

VitroGro® ECM Global Commercialisation Update

ASX Announcement 30 August 2012
Tissue Therapies Limited ABN 45 101 955 088

Announcement

Biomedical company, Tissue Therapies Limited (ASX: TIS) has released the following presentation as an updated and expanded summary of the current global commercialisation plans for VitroGro® ECM. This will be presented at the AusBiotech meeting, “Brokers Meet Biotech” in Perth, Western Australia, on Monday 3 September 2012.

ENDS

VitroGro® ECM Global Commercialisation Update

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What is VitroGro® ECM

- VitroGro® ECM is a topically applied, biomimetic scaffold, comprising a synthetic extracellular matrix (ECM) protein.
- **How it works:** VitroGro® ECM replaces the degraded matrix of a hard to heal wound. VitroGro® ECM binds to a prepared wound bed and provides a physical structure (a scaffold) for cell attachment, which is a primary requirement for subsequent cell functions critical for healing, such as cell proliferation and migration ^[1].
- **An optimal scaffold:** One of the characteristics of hard to heal wounds is prolonged inflammation, which damages the native ECM that would normally guide the wound healing process ^[1,2,3,4]. Replacement of this damaged ECM is a beneficial strategy for treating hard to heal wounds ^[1]. VitroGro® ECM is ideal as an ECM replacement since its structural and functional elements mimic those present in the ECM at the early stages of normal wound healing.
- 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.

[1] Widgerow AD . Deconstructing the stalled wound. Wounds 2012

[2] Schultz GS. Extracellular Matrix: review of its roles in acute and chronic wounds. World Wide Wounds. 2005

[3] Moor AN. et al. Proteolytic activity in wound fluids and tissues derived from chronic venous leg ulcers. Wound Rep Reg. 2009

[4] International consensus, Acellular matrices for treatment of wounds. Wounds Int. 2010

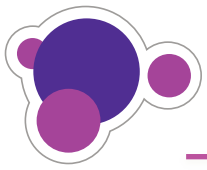
About Tissue Therapies Limited

Tissue Therapies Limited is a biomedical technology company that is developing significantly more effective treatments for acute and chronic wound healing applications, including chronic skin ulcers and burns. Tissue Therapies Limited is commercialising VitroGro® ECM, a technology created by cell biology, tissue engineering and protein engineering experts at the Institute of Health and Biomedical Innovation at the Queensland University of Technology. The company is also developing treatments for psoriasis, scar prevention and various cancers including those of the breast, colon and prostate. Tissue Therapies Limited's shares are traded on the Australian, Berlin and Frankfurt stock exchanges.

More information: www.tissuetherapies.com



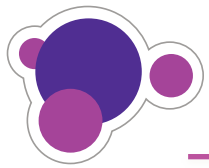
Tissue Therapies Limited
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Tissue Therapies Limited



Commercialising VitroGro® ECM



Tissue Therapies: Introduction

Tissue Therapies:

- An Australian biomedical company developing advanced technologies for more cost effective wound healing, tissue repair, cell culture and other global applications
- Worldwide exclusive rights to commercialise VitroGro® technology: first product – VitroGro® ECM for hard to heal wounds
- Patents granted in the USA, Europe, China, Hong Kong, South Korea, Japan, South Africa, Australia and New Zealand (pending applications in Canada & India)
- CE Mark (EU) approval expected late 2012: immediate sales launch in UK, Germany, Switzerland, Austria and the Netherlands
- Partnerships with Quintiles (hiring & support services) and Movianto (logistics) which minimise operational risk, restrain cost and optimise revenue
- Attractive margin product; more convenient and cost effective than existing wound care treatments
- USA FDA trials scheduled to start 2013

Tissue Therapies: Investment Summary

5 year Performance



Key Statistics

Code	TIS.ASX
Listed	ASX (2004), Frankfurt & Berlin (2009)
Current Price	A\$ 0.41
52 Week High	A\$ 0.615
52 Week Low	A\$ 0.330
Shares Outstanding	172.4m
Market Cap	A\$ 71m
Net Cash (30.06.12)	A\$ 5.2m
Top 20 Shareholders	~40% of issued capital; institutional & private investors, Directors, CSO

Major Achievements

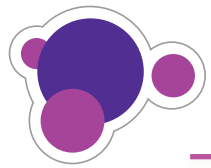
Finalisation of protein formulation, VitroGro [®] ECM; Successful EU trials	✓ 2010 & 2011
Commercial-scale Good Manufacturing Practice (GMP) standard	✓ 2011
Key commercial partners in place for commercialisation phase (incl. Quintiles)	✓ 2011
Successful regulatory classification with EU ("device") & USA ("biologic")	✓ 2011
CE Mark expected shortly	2012

Major Priorities

- Execute global roll-out plan / strategy
- Launch European Sales
- Specific focus on German-speaking Europe & UK
- USA FDA trials: Venus Ulcer Trial and Diabetic Ulcer Trial
- USA FDA approval and product launch

Top Shareholders

Asia Union Investments	13.33%
Queensland Uni. of Tech.	4.69%
ABN AMRO Nominees	2.48%
JP Morgan Nominees	2.22%



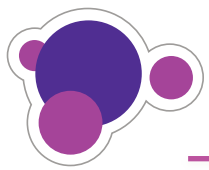
What is VitroGro[®] ECM?

VitroGro[®] ECM is a synthetic, extra-cellular matrix (ECM) protein creating a physical structure (a scaffold) that binds to the wound bed:

- Restores attachment sites in skin & guides cells during wound healing
- Diabetic, Venous & Pressure Ulcers is primary market
- Addressing a significant un-met need in providing a convenient, cost effective treatment
 - Accelerated healing, only 1 application per week x 10 weeks
 - Correction of wound tissue pathology by delivery of biologically appropriate matrix

VitroGro[®] ECM can also be used to address:

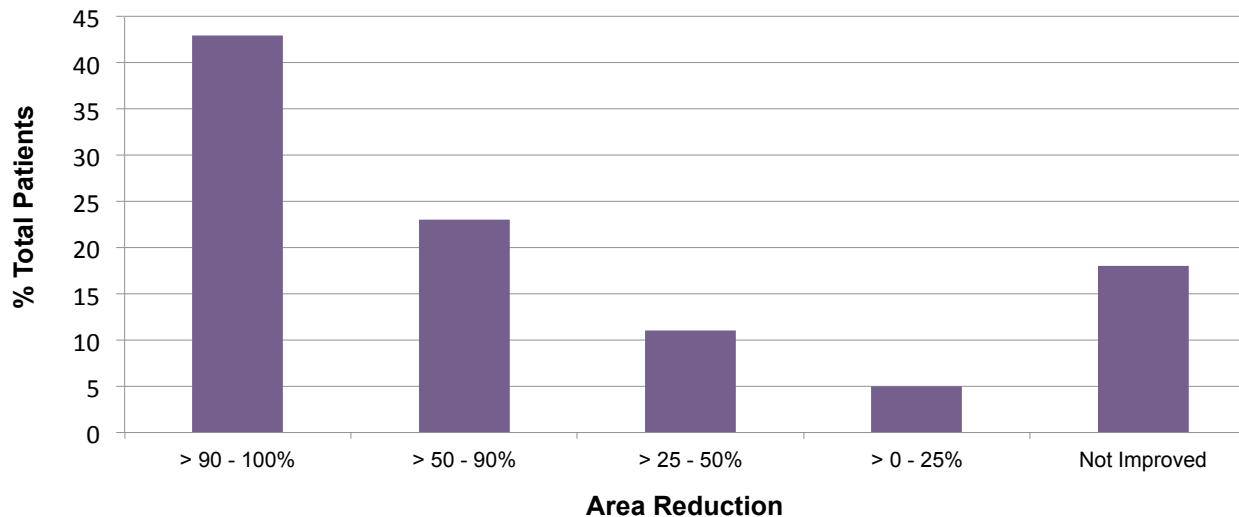
- Burns Dressings: Paediatric & Adult
- Surgical Wound Applications (especially at-risk patients)
- Specialist Units & Retail
 - Specialist unit – general hospital – outpatient – GP – pharmacy – retail
 - Potential retail applications include dressings, creams, lotions, product range for burns, chronic wounds, acute sunburn etc.



Clinical Trials: EU 5 Centre Venous Ulcer Study (N=44)

In human trials, VitroGro® ECM has demonstrated consistent and convenient restoration of healing of venous and diabetic ulcers that had not responded to expert care

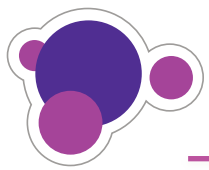
VitroGro® ECM Healing Venous Ulcers Consistency at 12 Weeks



Results:

- Trial patients were relatively old (average age 72 years) and had suffered venous ulcers that had not responded to expert care for an average of 36 months
- Strong results: 34 % completely healed & 43% more than 90% healed within 12 weeks*

*Refer Tissue Therapies ASX announcement 'Robust EU Final Clinical Trial Results', 11/11/2011.

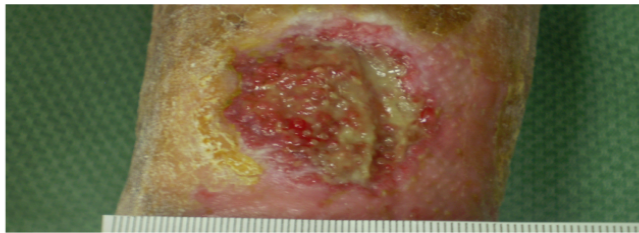


VitroGro[®] ECM: Consistently Heals Chronic Wounds

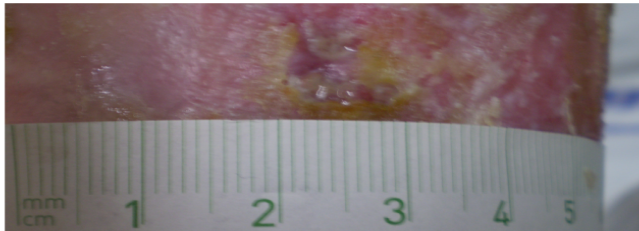
EU & earlier clinical trials indicate that VitroGro[®] ECM has the potential to transform the treatment of diabetic, venous and pressure ulcers: 2 venous ulcer examples:

EU Trial: Patient A (Venous Ulcer)

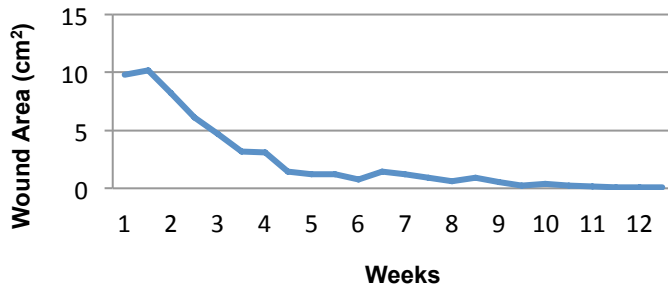
Week 1



Week 12

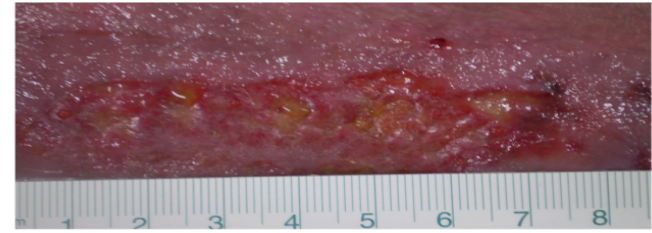


Change in Ulcer Size during Treatment

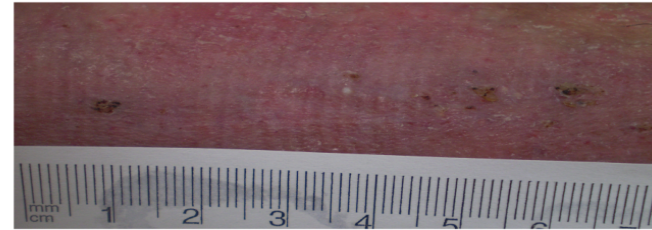


EU Trial: Patient B (Venous Ulcer)

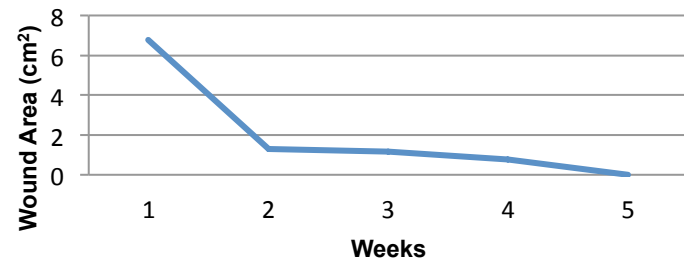
Week 1

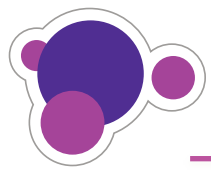


Week 12



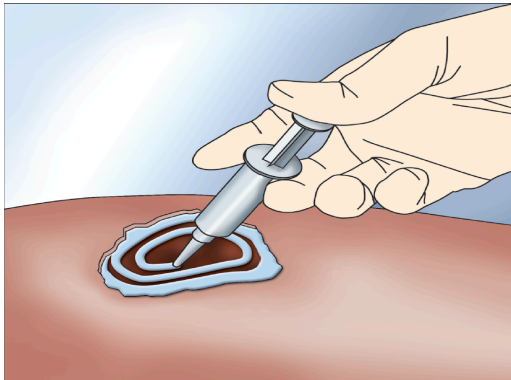
Change in Ulcer Size during Treatment

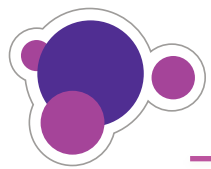




VitroGro[®] ECM: Advantages

- **Early-stage healing / reduced healing time:** VitroGro[®] ECM's efficacy is clinically proven
- **Efficiency of traditional treatments is modest:** ~50% of wounds remain unhealed after twenty weeks treatment. Some take years or even result in amputation (> 1million diabetic ulcer related amputations globally, per year). 3 year survival after amputation - 50%
- **Cost effectiveness:** One tube of VitroGro[®] ECM is required per week for 10 weeks for the average wound at routine dressing change
- **Convenience / ease of use:** VitroGro[®] ECM is administered quickly (~2-5mins)





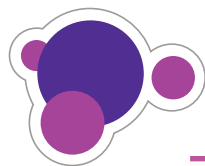
VitroGro[®] ECM: Competitive Landscape

- *Systagenix (Johnson & Johnson), KCI, ConvaTec, Smith & Nephew* have dominated the global market for treatment of chronic wounds*. Lack of innovation an issue for established companies: S&N CEO address 15 May 2012. At risk to new technology
- More recently, healing scaffolds derived from animal & human cells have emerged but none approach VitroGro ECM's efficacy, convenience and cost effectiveness

Company	Product	Composition	Early stage wound healing	Ease of use
Cook Biotech Inc.	Oasis [®]	Animal	X	X
Integra Life Sciences Corp.	Integra [®]	Animal	X	X
Systagenix	Promogran [®]	Animal & plant	X	X
Shire (previously Advanced Biohealing)**	Dermagraft [®]	Human	✓	X
Molnlycke	Xelma [®]	Animal	X	✓
Tissue Therapies	VitroGro[®] ECM	Synthetic	✓	✓

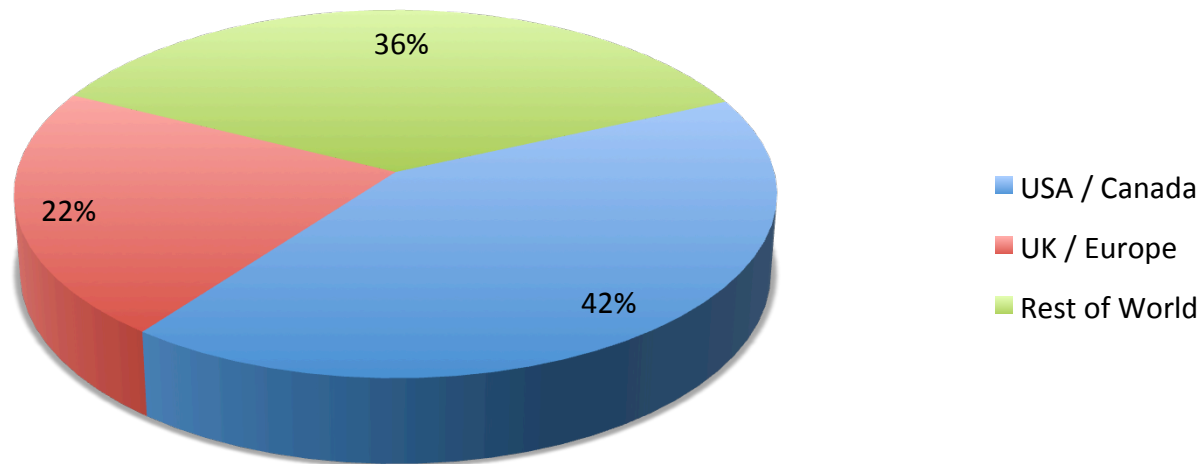
*Methods include: compression & moist dressings, hyperbaric treatment, vacuum dressings and anti-microbial dressings

**May 2011 – Shire Plc purchased Advanced BioHealing Inc for US\$750m. NB: Following, in their international pivotal trial (500+ patients), data did not meet the primary end point mutually agreed upon with the FDA & EMA



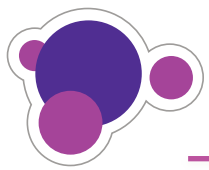
Global Venous & Diabetic Ulcer Market 2008

% Share of Global Venous Leg Ulcer (VLU) and Diabetic Foot Ulcer (DFU) Market by Region



Large market growing rapidly:

- In 2008, the market size was estimated at US\$14 Bn & growing at ~15% per annum
- Multiple publications now suggest true market size is US\$30 – 40 Bn (refer publications, Appendix)
- Growth driven by an aging population, increasing incidence of venous disease & diabetes as well as expanding affordability of health care, primarily in developing countries
- Further potential in consumer, retail and acute wound care products

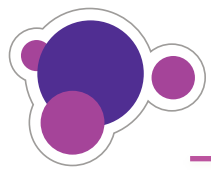


VitroGro[®] ECM: Health Economics

- Healthcare expenditure for chronic wound treatment is growing at >15% p.a. Estimates on market size are escalating rapidly.
 - **UK:** NHS expenditure on wound care > £1 Bn (2009)*
 - **German, Austrian, Swiss:** wound care expenditure > €2.5 Bn (2009)
 - **USA:** largest single global market at US\$15.3Bn (2010)**
- Influential key opinion leaders (KOL's) supportive of VitroGro[®] ECM in UK, German speaking Europe and the Netherlands
- Reimbursement process: well advanced; not a significant barrier after CE Mark
 - **UK:** immediate sales to specialist wound clinics: formulary discretion
Drug Tariff application in parallel: pharmacy access (minority of market)
 - **Germany, Austria, Switzerland:** 550 patient accelerated 137e Review for public reimbursement:
90% of market: target 2014: VitroGro[®] ECM purchased for review
Private insurance 10% of market: 50 patient assessment: approval target Q2 2013
 - **USA:** venous ulcer trial complete 2014, diabetic ulcer trial complete 2015
12 months for approval for sale
6 months reimbursement negotiation with CMS: establishes price for all payers

*Refer publications, Appendix (Madden, M)

** Refer publications, Appendix (Chandan, KS et al)

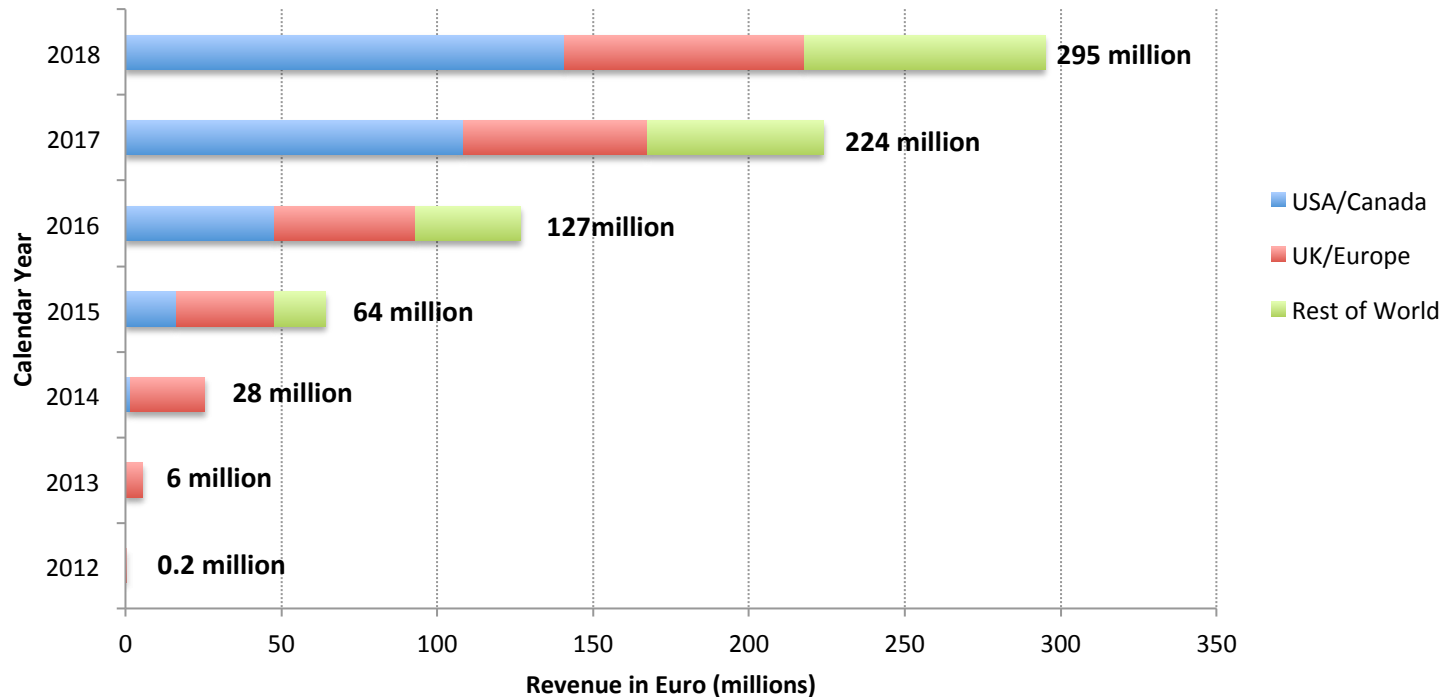


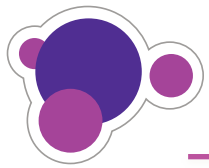
VitroGro[®] ECM: Sales Estimates

VitroGro[®] ECM's revenue prospects are promising:

- Initial focus on UK, German speaking Europe and the Netherlands
- Cost competitive, convenient, consistent healing versus existing treatments

Revenue estimates (Euro) per market size phased with start of sales



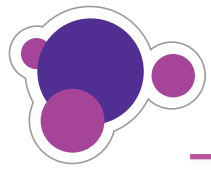


Commercialisation: Partnership Structure

Tissue Therapies has in place partnerships that minimise operational risk, restrain cost and optimise revenue while maintaining flexibility and control.

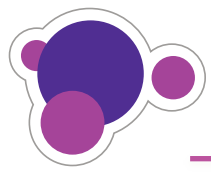
- **Quintiles:** specific VitroGro® ECM Sales team; shared risk/reward
- **Movianto:** Integrated Logistics, Multi-lingual Customer Support, Order Entry, Supply, Accounts Receivable
- **Eurogentec:** Manufacture of VitroGro® ECM Protein
- **Catalent:** Fill, finish & release
- **Queensland University of Technology (QUT):** Research & Development; royalty to be paid to QUT



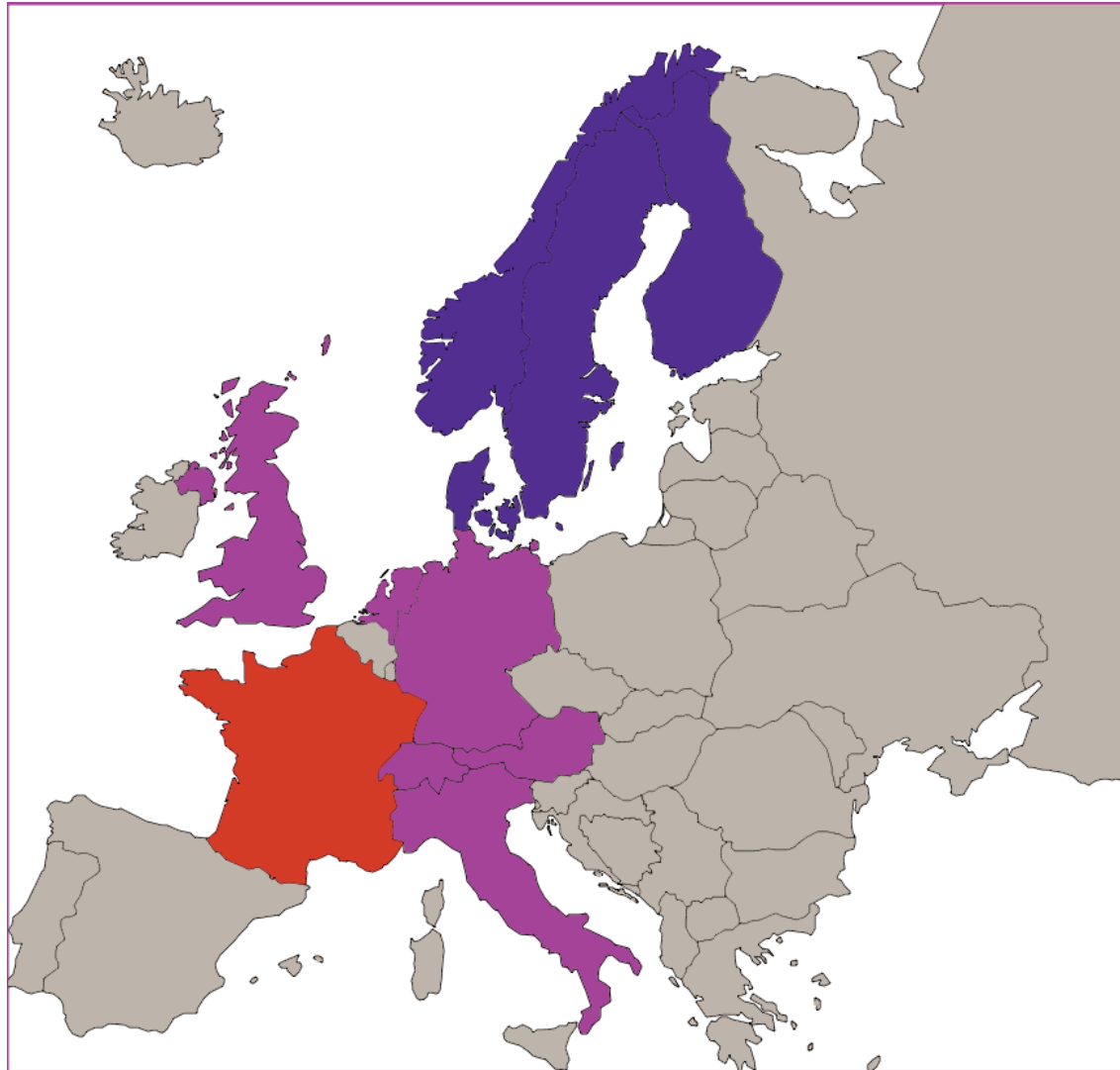


VitroGro[®] ECM: Product Ready





VitroGro[®] ECM: Commercialisation - Europe



Sales Timeline:

2012 2H

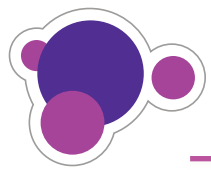
- UK
- Germany
- Netherlands
- Austria
- Switzerland
- Northern Italy

2013 2H

- Denmark
- Sweden
- Norway
- Finland

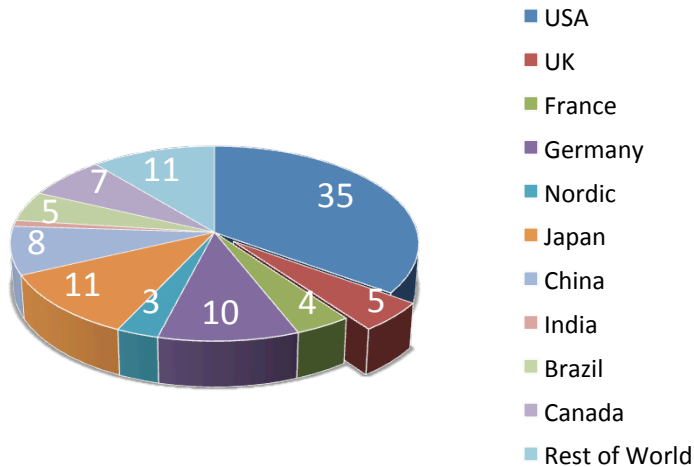
2015 1H

- France



VitroGro[®] ECM: United Kingdom

UK % Share of Global VLU and DFU Market



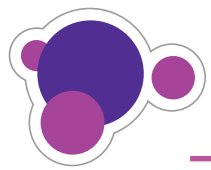
Marketing Preparation:

- NHS expenditure on wound care > £1 Bn in 2009 *
- 12 months work with most influential key opinion leaders (KOL's)
- Health economics analysis: data ready now
- Prep for journal advertising
- Publications written with UK experts
- 72 PCT Wound Care Clinics generate > 80% of wound care expenditure

* Refer publications, Appendix (Madden, M)

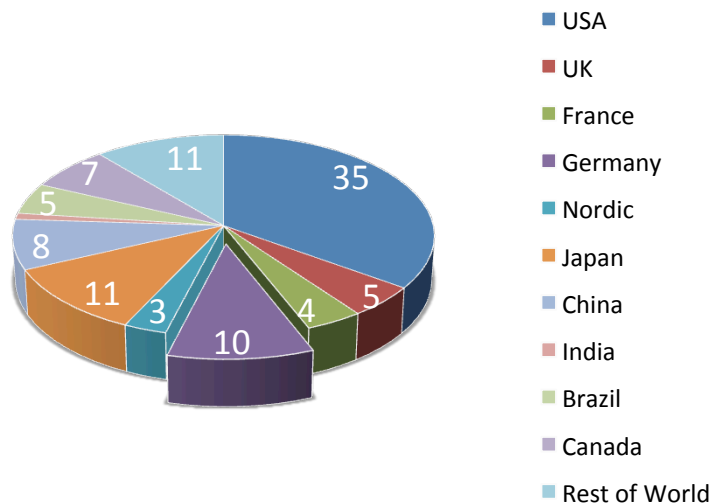
Sales Strategy:

- UK launch immediately after CE Mark
- Sampling program to key 72 specialist wound clinics
- Application for Drug Tariff inclusion (pharmacy access)
- Immediate sales to PCT wound clinics: formulary discretion



VitroGro[®] ECM: Germany, Austria, Switzerland

German % Share of Global VLU and DFU market

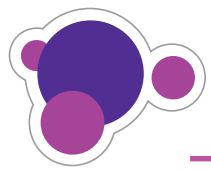


Marketing Preparation:

- 10 months work with most influential KOL's
- Health economics project with German data
- Publications planned based on clinical results and health economics
- German, Austrian, Swiss wound care expenditure x 2.5 UK: €3 Bn in 2009
- 800 specialist wound care private clinic network

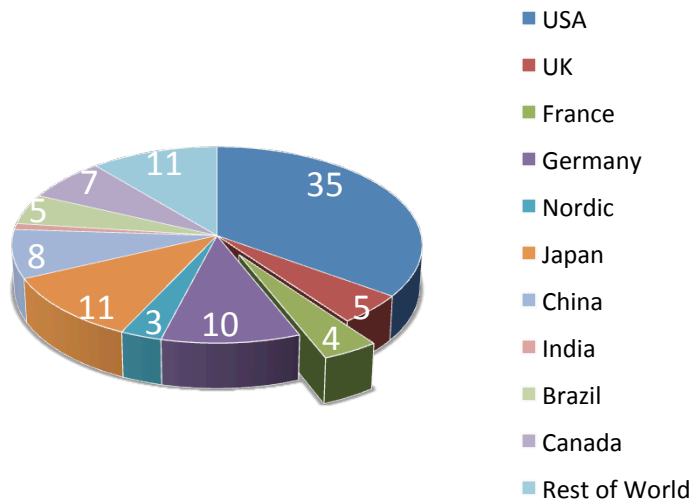
Sales Strategy:

- Launch immediately after CE Mark
- Immediate sales to 10 most influential clinics: pyramid rollout
- Private Insurance: 10% population: KOL led assessment of 50 patients. Guideline doc for private insurance application: approval target Q2 2013.
- Public reimbursement: 90% population: Accelerated 137e Review, target approval 2014: VitroGro[®] ECM purchased for approx. 550 patients. Earlier approvals of smaller 40 public reimbursement agencies during 137e Review.



VitroGro[®] ECM: France

France % Share of Global VLU and DFU Market

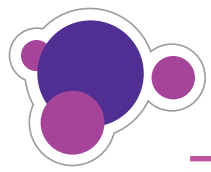


Marketing Preparation:

- 10 months work with 3 influential KOL's
- Most difficult EU country for reimbursement: French clinical data 2015
- 3 x French sites in FDA VLU & DFU trials
- Publications planned based on clinical results and health economics
- Almost entire market is reimbursement based: 100% population coverage
- very few private, cash wound care clinics

Sales Strategy:

- Clinical data from 3 sites in FDA VLU & DFU trials: basis of LPPR reimbursement applications: target approvals 2015 (VLU) , 2016 (DFU)
- Supplement reimbursement submissions with health economic data
- Continue / expand KOL work
- Sampling program in lead up to reimbursement approval
- Publications, presentations, conference attendances



VitroGro[®] ECM: Commercialisation North America



Sales Timeline:

2013

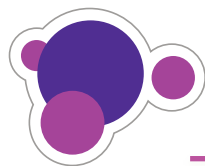
- Start FDA venous ulcer trial: 320 patients, USD\$8M, 18 months, 12 months for approval: 2.5 years total
- Start FDA diabetic ulcer trial: 380 patients, USD\$9M, 18 months, 12 months for approval: 2.5 years total
- Application for approval to Health Canada under Mutual Recognition Agreement with EU

2014

- Progress with venous & diabetic ulcer trials

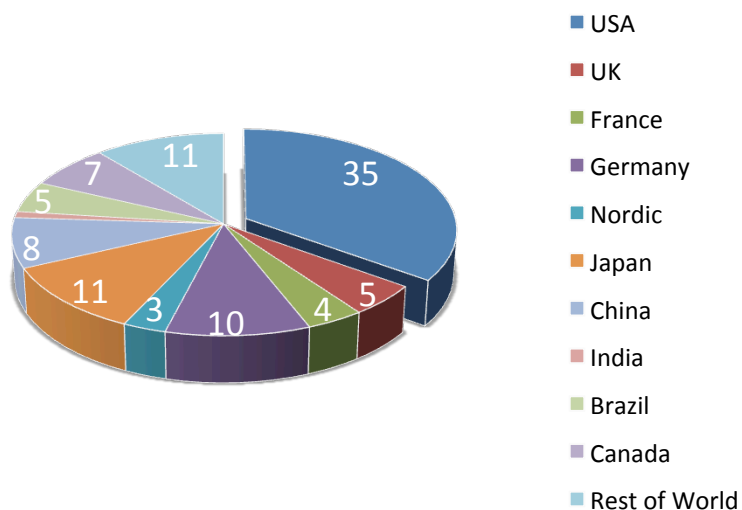
2015

- Commence sales



VitroGro[®] ECM: USA

USA % Share of Global VLU and DFU Market



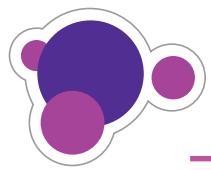
Marketing Preparation:

- Largest single global market: US\$15.3Bn in 2010 *
- 18 months work with KOL's, Chief Clinical Investigator & Clinical Research Org.
- Venous & diabetic ulcer trial protocols complete
- All clinical trial sites identified including reserve sites
- FDA Biologics classification; practical benefits in clinical trials & reimbursement

Sales Strategy:

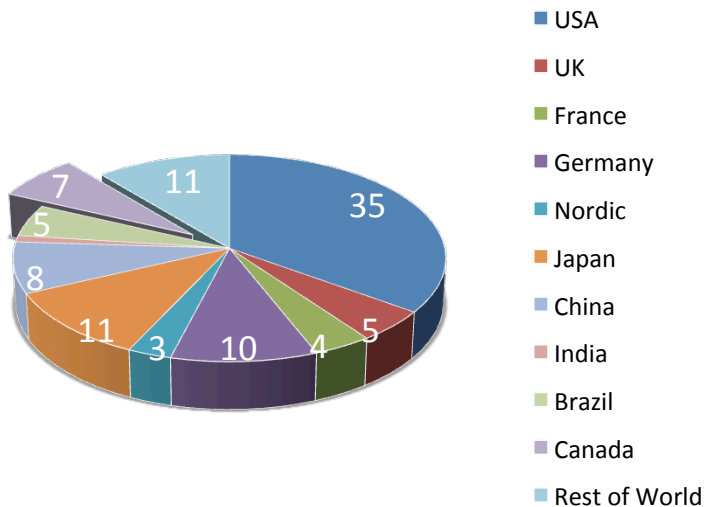
- Complete VLU trial 2014 & DFU 2015: 12 months for approval
- Single reimbursement negotiation with Centers for Medicare & Medicaid Services (CMS): avoids device reimbursement negotiations with all private insurance payers
- Extended health economics based on US data: agreement with hospital network
- Decision on North American fill / finish / release, logistics, sales, customer service
- Sampling program

* Refer publications, Appendix (Chandan, KS et al.)



VidroGro[®] ECM: Canada

Canada % Share of Global VLU and DFU Market

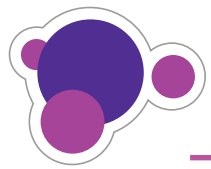


Marketing Preparation:

- First VidroGro[®] clinical trial in Toronto
- Health Canada Device classification
- Regulatory affairs mutual recognition agreement with EU
- Universal reimbursement via Canadian Medicare

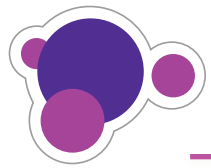
Sales Strategy:

- Lodge application for approval for sale based on mutual recognition of CE Mark
- Application for inclusion in Medicare reimbursement
- Sampling program to KOL clinics
- Health economic data expansion
- Decision on North American fill / finish / release, logistics, sales, customer service



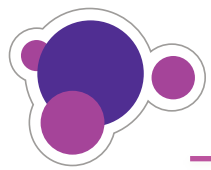
VitroGro[®] ECM: USA FDA Venous Ulcer Trial

- Prospective randomised control trial; 320 patients, H1 2013, 18 months duration
- Double blinded – at choice of TIS – exceeds FDA requirements
- US\$8m cost
- Chief Clinical Investigator, Dr Tom Serena
- 30 sites USA, 3 UK, 3 France, 3 Germany
- French sites included for French reimbursement
- CRO: Amarex Clinical Research
- Estimate evaluation and approval time 12 months (conservative)
- Clinical trial material ready in EU warehouse



VitroGro[®] ECM: USA FDA Diabetic Ulcer Trial

- Prospective randomised control trial; 380 patients, H2 2013, 18 months duration
- Double blinded – at choice of TIS – exceeds FDA requirements.
- US\$9m cost
- Chief Clinical Investigator, Dr Tom Serena
- 40 sites USA, 3 UK, 3 France, 3 Germany
- CRO: Amarex Clinical Research
- Estimate evaluation and approval time 12 months (conservative)
- Clinical trial material ready in EU warehouse



VitroGro[®] ECM: Commercialisation – Rest of World



Sales Timeline:

2013

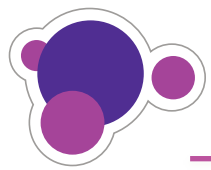
- Australian application for accelerated approval for sale. Define requirements
- Finalise & lodge applications in Japan, India, China, East Asia, Brazil & Argentina

2014

- Final decisions on global / regional supply chain

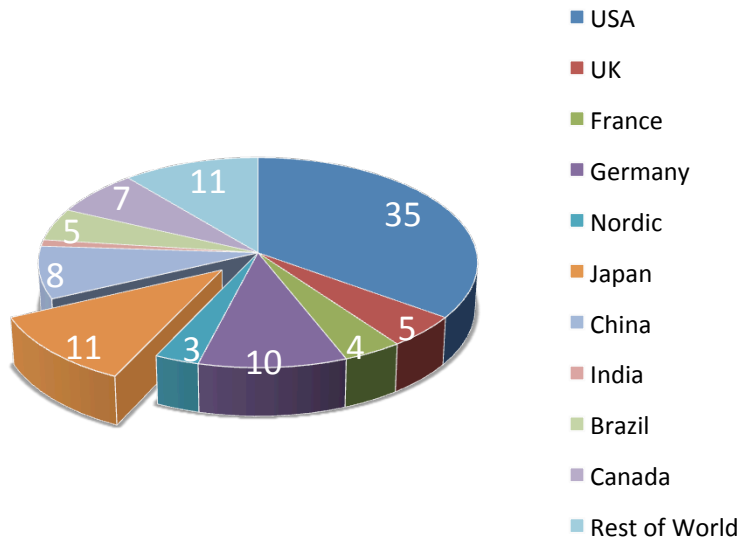
2015

- Sales commence across several Rest of World countries



VitroGro[®] ECM: Japan

Japan % Share of Global VLU and DFU Market

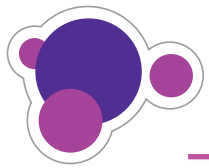


Marketing Preparation:

- 3rd largest single market after USA & EU
- Most expensive and longest regulatory approval process
- Highest end-user priced market
- Net revenue potentially excellent but dependent on supply chain arrangements
- High level project summaries and quotes for regulatory approval from 2 consultants

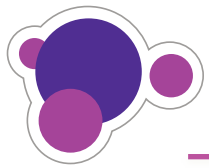
Sales Strategy:

- Proceed with final application approval
- Negotiate supply chain arrangements
- Decision on fill / finish / release, logistics, sales, customer service
- Health economic data
- Sampling program



Tissue Therapies: Summary

- Worldwide exclusive rights to commercialise VitroGro® ECM in large and fast growing markets
- European CE Mark approval expected shortly allowing transition into commercialisation phase
- USA FDA trials commencing in 2013 with North American sales to follow
- Clinically proven results with advantages over traditional products and recent technologies
- Promising revenue prospects with attractive margins
- Health economics attractive to Governments
- Global roll-out strategy in place and progressing rapidly adding to potential



Disclaimer

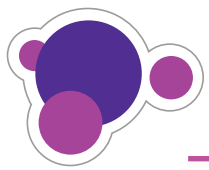
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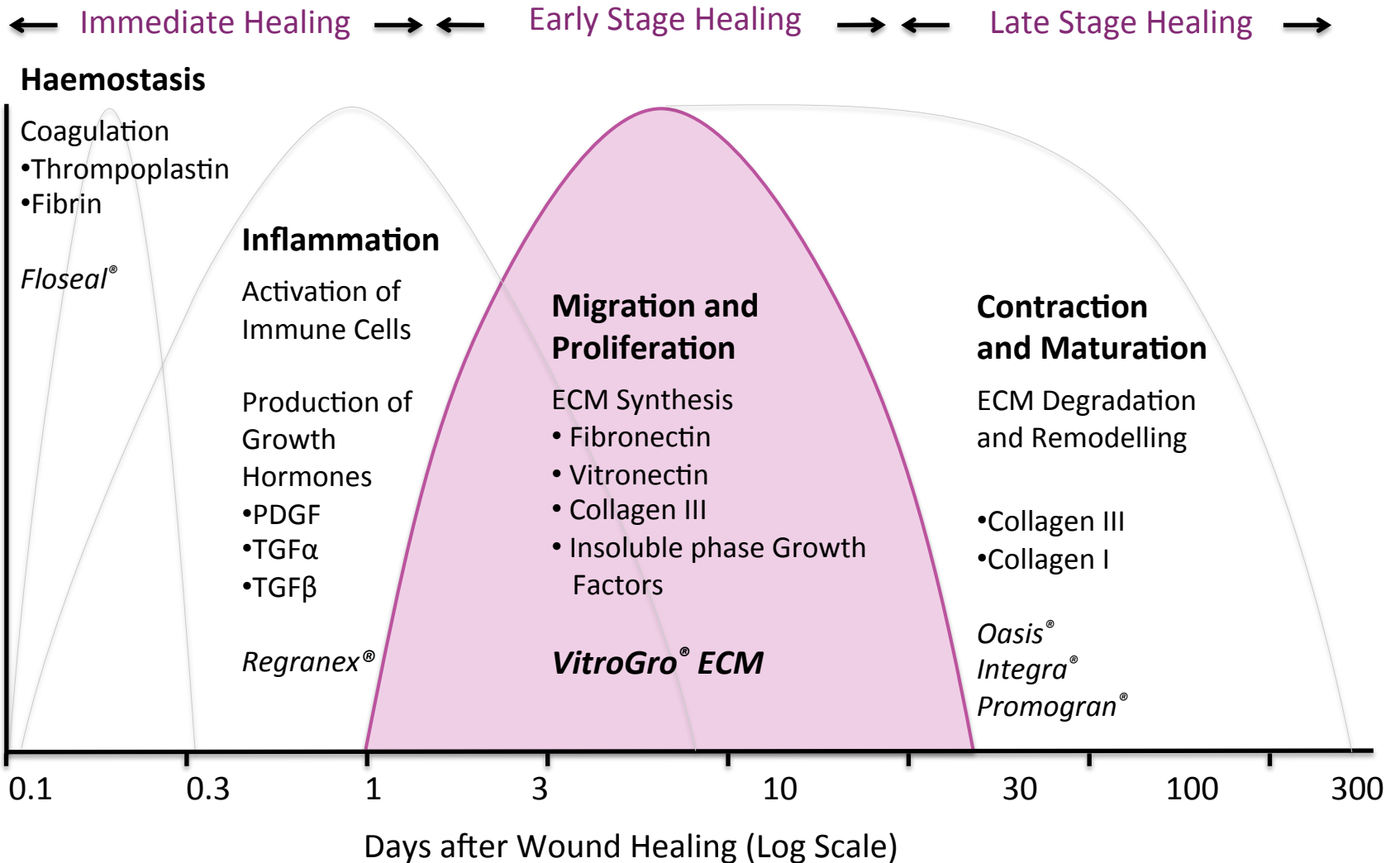
Tissue Therapies Limited Commercialising VitroGro[®] ECM

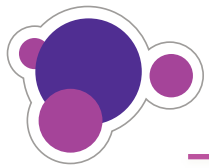
Appendix





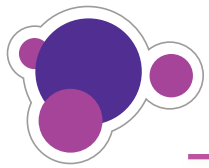
VitreGro[®] ECM: appropriate for breaking chronicity





Tissue Therapies Board

- **Mr Roger Clarke** (Chairman): Chairman of Board of Advice RBS Morgans Holdings, NextDC Ltd, Coalbank Ltd and MTQ Insurance Ltd.
Director of Trojan Equity Ltd and Maverick Drilling & Exploration Ltd and former Director of PIPE Networks Ltd
- **Mr Mel Bridges**: past & present Chairman & Director of multiple listed and private biotech, healthcare and other technology companies including Alchemia Ltd, ImpediMed Ltd, Benitec Ltd, ALS Ltd, Genetic Technologies Ltd and Genera Biosystems Ltd
- **Dr Cherrell Hirst AO**: past and present Chair and Director of multiple biotech and other companies including Alchemia Ltd, Peplin Ltd, ImpediMed Ltd, QBF, Medibank Private Ltd, Suncorp Metway Ltd and Xenome Ltd
- **Mr Iain Ross**: more than 30 years international life sciences senior management experience including as Chairman, Director and CEO. Current Chairman of Ark Therapeutics plc, Biomer Technology and Pharminox Ltd
- **Dr Steven Mercer**: CEO Tissue Therapies, formerly Mercy Tissue Engineering, Smith & Nephew Surgical, IBM Health Industries. Extensive international experience in biotech clinical commercialisation.



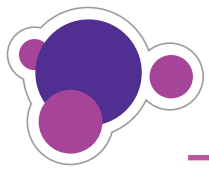
Management & Advisory Team

Management:

- Chief Executive Officer: Dr Steven Mercer
- Chief Operations Director: Mr Nigel Johnson
- Chief Financial Officer: Mr Drummond McKenzie
- International Product Manager: Dr Brian Ziegelaar
- Regulatory & Intellectual Property Manager: Dr Hedio Meka
- Mr Andrew Thelwell, UK, Managing Director, Commercial Operations EU
- Dr Eva-Lisa Heinrichs, UK, Medical Director

Advisors:

- Prof. Zee Upton, QUT; Chief Scientific Advisor
- Mr Geoffrey Morris, USA; Global Commercialisation Consultant
- Global Health Economic Projects, USA; Epidemiology, Sales Modelling & Health Economics
- Prof. Keith Harding, Cardiff University; Clinical Research Consultant
- Prof. Robert Baxter, Kolling Institute, University of Sydney; Scientific Advisor



Relevant Market Size Publications

- Chandan K. Sen, Gayle M. Gordillo, Sashwati Roy, Robert Kirsner, Lynn Lambert, Thomas K. Hunt, Finn Gottrup, Geoffrey C Gurtner, Michael T. Longaker. Human Skin Wounds: A Major and Snowballing Threat to Public Health and the Economy. *Wound Repair Regen.* 2009 ; 17(6): 763–771
- Drew P, Posnett J, Rusling L, on behalf of the Wound Care Audit Team. The cost of wound care for a local population in England. *Int. Wound J* 2007;4:149–155.
- Harding K, Queen D. Chronic Wounds and Their Management and Prevention is a Significant Public Health Issue. Editorial. *Int. Wound J* 2010; Vol 7; 3:125-126
- Madden, M. “Alienating evidence based medicine vs. innovative medical device marketing: A report on the evidence debate at a Wounds conference.” In press *Social Science & Medicine* xxx (2012) 1e7
- Purwins S, Herberger K, Debus ES, Rustenbach SJ, Pelzer P, Rabe E, Schafer E, Stadler R, Augustin M. Cost-of-illness of chronic leg ulcers in Germany. *Int. Wound J* 2010; 7:97–102