benefits of achieving wound healing with the single-protein New Formulation VitroGro® 1 instead of the original multi-protein VitroGro® include:

1. reduced cost and time of manufacture
2. reduced cost and time of preparation and testing for clinical trial approval
3. reduced cost and time for regulatory approval
4. reduced cost and time of incorporation into wound dressings
5. reduced patient cost of VitroGro® wound dressing products, for faster and wider market penetration
6. improved margins to Tissue Therapies and collaboration partners

VitroGro® Human Trial Update

The already reported Australia clinical trial of 8 venous ulcer patients treated with VitroGro® for only 2 weeks showed a reduction in median wound area from 9.2 to 5.2 square centimetres in 24 days. (Please see **ASX: TIS Results of VitroGro® Venous Ulcer Human Trial, 19 January 2009**. This rate of healing was highly statistically significant ($p < 0.01$) and was an excellent result particularly when the best available treatment had failed for up to 2 years.

The human trial of VitroGro® in Toronto, Canada continues to produce excellent results but Tissue Therapies has been informed that patient recruitment has been disappointingly slow.

To date 8 Canadian patients have been recruited and clinical data for 6 of these has been provided to Tissue Therapies and is summarised in the following pages. Under the approved Canadian clinical trial protocol, patients were treated with VitroGro® once per week for 6 weeks. The following data includes the results of the 2 patients already announced (please see **ASX:TIS 29% Healing of Chronic Ulcer in Six Weeks, 2 February 2009**; and **VitroGro® Produces 32% Healing of Chronic Diabetic Ulcer in 6 Weeks, 29 April 2009**.)

The CEO of Tissue Therapies, Dr Steven Mercer said, "Once again VitroGro® has shown excellent wound healing results in a group of patients who clinically are at the most extreme end of difficulty and for whom the best available treatments had failed. Positive VitroGro® results, even in patients with chronic wounds as severe as these, make the delays in patient recruitment even more disappointing and frustrating."

Dr Mercer went on to say, "Given we have excellent results but slow recruitment in Canada, the Board of Tissue Therapies is negotiating with the Australian clinical trials team headed by Professor Michael Stacey to quickly increase patient recruitment, with the focus on venous ulcer patients. We already have Ethics Board approval for another 4 venous ulcer patients and will be lodging an application shortly for an additional 20"

This will more than fulfil the original target of 30 patients targeted with the Canadian human trial. We already have data for 14 patients including the already announced 8 venous ulcer patients."

He also said, "Venous ulcer patients represent the majority of the chronic wound care market and increasing venous ulcer patients will produce more representative data for commercial negotiations."

The single-protein VitroGro® preclinical data is so compelling, Tissue Therapies will place priority on manufacturing the New Formulation VitroGro® 1 for the final clinical trial and regulatory approval of VitroGro® for the sale of a new range of advanced wound healing products, as previously announced (please see **ASX: TIS Rights Issue Prospectus, 28 January 2009**).

The regulatory classification of VitroGro® as a device for the treatment of chronic wounds means that data from only a single clinical trial is required for regulatory approval for sale.

Dr Mercer said that Tissue Therapies is anticipating that the VitroGro® wound healing commercialisation program will require up to one additional quarter due to the unexpectedly slow Canadian clinical trial recruitment.

VitroGro® Human Trial: Progressive Results

Results for six patients have been received from the Canadian human trial so far. The first two of these have already been announced but are included here again for completeness.

Patient 1 – 29% reduction in diabetic ulcer



- 73 year old male, Type II diabetic, high blood pressure, smoker
- Diabetic ulcer at base of right big toe
- Conventional treatment ineffective for more than 2 years – amputation considered
- 29% reduction in diabetic ulcer area in 6 weeks with VitroGro® treatment
- Infection resolved
- Improved health of tissue at ulcer edge
- No adverse reactions to VitroGro®

Patient 2 – 32% reduction in diabetic ulcer



- 60 year old male, diabetic
- Renal dialysis since kidney failure in early 2008
- Right below knee amputation due to diabetes & uses a right lower leg prosthesis
- Diabetic ulcer on left heel
- Right artificial leg increases pressure on left foot, making treatment of left heel ulcer more difficult
- 32% reduction in diabetic ulcer area in 6 weeks with VitroGro® treatment despite heavy presence of bacteria
- Rapid healing of ulcer from the edges and from the base with healthy new tissue in floor of the ulcer
- No adverse reactions to VitroGro®

Patient 3 – Diabetic ulcer healing from base; larger but shallower: no change in volume



- 22 year old male diabetic
- Congenital neuropathy (reduced movement and sensation since birth)
- Wears bilateral leg braces
- Diabetic ulcer at base of right big toe
- Computer industry worker, started full time job 1 week after beginning VitroGro® trial: more weight bearing on ulcer
- Leg braces limit ability to offload ulcer
- After 6 weeks ulcer showed healing from base but no change in volume due to increased diameter
- No adverse reactions to VitroGro®

Patient 4 – 15% reduction in diabetic ulcer



- 70 year old male, diabetic
- Diabetic ulcer over left Achilles tendon secondary to trauma
- Ulcer is at site of old scar following correction of club foot as a child
- 15% reduction in diabetic ulcer after 6 weeks
- Position of ulcer and inability to unload means that shoes and socks were creating pressure and friction on the wound impeding healing
- No adverse reactions to VitroGro®

Patient 5 – Venous Ulcer healing from base; larger but shallower: no change in volume



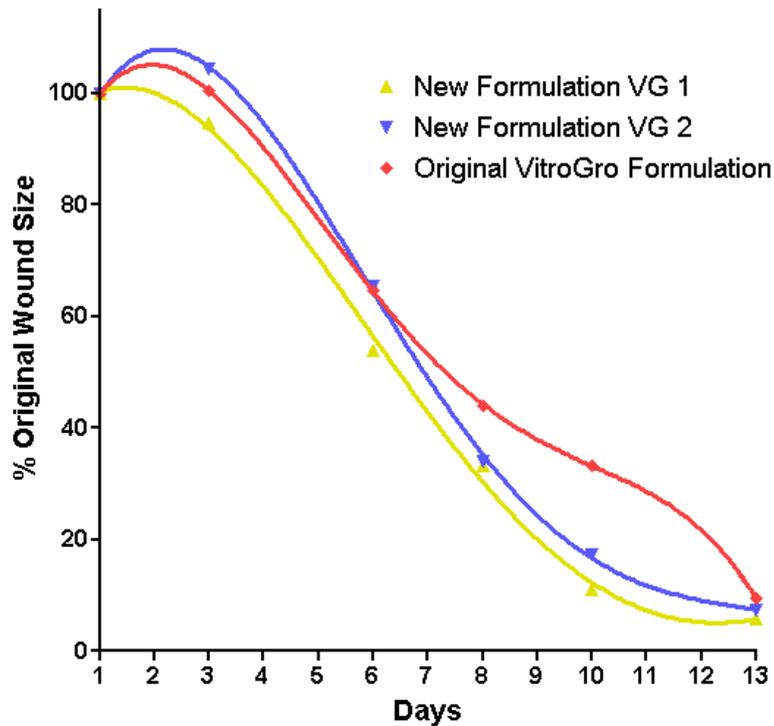
- 49 year old female
- Recurrent venous ulcer secondary to trauma on left ankle
- Repeated recurrences at same site
- Unusually resistant to conventional treatment for a venous ulcer
- After 6 weeks ulcer showed healing from base but no change in volume due to increased diameter
- Ulceration site scarred from previous ulcers
- No adverse reactions to VitroGro®

Patient 6 – 26% reduction in venous ulcer



- 52 year old female
- Venous stasis and ulcers secondary to systemic lupus (severe autoimmune disease)
- Recurrent venous ulcer on left lower leg, resistant to conventional treatment
- 26% reduction in venous ulcer after 6 weeks treatment with VitroGro®
- Works as school / playground / lunch supervisor and stands and walks most of the working day
- Work prevents elevation and adequate compression treatment and results in repeated minor trauma to ulcer site
- No adverse reactions to VitroGro®

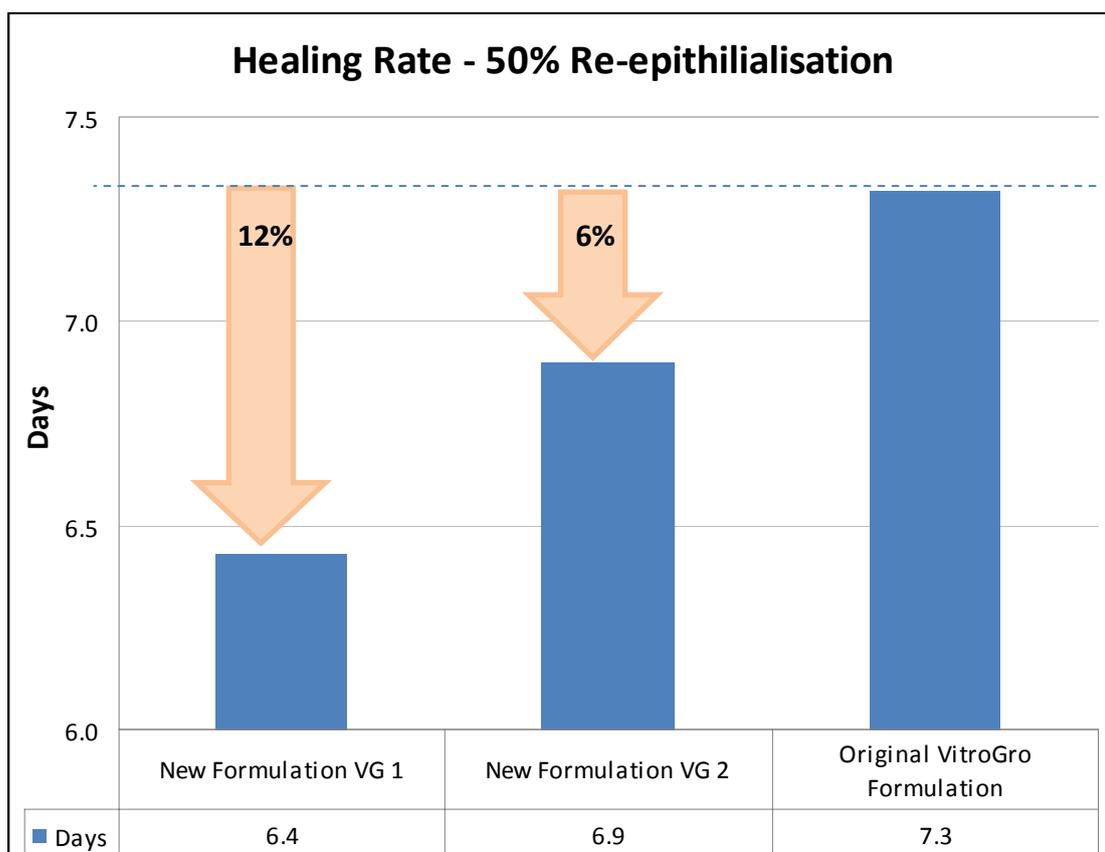
Preclinical Data: New Formulation Single-Protein VitroGro®



The chart above shows that wound healing is accelerated with two new single-protein New Formulations of VitroGro®, compared to the original multi-protein VitroGro®.

New Formulation VitroGro® 1 has performed better than New Formulation VitroGro® 2 in laboratory, live cell and now preclinical trials. New Formulation VitroGro® 1 is the material that Tissue Therapies will take forward to clinical trial and regulatory approval for sale.

The performance of New Formulation VitroGro® 1 is more pronounced on the next chart, showing time to 50% wound healing.



New Formulation VitroGro® 1 was 12% faster to achieve 50% wound healing compared to the original multi-protein formulation, while New Formulation VitroGro® 2 was 6% faster.

Further information:

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About Tissue Therapies Limited

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

The Company has worldwide exclusive rights to commercialise VitroGro®, a technology developed by tissue engineering experts at the Institute for Health and Biomedical Innovation at QUT for enhancing cell growth and migration. VitroGro® has particular commercial applications in wound healing, tissue regeneration, stem cell therapies and other cell culture uses.

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

Tissue Therapies also provides cell culture reagents to enhance the growth of mammalian cells for emerging cell-based therapies, along with research and industrial cell culture markets internationally.

More information: www.tissuetherapies.com