# FACTOR THERAPEUTICS

# Investor Presentation



March, 2016

Tissue Therapies Limited trading as "Factor Therapeutics", ACN 101 955 088

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# FACTOR THERAPEUTICS



# Company Introduction

*Tissue Therapies Limited trading as "Factor Therapeutics"* 

# **Investment Highlights**



Pharmaceutical strategy	Previously pursued an EMA device route, now focused on FDA biologic drug pathway. Greater value capture for shareholders
Pipeline	A significant pipeline of best-in-class wound care products
Major Market Opportunity	Our products target major unmet needs in chronic wound care, with the efficacy to capture significant market share
Strong Science	Technology has a novel mechanism of action that offers a compelling scientific rationale for efficacy
Manufacturing Scale-up Experience	Company has completed pre-commercialisation production scale- up of product, a major investment and achievement
Significantly De-Risked	Historical EMA challenges means that the company now has a well-documented pathway to success
Team	Restructured board and management team, capable of executing for the future
Intellectual Property (IP)	Excellent (broad/deep) IP portfolio with international coverage and duration

# **Company Snapshot**





ASX ticker <sup>1</sup>	TIS
Product focus area	Wound healing
Headquartered	Brisbane, Australia
Clinical stage	Phase II
Total issued capital	302,878,835 shares
Options	2,500,000 options
Share price <sup>2</sup>	\$0.047
Market capitalisation <sup>3</sup>	\$14.2m
Cash position	~\$70m raised to date, \$2m current
Top 20 ownership	~44% of cap table

#### **Ownership Structure**



# **Experienced Team**





#### Dr. Cherrell Hirst AO FTSE MBBS BEdSt D.Univ (Hon) : Chair

Dr. Cherrell Hirst has had a distinguished clinical career in the detection and diagnosis of breast cancer and extensive and respected achievements as a director of multiple commercial, government and not-for-profit organisations including as Chancellor of QUT from 1994-2004. Dr Hirst is currently Chair of ImpediMed Ltd and a director of Medibank Private Ltd, Gold Coast Hospital and Health Service and RSLCare and in addition she chairs the Advisory Board of the Institute of Molecular Biosciences at UQ. She has previously been a director of Hatchtech, Peplin, Suncorp and Avan amongst others.



#### Timothy Hughes BSc (Hons) BA (Hons) M.NatRes : Non-Executive Director

Mr. Timothy Hughes has over 30 years experience in senior roles in the investment management and investment banking industries. This includes having been Chief Investment Officer at Rothschild Australia, Value Capital Management and Catholic Super. He also wrote a column on economics and investment for the Courier-Mail for 17 years. Tim currently sits on the Investment Advisory Panel of HESTA, one of Australia's largest super funds, and is on the Advisory Board of the Centre for Investor Education.



#### Dr. Christian Behrenbruch B.Eng (Hons) MBA D.Phil (Oxon) JD GAICD : Executive Director

Dr. Christian Behrenbruch has over 15 years of healthcare executive leadership experience. Prior CEO (and executive director) appointments include Mirada Solutions, CTI Molecular Imaging (now Siemens), Fibron Technologies and ImaginAb, Inc. He is a former director of Momentum Biosciences LLC, Siemens Molecular Imaging Ltd, Radius Health Ltd (now Adaptix) and Cell Therapies P/L (a partnership with the Peter MacCallum Cancer Centre). Chris is currently a member of the Monash Engineering Foundation Board and holds adjunct appointments at Monash University and RMIT University.

#### Nigel Johnson B.AppSc(Med&AppBiotech) : CEO

Mr. Nigel Johnson has been with the company in an operational capacity since early inception, and has over 20 years of experience in developing healthcare products in both the private and public sector. Nigel has broad experience in manufacturing, supply chain management, quality, R&D and regulatory affairs. He's been involved in delivering multiple regulated products from a blank sheet of paper into manufacturing, including leading the clinical translation of five recombinant proteins. He began his career with Queensland Health in tissue banking, followed by a role with the Australian Red Cross Blood Service where he was involved in developing a human cell-based product. Nigel has conducted post-graduate coursework in strategic management and is a member of both the Parenteral Drug Association and the American Society for Quality.



#### Dr. Gary Shooter BSc (Hons) Ph.D : Director of R&D

Dr. Gary Shooter is an experienced Protein Chemist and has a proven track record in the GMP manufacture and characterisation of protein-based therapeutics and products. Prior to joining the company, Dr Shooter was a Senior Research Fellow and Leader of the Tissue Repair and Regeneration Program at QUT. Gary has a strong foundation in IGF-I research that stems from his PhD studies at Adelaide University and developed a complementary strength in the science of wound healing while working at QUT from 2004 to 2014. During this period, Gary was primarily involved in developing the protein technology that forms the basis of Factor Therapeutics' intellectual property while supervising various postgraduate research projects aimed at elucidating the biochemical signatures of non-healing wounds.



#### Saskia Jo BCom GIA CPA : Director of Finance

Ms. Saskia Jo has over 10 years commercial experience in finance and compliance. She has been with the Company since 2011 and in additional to her financial management roles, serves as Company Secretary. Prior experience in international sales with Shiseido Corporation in Tokyo, and five years in accounting/finance functions with Burrell Stockbroking.



# **Our Products**

Transforming Wound Care

# What do our products do?

FACTOR THERAPEUTICS

- The company produces biotech products used in advanced wound healing applications – a multi \$billion market opportunity with major unmet need for more effective products
  - ✓ We focus on <u>chronic wounds</u> where the normal processes inflammation / healing cease to function properly
  - ✓ Our first indication is <u>Venous Leg Ulcers</u> (VLUs)
- Our products are biomolecules that re-introduce cell attachment sites and growth factors into wounds that have become barren and difficult places for new skin cells to survive
  - Because we can recruit, attach and propagate cells into the wound bed, we can heal wounds faster
- Hard-to-heal wounds can take months to heal. Accelerating this process has a massive cost-benefit advantage to the healthcare system and to patients
  - ✓ We have future upside potential in other speciality wound care areas with large markets (for example, mucosal burns from radiation therapy, wounds from ocular surgery)



# "Anatomy" of a Chronic Wound?



Lack of attachment sites and growth factors, which encourages new tissue to grow

Skin is breached and subcutaneous tissue is exposed, causing pain

A "crater" rim of dead and inactive cells that is the result of the futile attempt of skin cells to "migrate" into the wound

Chronic wounds can last for months or years. They are recurrent, are prone to infection and are painful. The incidence is growing (venous leg ulcers, diabetic foot ulcers) and are major burden to our healthcare system.

# Our Technology : Molecular "Velcro" + Growth Factors





- ✓ Advanced biologic products for wound care using a targeted growth factor approach.
- ✓ Our products promote healing by 1) providing an anchor point for new cells and 2) providing growth factors to encourage the proliferation of skin cells.
- ✓ Proven potency and safety.
- ✓ A platform technology with multiple clinical applications.

# Visualisation of our Technology



Part 1) and Part 2) work together to create an attachment site for new cells "Skin cells" (keratinocytes, fibroblasts)

Growth factor (IGF-1) < stimulates cell growth

Our molecules provide a kind of "molecular velcro" that enables skin cells to migrate into the wound bed, find attachment sites and then respond to growth factors by dividing and propagating.

# **Unique Mechanism of Action**









\*Diameter of spheres represent relative size of the patient population, 1) Margolis 0,1 classification patients

# Low Competition in the Highest Volume Segment







Our product shows efficacy.

Most importantly it is intended for use in the community setting.

#### AND this is the largest, most important market



- Competing products (animal-derived and synthetic scaffolds, skin suspensions, human tissue-derived products) require physician supervision – "a procedure" – and are considerably more expensive.
- Our product will be suitable for application by a nurse in conjunction with standard of care (compression bandaging).
- Healthcare economics are driving wound care out of the specialty clinical environment into the GP/home and assisted living environment. Our product is highly suited to this trend.
- Health economics : ~USD \$1,000 cost-benefit has been established for a 12 week course (VLU indication). Applicable to both US and EU5.

# **Our Product Shows Promising Efficacy**



In preliminary clinical studies, VF-001 was found to promote healing: <u>1/3 of patients fully healed within</u> <u>12 weeks. 64% of patients ≥ 50% wound area</u> reduction in 12 weeks



# A Typical Result – Venous Leg Ulcers

- Weekly wound irrigation with the product, combined with standard care (compression bandaging)
- Greatest reduction in wound area around ~8<sup>th</sup> week of treatment





- 90% of future investment will focus on the lead program (VF-001\*) for chronic wounds, with first indication for venous leg ulcers (VLUs).
- We have started to explore ways to expand the utility of our technology platform.



## **Intellectual Property Snapshot**



- Potential to be the first approved\* biologic combining an extra-cellular matrix protein with a growth factor no other company is developing proteins that comprise components of vitronectin and growth factors such as IGF-1 and EGF.
- 5 patent families that robustly protect our core products and platform technologies.
- Potential for market exclusivity extensions in the US.

Durable	<ul> <li>Key asset has well defined claim scope</li> <li>Portfolio covers both "next generation" products and practical alternatives</li> </ul>
Exclusive	<ul> <li>Lifespan out to 2024 for lead product</li> <li>Clear strategies to further extend IP life (in progress)</li> <li>New constructs have patent life out to 2031</li> </ul>
Granted	<ul> <li>Major jurisdictions protected, global reach</li> <li>Broad indication support</li> <li>Unequivocal asset ownership</li> </ul>

\*None of the company's products currently have marketing authorisation in any jurisdiction.



# Commercial Strategy

A Corporate Turn-Around

# 2015 : We Restructured the Company





# Key Accomplishments : Past 12 Months



The company has achieved major outcomes for shareholders in the past 12 months, despite EMA setback. We are back on track...

Human Capital	Technical	Regulatory / Clinical	Strategy	Financial
Board restructured and streamlined	"Bridged" our manufacturing process between EMA and FDA. <u>Major</u> <u>achievement.</u>	Augmented internal resource with world- class external expertise	US / FDA-focused strategy to further build value while preparing for EMA resubmission	Substantially reduced burn rate, terminated non-core programs and collaborations
Management team restructure, additional experienced leadership on-board	Acceptance of FDA of CMC/material release assays for Phase II study*	Design of an efficacy study that will assist both FDA progress and EMA re- submission	Articulate company as a biologics company, accentuate the value of our platform technology, rebranding	Cleaned balance sheet, write-off of EU inventory
			Indication / application expansion of core technology	QUT IP assignment completed, simplifies future IP royalty structure



Challenge	Opportunity
Device route proven not to be feasible for the company with current clinical data set.	Pharmaceutical route enables much larger market opportunity / superior price point.
Clinical development rolled-back to Phase II.	Company will have necessary efficacy signals to engage partners in a higher-value proposition.
Transition from EMA to an FDA-focused process.	A larger, more homogeneous (reimbursement) market opportunity for the company.
Additional manufacturing requirements to prepare for Phase III.	Existing scale-up experience can be largely "re-used", better product control = lower COGS, stability, etc.

# Change of Regulatory Strategy





# Significant team effort the past 12 months to transition from device to IND model.

- Sophisticated and detailed gap analysis in collaboration with a top-tier CRO.
- Manufacturing / product characterisation taken to a superior level
- Effective re-engagement with the FDA (<u>Type A</u> meeting), with planned ongoing engagement.
- Clinical plan well-defined for a multi-centre US clinical trial that will pave the way to Phase III.
- The opportunity to revisit EMA at the end of Phase II IND still remains.
- Clear guidance from the FDA on characterisation requirements for Phase III

# High-Level Clinical Plan (VF-001)



# **Business Development Opportunities**

#### Lead Program (VF-001):

- Have already re-engaged with major wound-care players
- New product development strategy a better perceptual "fit"
- Actively pursuing partnership opportunities
- Also interest in diabetic foot ulcers we will pursue a separate IND filing (Q1 2017) with the goal of partnering for this indication

#### Ocular Program (VF-003/4):

- Already collaborative interest
- Major unmet clinical need and a well-identified market opportunity by the major ophthalmology players
- Comparatively low level of competition

Significant business development opportunities exist for our pipeline but strong clinical data at the end of Phase II will maximise the company's value in partnership discussions.





# **Building Value : The Next 18 Months**





including EMA feedback.

 Meet the additional safety database requirements for EMA to enable CE Mark resubmission

\*Diabetic foot ulcers

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# **Capital Raise**

Financing the Next Value Inflection

# Capital Requirements & Use of Proceeds





# **Phase II Trial Objectives**



#### **1.** Show further evidence of efficacy

- Initial clinical experience with VF-001 has been very compelling. Now need to undertake a blinded/randomised, placebo-controlled study – powered to show efficacy
- Build experience in a larger number of sites / treatment settings
- Primary end-point % fully-healed at 12 weeks, secondary end-point(s) pain/safety
- Experience at a higher dose (mostly for safety validation)
- ~200 patients (100 treated), 20+ sites

#### 2. Obtain a larger safety database to satisfy EMA / CE Mark process

- Based on current AE<sup>1</sup> profile, ~100 additional patients required to complete CE Mark process for EMA, based on EMA guidance
- Safety is a key decision-making criteria for Phase III IND process

#### 3. Build a robust data pack to attract partnerships

- Planned investment in manufacturing and clinical data collection will produce the type of validation required to attract partnerships
- Will also lead to opportunities to expand indications for use

# Pipeline Opportunities : Beyond VF-001



Lead Product: Majority investment focus in lead product. Demonstrate efficacy in a manner suitable for both driving partnering and Phase III decision making.

Advanced wound care: \$5Bn global market

**VF-001\*** 



<u>New Product:</u> Formulation development of a viscous form of lead product (incl. barrier formulations) to enable the company to start to evaluate burn market opportunities, including possibly mucosal burns.

> Advanced burn products: \$2Bn global market

> > **VF-002**

<u>New Product</u>: Leverage core IP to further develop a 2<sup>nd</sup>-generation product for ocular wound care. Growth in the number of eye surgical procedures, use of glaucoma stents, etc. has created a significant demand for advanced wound care products to accelerate healing, reduce fibrosis and minimise negative effects of ocular surgery. We have <u>two drug candidates</u> that are potentially first-in-class. Post-surgical eye-care \$1.5Bn global market

> VF-003 VF-004

# Offer details



Details	A two tranche placement to institutional and sophisticated investors of approximately 275 million shares at an offer price of \$0.035 per new ordinary share ( <b>Offer Price</b> ) to raise \$9.65 ( <b>Placement</b> ), together with a non-renounceable entitlement offer to existing shareholders ( <b>Entitlement Offer</b> ) (together the <b>Offer</b> ). The Entitlement Offer will be offered at a ratio of 2 new shares for every 5 shares held.
Pricing	<ul> <li>The Offer Price of \$0.035 represents:</li> <li>19.0% discount to the 15 business day volume Weighted Average Price up to and including 15 March 2016</li> <li>17.5% discount to the 30 business day volume Weighted Average Price up to and including 15 March 2016</li> <li>20.5% discount to the theoretical ex rights price</li> <li>25.5% discount to the closing price on 15 March 2016 of \$0.047</li> </ul>
Use of funds	<ul> <li>As well as providing the Company with working capital to meet operational costs, the Company intends to use existing cash and proceeds for:</li> <li>execution of a Phase II clinical trial in the United States under an FDA Investigational New Drug Application (IND);</li> <li>manufacturing, material certification and stability testing to meet the needs of Phase III clinical trial and beyond as a pharmaceutical; and</li> <li>further development of core technology into new indication areas including ocular wound healing.</li> </ul>
Other	<ul> <li>New securities issued pursuant to the Offer will rank equally with the Company's existing securities</li> <li>Taylor Collison are the Lead Manager and Underwriter to the Offer</li> </ul>

# Timetable



Activity	Date
Announcement of the Entitlement Offer	18 March 2016
Mailing of the Entitlement Offer details	21 March 2016
Settlement of tranche 1 placement shares	23 March 2016
Ex date	29 March 2016
Record Date for Entitlement Offer (7.00pm (AEDT))	30 March 2016
Information Booklet and Entitlement & Acceptance Form despatched	1 April 2016
Entitlement Offer opens	1 April 2016
Closing date for acceptances under Entitlement Offer (5.00pm (AEDT))	19 April 2016
New Shares quoted on deferred settlement basis	20 April 2016
Company notifies ASX of under subscriptions	22 April 2016
Allotment of New Shares under the Entitlement Offer	26 April 2016
Despatch of holding statements for New Shares issued under the Entitlement Offer	27 April 2016
Normal ASX trading for New Shares issued under the Entitlement Offer commences	27 April 2016
Extraordinary general meeting to approve second tranche placement	28 April 2016
Anticipated settlement of tranche 2 placement shares	3 May 2016

This timetable is indicative only and subject to change. The Directors may vary these dates, subject to the Listing Rules. The last date to extend the closing date is14 April 2016. An extension of the Closing Date will delay the anticipated date for issue of the New Shares. The Directors also reserve the right not to proceed with the whole or part of the Entitlement Offer any time prior to issue of the New Shares. In that event, the relevant Application Monies (without interest) will be returned in full to Applicants.

	31-Dec-15 Reviewed	Placement	Entitlement Offer	31-Dec-15 Pro-Forma
	\$ 000's	\$ 000's	\$ 000's	
Current Assets				
Cash and cash equivalents	2,737	9,057ª	4,851 <sup>b</sup>	16,645
Receivables	62	-	-	62
Incentives – R&D claim	84	-	-	84
Inventories	352	-	-	352
Other assets	67	-	-	67
Total Current Assets	3,302	9,057	4,851	17,210
Non-Current Assets				
Inventories	716	-	-	716
Property, plant and equipment	99	-	-	99
Intangible assets	557	-	-	557
Total Non-Current Assets	1,372	-	-	1,372
Total Assets	4,674	9,057	4,851	18,582
Current Liabilities				
Payables	674	-	-	674
Current tax liabilities	12	-	-	12
Provisions	131	-	-	131
Other liabilities	30	-	-	30
Total Current Liabilities	847	-	-	847
Non-Current Liabilities				
Other liabilities	60	-	-	60
Total Non-Current Liabilities	60	-	-	60
Total Liabilities	907	-	-	907
Net Assets	3,767	9,057	4,851	17,675
Fauity				
Contributed equity	66 029	9 057	4 851	79 037
Reserves	(33)		-,001	(33)
Accumulated losses	(62 229)	-	-	(62 229)
Total Equity	3,767	9,057	4,851	17,675

#### Notes to the Pro Forma Consolidated Statement of Financial Position:

Pro Forma Adjustments

The Pro Forma Consolidated Statement of Financial Position has been prepared on the basis that the following significant transactions occurred as at 31 December 2015:

Material transactions since 31 December 2015:

- a) The issue of 275,719,708 New Shares arising from Placement to professional and sophisticated investors at \$0.035 per Share less raising costs of \$0.6m totalling \$9.1m. The Placement will be conducted in two tranches being:
  - Tranche One issue of 75,719,708 Shares to raise \$2.7m less Offer Costs of \$0.2m; and
  - Tranche Two issue of 200,000,000 Shares to raise \$7.0m less Offer Costs of \$0.4m, subject to Shareholder approval following the Entitlement Offer.
- b) The issue of approximately 151,439,417 New Shares via the Entitlement Offer, at \$0.035 per Share less Offer Costs of \$0.5m totalling \$4.8m.



Regulatory Approvals	Company may not obtain the regulatory approvals (including US Food and Drug Administration (FDA) approval) that it requires for sale of its products or the reimbursement approvals required for sales growth, or such approvals may be subject to delay
Clinical Trials	Clinical trials may prove unsuccessful
Requirement to Raise Additional Funds	Company currently has no material revenues. It may need to raise additional funds in the future, which may not be available on favourable terms, and which may have a dilutive effect on existing shareholders
Dependence on Commercial Partners	Company is dependent on the performance of its commercial partners and the retention of key consultants and personnel for its specialised business
Intellectual Property	Company's value may be impacted if its intellectual property is not able to be adequately protected
Competition	Company may face competition from better-resourced industry participants



#### Key Messages:

- Company has undergone a major change in the last 12 months. Transition from a device to a biologic drug strategy.
- Orderly response : major management and board restructuring.
- Company has the opportunity to significantly advance the articulation and development of its technology, is back on track with its regulatory and clinical strategy.

Seeking \$15m in capital to get lead program through Phase II and to realise the potential of the company's wound healing platform, including some preliminary work around indication expansion.

- ✓ Clear use of proceeds, primarily focused on lead program.
- ✓ Significant commercial and clinical value inflections in the next 18 months.
- ✓ Biologic/IND pathway broadens the market opportunity for the company.



# Appendix : Clinical Summary VF-001

**Our Lead Product in Action** 

# **Clinical Objectives**

FACTOR

- Initial focus : chronic wound application Venous Leg Ulcers (VLUs)
  - Major patient population (3% of the population, ~3m people in the US alone)
  - Major burden on the healthcare system, major unmet need for better, cost-effective treatments
  - Standard of care is compression bandaging
- We want to treat *all* patients, not just those with the most severe wounds
  - The most severe cases will end up in specialty wound care clinics, disease is multifaceted
  - Severe cases will be treated with more complex products/procedures
  - Severe cases are a relatively small % of the market for VLUs (~6%)
- We are <u>very</u> interested in treating mild-moderate severity patients
  - Accelerated healing time means big cost savings
  - Treatment in the community setting is a huge differentiation
  - > Our products are easily combined with standard care weekly compression bandaging
  - ➢ 94% of the patient population



Severity	Proportion in the real world population	Probability of Healing within 24 Weeks with Limb Compression (%)*	Baseline Ulcer Area (cm²)	Ulcer Duration (months)
0 (least severe)	~ 69%	93.0 %	≤ 5	≤ 6
1 (middle)	~ 25%	65.0 %	≤ 5	> 6
r (maale)			> 5	≤ 6
2 (most severe)	~ 6%	13.0 %	> 5	> 6
		To have pa healthcare the entire p just the mo	atient benefit impact, we population o	t and need to trea f patients, no

\* Margolis DJ, Berlin JA, Strom BL. Which venous leg ulcers will heal with limb compression bandages? Am J Med. 2000 Jul;109(1):15-9.

# Summary of Clinical Experience to Date



- Evaluated in 53 patients to date. Demonstrated efficacy, indicating that VF-001\* delivers significant clinical benefit to a hard-to-heal patient population
- VF-001 plus standard care (SC) compared to SC only Day 90:
  - Cross-trial data 1:1 propensity score matched from raw data on major prognostic factors for healing (ulcer area and duration) and age. Comparator is large published UK data set on chronic VLUs



# Significantly faster healing profile with VF-001

# Moderately Severe Patients Respond the Best



"Margolis 1" patients are moderately severe patients.

VF-001 almost doubles healing rates in this patient population with statistical significance.

Log-Rank Test:			
Statistic	DF	P Value	
12.065	2	0.002	



\* Margolis DJ, Berlin JA, Strom BL. Which venous leg ulcers will heal with limb compression bandages? Am J Med. 2000 Jul;109(1):15-9.

## **Illustrative Examples**



- 15.4 cm<sup>2</sup> ulcer at entry
- 5 years duration
- Healed at week 7

- 4.4 cm<sup>2</sup> ulcer at entry
- 7 years duration
- Healed at week 8

# **Before** PATIENT:

After





# Study Ulcer Comparison with Adjacent Ulcer





#### **Treatment:**

VF001 applied to study ulcer only while adjacent ulcer remained untreated

Study ulcer duration: 3 yrs

Adjacent ulcer duration: 3 yrs

# Study Ulcer Comparison with Adjacent Ulcer





#### Time point: Week 8

Study ulcer: Ulcer area reduction

#### Adjacent ulcer:

Enlarged and deteriorated. Serves to illustrate how localized the treatment is

# Study Ulcer Comparison with Adjacent Ulcer



#### Visit: 0 (Enrolment)





Healing of VF001 treated ulcer and deterioration of untreated ulcer



- ✓ ~90 patients have been treated with our technology, 53 with the current recombinant product (VitroCard study). The VitroCard study was enriched with Margolis 1 and 2 patients
- ✓ A 1/3 of refractory ulcers healed in 12 weeks, in a very hard-to-heal patient population
- ✓ Healing trajectory restored in ¾ of patients in 12 weeks
- ~ Half of all treated patients achieved a reduction in wound area of > 70% in 12 weeks
- Evidence for effectiveness includes cross-trial comparison to standard care data from 3 large studies
- ✓ Good product safety profile observed to date, comparable to standard care (compression bandaging)