



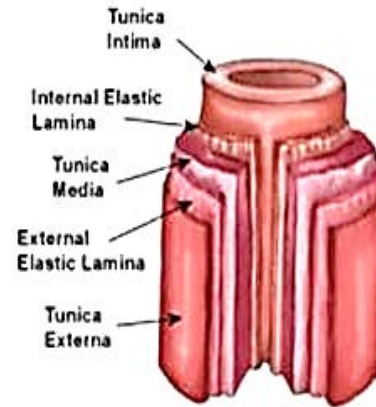
Elastin – next generation medical biomaterials

Anthony S. Weiss

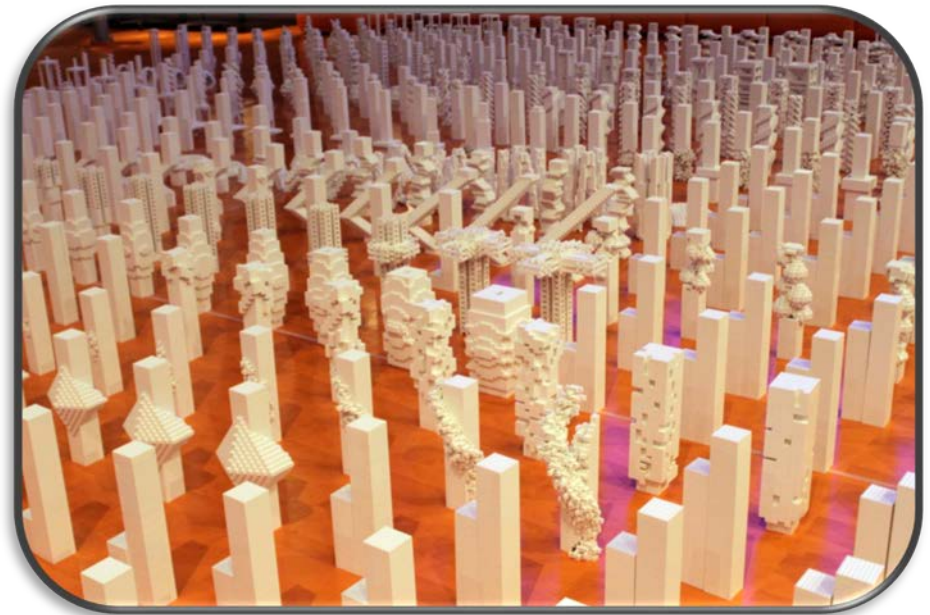
- McCaughey Chair in Biochemistry
Professor of Biochemistry and Molecular Biotechnology
Leader Charles Perkins Centre Tissue Engineering and Regenerative
Medicine Node, University of Sydney
- Inventor/Founder Elastagen Pty Ltd. International Elastin
Biomaterials Company Focused on Tissue Repair - Clinical Stage

May 2017

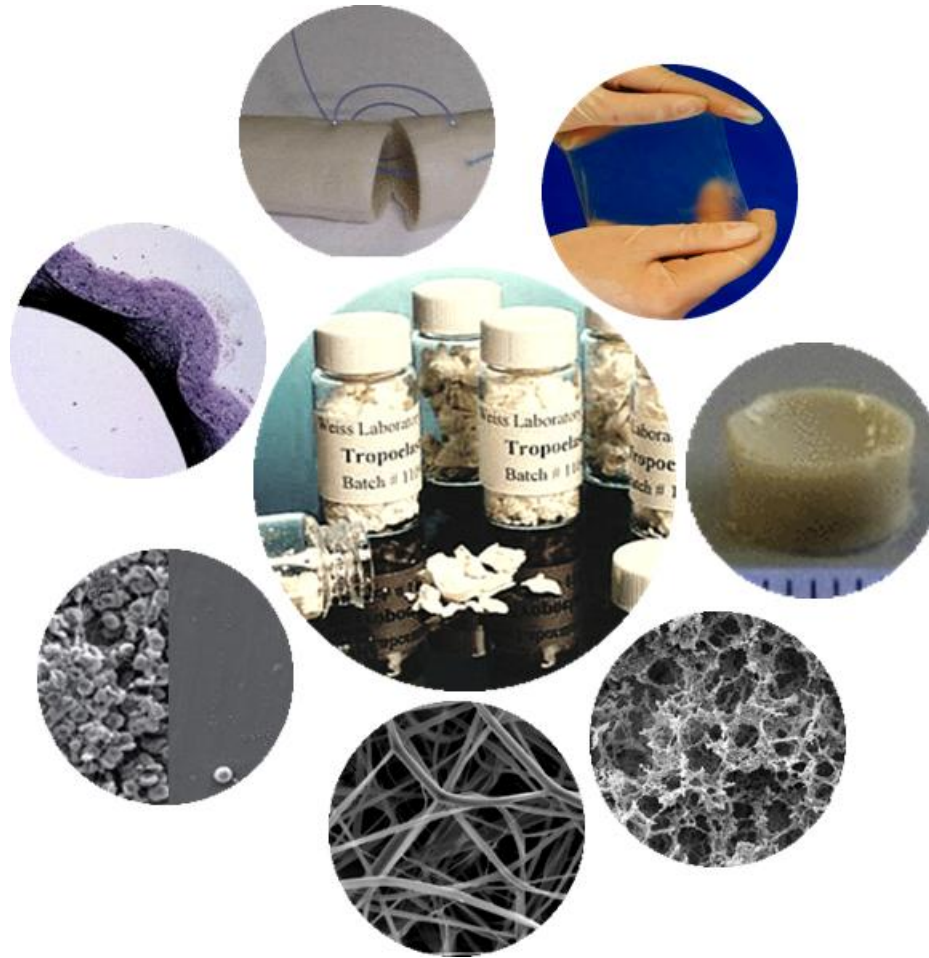
Elastin confers elasticity and modulates biology



Assemble
tropoelastin → elastin



Tropoelastin is versatile



Iterations within the University of Sydney

- External commercial sponsor
- Develop within the Tech Transfer Office
- Form company
- Tech Transfer Office and royalty flow model
- ...

Johnson & Johnson

- Johnson and Johnson Research Pty Ltd
 - Report to COSAT/Head Office, USA
- Extraordinary early stage recognition model
 - Financial support, technology 'fast-track' into J&J group of companies
- Funding for research, progressive IP protection strategy

Setting up Elastagen Pty Ltd

- University metric (trend at the time)
- Shell company
- Initially 100% University ownership
- Run from within Tech Transfer Office (BDM as acting CEO).
- Scientific R&D internal
- Faced some problems: focus, funding, expertise, distractions...



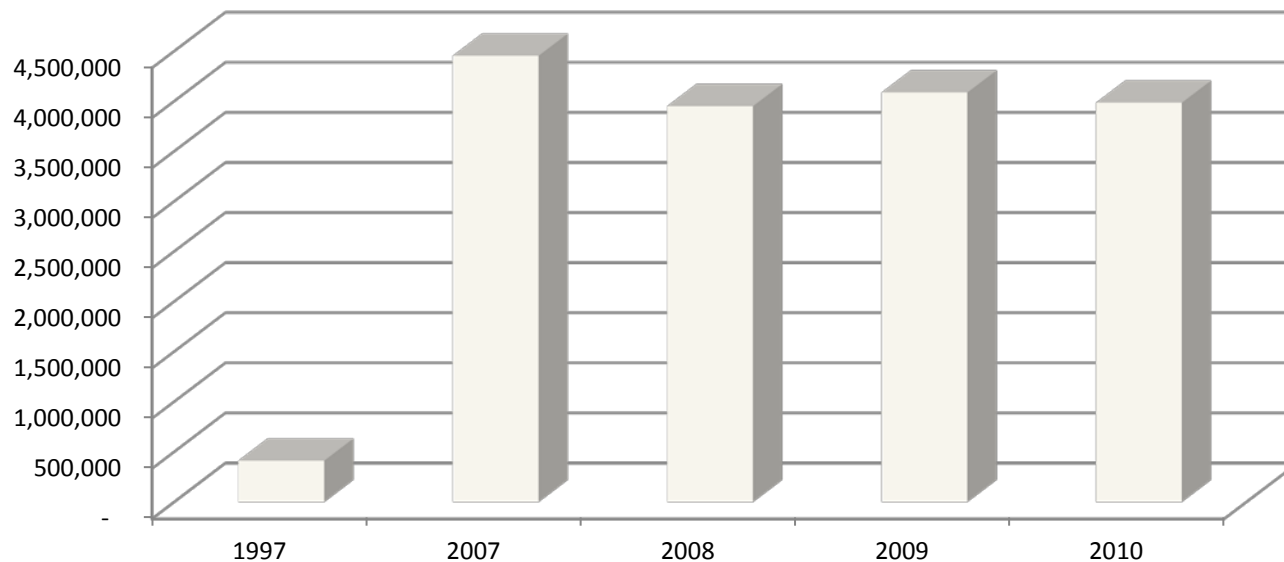
Interest by various companies

- Early multiple potential commercial partners
- For example:
 - International collagen company (pre-Elastagen tech transfer etc.)
 - International generic protein manufacturer (early Elastagen days)
 - International cosmetics company (early Elastagen days)



Why injectable aesthetics market?

- US Injectable procedure no.s
- EU assumed = US market size
- Defensive vs recession
- 10-fold growth in ~10 years
- US\$ 1.9B on injectable procedures in US in 2010
- US\$ 1.8B on skin rejuvenation in US in 2010



Source: American Society for Aesthetic Plastic Surgery

Transition towards an independent company

- First external investor: ATP Innovations (con note)
- People + technology
- Series A
 - Venture capital consortium
 - GBS Ventures and Brandon Capital
- University reduced its shareholding
 - retain model of royalty flow

People before investment: transition towards an independent company

- Recruitment of CEO, Dr Rob Daniels
- Establishment of robust Board



Hamish Hawthorn
Director

Hamish is the Chief Executive Officer of ATP Innovations – Australia's leading business incubator. ATP Innovations delivers commercialisation and business expertise to emerging technology businesses, helping entrepreneurs build successful high-growth companies. Hamish has been involved in the commercialisation of technology for over 15 years with experience in the advanced manufacturing and life sciences sectors.

[Read more](#)



Robert Daniels
Director & CEO

Robert has successfully guided Elastogen from its early research phases through to the current clinical development of its ElastocoreSM treatments for the rapidly growing cosmetic and medical dermatology markets.

[Read more](#)



Andrew Sneddon
Chairman

Andrew was appointed to the Board of Elastogen Pty Ltd as Chairman in September 2008. Andrew is a former partner of PricewaterhouseCoopers (PWC). In his PWC role, Andrew led the technology practice for a period of time and specialised in fast-growth and emerging technology companies working with many companies from start-ups to successful global corporations.

[Read more](#)



Dr Steve Gourlay
Director

Dr Steve Gourlay is a partner at GBS Ventures Partners, Australia's largest life sciences venture firm. He has more than 20 years' experience in drug and medical device development (Monash University, University of California, San Francisco, Genentech, Life Science Angels).

[Read more](#)



Stephen Thompson
Director

Stephen is a founding partner of Brandon Capital Partners. Prior to moving to Australia in 2009 Stephen was a Director of Asax Partners, a leading international private equity group. Before joining Asax Partners, he fulfilled roles in product development with UK biotechnology company Corvas Pharmaceuticals.

[Read more](#)

Value Proposition for Investors

- Broad and deep technology know-how
- Solid IPR platform with willing licensor (USyd)
- Product focus driven by Partner interest
- Unusual commercial opportunity for life sciences – investor portfolio
- Time to exit fits with investor requirements

Series A of \$5M secured through syndicate of GBS Venture Partners & Brandon Capital Partners in Aug 2008.

Need to build team/people: governed by an experienced Board of Directors

- Andrew Sneddon (Chairman): PWC, Aus/UK/US M&A, Finance, Strategy
- Xavier Yon: Pfizer, Solvay, Alcon, Galderma (CEO >15 years), Graceway
- Stephen Thompson: Brandon Capital, Terra Rossa, Apax
- Brigitte Smith: GBS, Bain & Company
- Sangwoo Lee: Director, Korean Investment Partners
- Marc Gleeson: Allergan, VP US & Global Strategic Marketing
- Robert Daniels (Director & CEO)



Elastagen has a Dominant IP Position Around Tropoelastin

Tropoelastin Production:

Patent Name	Publication Number	Status	Scope
Tropoelastin Derivatives	WO/1999/003886	Granted – AU, USA, USA div, USA div 2, NZ, SK, GB, FR, DE, CA	Recombinant tropoelastin production
Protease Susceptibility II	WO/2000/004043	Granted – AU, USA, JP, CH, DE, FR, GB, CA	Reduced tropoelastin protease susceptibility
Novel Method For The Extraction Of Proteins	PCT/AU2014/000932	Pending – AU, USA, EP, CA, CN, IN, SK, JP, BR, SG	Extraction of soluble proteins from host cell systems



Elastagen has a Dominant IP Position Around Tropoelastin

Patent Name	Publication Number	Status	Scope
Use of Tropoelastin for Repair or Restoration of Tissue	WO/2008/058323	Granted – AU, USA	Novel polymerisation process
		Pending – EP, CA, CN div, IN, BR	
Injectable Biomaterials	WO/2010/102337	Granted – USA, CN Pending –AU, EP, CA, IN, SK, JP, BR	Injectable biomaterials
Preparation and/or Formulation of Proteins Cross-linked with Polysaccharides	WO/2012/068619	Granted - USA Pending – AU, USA div, EP, CA, CN, IN, SK, JP, BR, MX	Polysaccharide cross-linkers
Elastic Hydrogel	PCT/2013/0012309	Pending – AU, USA, EP, CA, CN, IN, SK, JP, BR, MX	Temperature controlled polymerisation
Biosynthetic Devices	AU2016904516	Provisional	Ex-vivo elastin fibre formation



Elastagen has a Dominant IP Position Around Tropoelastin

Application IP:

Patent Name	Publication Number	Status	Scope
In vivo Synthesis Of Elastic Fibre	WO/2013/044314 04.04.2013	Pending –AU, USA, EP, CA, CN, IN, SK, JP, BR, MX, RU	De novo synthesis of elastic fibers
Regeneration of damaged tissue	AU2013903092	Pending – AU, USA, EP, CA, CN, IN, SK, JP, BR, MX	Use of tropoelastin in wound repair applications

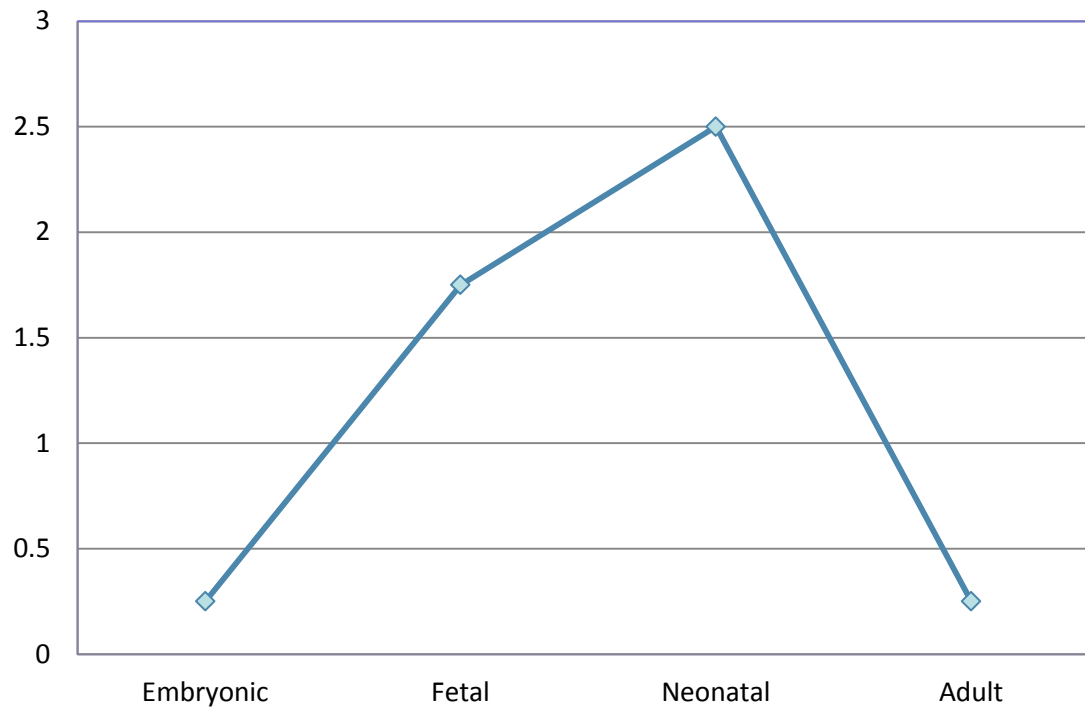


Market Drivers

- Baby boomers and aging population
- Users are early adopters
- Effective products stick
- Search for natural anti-aging effect
- Market driven by new products - “shiny new pennies”

Elastin Expression in Development

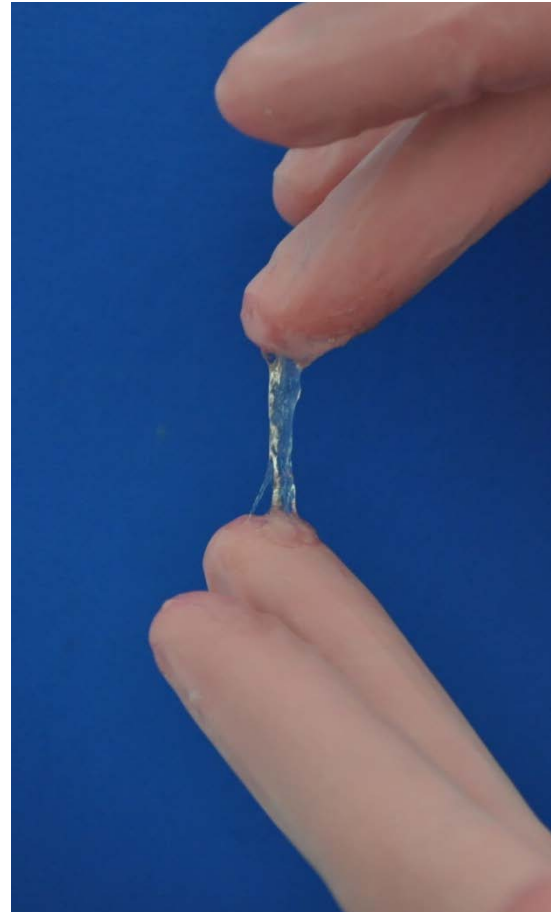
- Elastin is produced during early development
- Elastin expression is minimal in adults



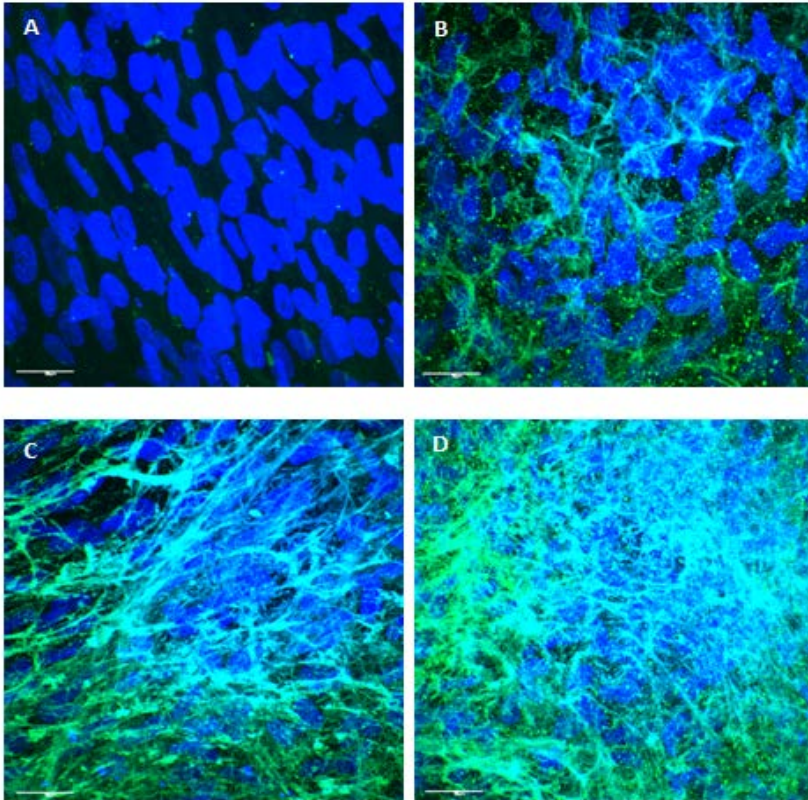
Source: Shifren & Mecham 2006 – Normalised elastin mRNA levels in the developing mouse lung.

Elastatherapy™

- Synthetic human tropoelastin.
- Full length, natural building block of elastin.
- Novel formulation 'liquid skin'.
- No crosslinkers (no glutaraldehyde etc.) – reduced toxicity.
- Reversible.
- Smooth clear non particulate formulation.
- Improve skin elasticity, thickness and tone.



Fibroblasts Can Regenerate Elastin Fibers from Tropoelastin

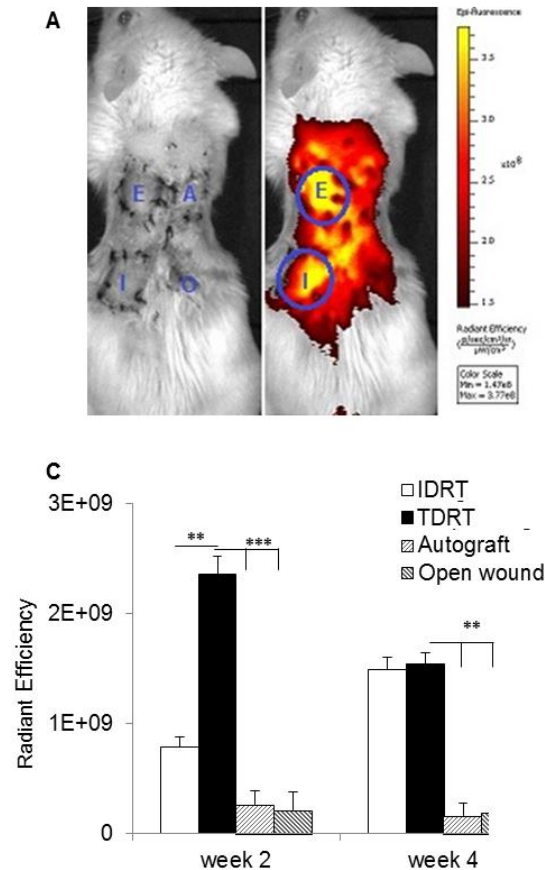


A. Cells; B. Cells + tropoelastin addition on Day 10; C. Cells + tropoelastin additions on Day 10 and Day 17; D. Cells + tropoelastin additions on Day 10, Day 17 and Day 24. All samples were fixed for imaging on Day 31.

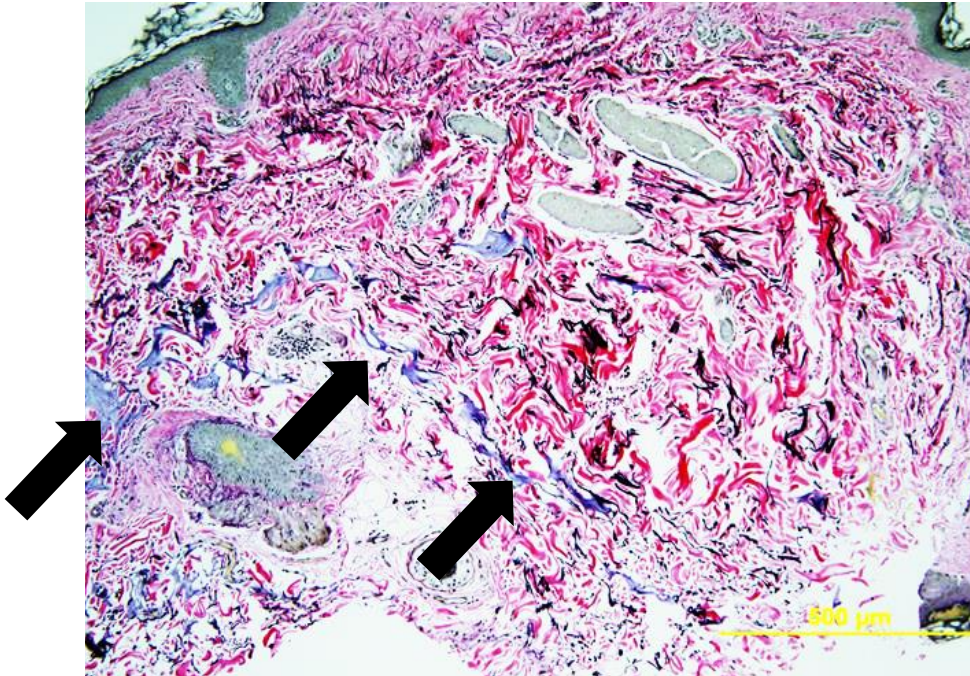
- Majority of elastin is produced during foetal and early neonatal period
- As adults we have limited ability to regenerate new elastin
- Fibroblasts cultured alone produce little new elastin
- However, fibroblasts retain ability to produce elastin if provided with tropoelastin

Tropoelastin Aids the Formation of Blood Vessels in Regenerating Skin

- TDRT induces significantly more angiogenic signals than IDRT as early as 2 weeks. The fluorescent radiant efficiency on TDRT was ~3 times that on IDRT (**A & C**).
- Enhanced levels of the endothelial cell adhesion molecule CD146 in 2 week wound sections in TDRT (**B**), supporting a model of extensive angiogenesis in TDRT during this early stage of wound healing.



Tropoelastin implants in clinical studies integrate into human dermal tissue



Biopsy taken 85 days after implantation VVG staining for elastin (black) with ELA implant stained purple/black (indicated by black arrows)

Company History...

Broadening the pipeline/tissue repair focus

- 2005:
 - Seed funding
 - Licensed Elastin technology from University of Sydney
 - Initiated proof of concept production and formulation
- 2008:
 - Series A investment secured
 - Initiated commercial and clinical operations
- 2009:
 - ISO 13485 & 21CFR820 QM systems in place
 - cGMP Tropoelastin production & formulation process in place
 - Clinical advisory in place
- 2010:
 - Biocompatibility under ISO10993 and PMA complete
 - Clinical program initiated
- 2011:
 - First in man clinical trial complete
 - 'elastatherapy' and nasolabial fold clinical trials initiated

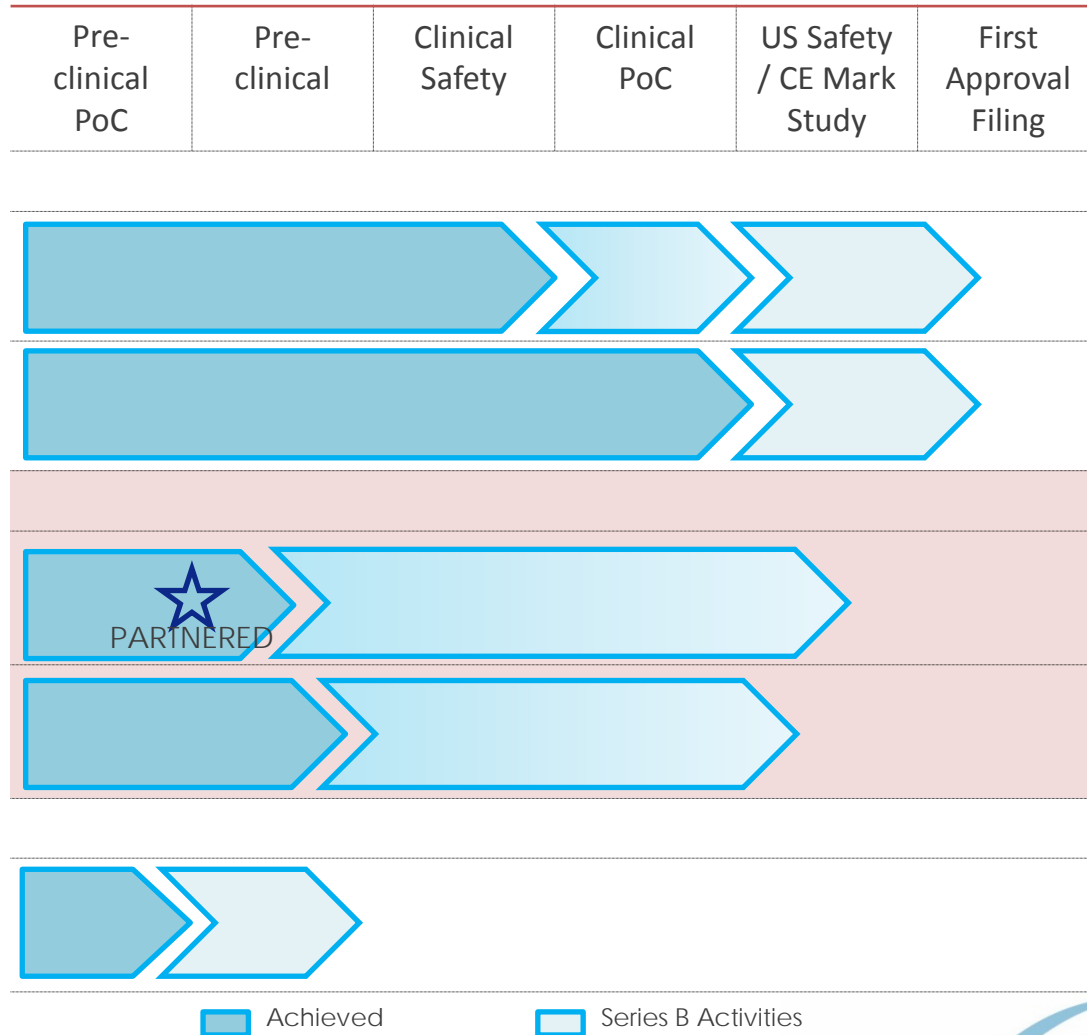
Elastagen is Leveraging its Tropoelastin Platform in Multiple Product Programs

- Elastagen and its scientific founder have pioneered the scientific understanding of tropoelastin and its unique physical and biological properties
- Developed a dominant patent position covering the manufacture, formulation and application of tropoelastin
- Leveraging our tropoelastin platform across three main product areas all of which are class III medical devices:
 - Surgical revision of scars and wound repair
 - Injectable stretch mark scar treatment
 - Dermo-aesthetic for skin rejuvenation
- Established cGMP manufacturing and in process of tech transfer to commercial scale
- Established the safety and biology of tropoelastin in preclinical and clinical settings
- Private, venture backed business – Brandon Capital / GBS Ventures

Clinical Data Demonstrates Safety and Efficacy of Tropoelastin in Dermatology

- Completed three clinical trials comprising ~40 subjects who have received one or more dermal implants of tropoelastin formulations.
- Established excellent safety and biocompatibility profile.
- No evidence of development of circulating antibodies to tropoelastin implants – even after multiple implants.
- Clinical data confirmed biology of tropoelastin based materials, including:
 - Fibroblast recruitment, collagen deposition and tropoelastin implant remodelling
 - Increased skin thickness while maintaining natural skin elasticity
 - Evidence of skin tissue repair properties applicable to treatment of atrophic scars and skin regeneration
- Clinical program ongoing

Advancing Broader Pipeline to Major Clinical Milestones



* Single study, timing dependent on 510k vs PMA regulatory path



Completed Series B Financing in May 2016: Size of opportunity

- Series B round of A\$14M
 - Asian derm player with US managed venture fund – AMOREPACIFIC
 - Korea's leading life science venture investor – Korea Investment Partners
 - Japan's leading regenerative medicine investor – Cell Innovation Partners
 - UK's leading healthcare charitable trust – the Wellcome Trust
 - Internal investors - Brandon Capital and GBS Ventures
 - Brings total equity to date to A\$20M
- In parallel, a partnership with a major US tissue and wound repair company finalised and development program initiated
 - Major go/no go decision end 2017
- Oct 2016 received additional A\$4M from Australian healthcare grant for wound applications
 - Brings total non-dilutive funding contribution to ~\$15M



Elastagen is leveraging its tropoelastin platform in multiple product programs

- Elastagen and its scientific founder have pioneered the scientific understanding of tropoelastin: unique physical and biological properties
- Developed a dominant patent position covering the manufacture, formulation and application of tropoelastin
- Leveraging our tropoelastin platform across three main product areas all of which are class III medical devices:
 - Surgical revision of scars and wound repair
 - Injectable stretch mark scar treatment
 - Dermo-aesthetic for skin rejuvenation
- Established cGMP manufacturing and in process of tech transfer to commercial scale
- Established the safety and biology of tropoelastin in preclinical and clinical settings
- Private, venture backed business

