



Tissue Repair Limited Progress & Company Update

Tony Charara
Co-founder and Executive Director

Achievement of prospectus objectives are within sight



Phase 3 first patient expected September 30



Sites secured in principle



Secured TGA approval for Glucoprime® as a Listed Medicine



Device application for Glucoprime ahead of drug approval



+100% sales growth last quarter

The first patient randomisation is scheduled to occur on 30 September 2024.

Target 18-month recruitment time frame, subject to enrolment. No additional FDA feedback expected.

Twenty-five sites were secured - with 20 wound clinics and hospitals in the US and five major Australian hospitals participating in the trial.

We have secured Listed Medicine status with the TGA for Glucoprime®. PR launch expected in Q1 2025. The listing will allow for healing claims and marketing of the complete data pack across additional wound and derm indications.

Device application for Glucoprime® as a skin substitute expected to be filed in the US next quarter. Reimbursement code (USD1500).

Will allow market entry ahead of drug approval in chronic wounds (subject to reg approvals).

Last quarter sales growth for TR Pro+™ c100% over the prior quarter. Cosmetic monthly sales now at c\$26k per month and in around 150-200 clinics with a strong retention rate.

Consistent and strong, real-world feedback on product effectiveness.

**DRUG - TR987® Phase 3 final stage drug trials
18-month recruitment period from September 30**

Commercialisation

Quick recap on Tissue Repair Ltd

Tissue Repair is a Phase 3 biotechnology company with a technology platform applicable to all wounds in animals or humans.

The Company is fully funded to conduct two global pivotal trials for its drug candidate, TR987®, it could be the first drug approved for chronic wounds in around 25 years.

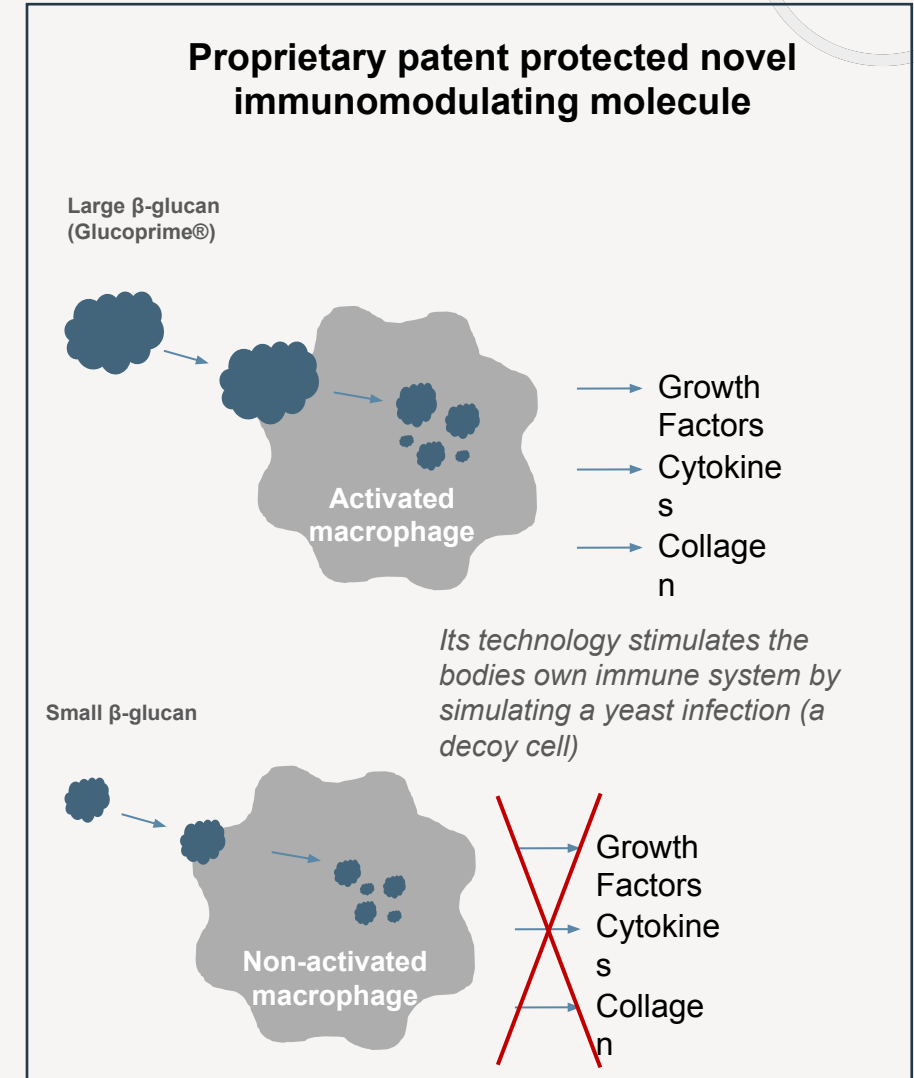
Phase 2 data shows a treatment effect of 20% in the incidence of complete closure; considered by most KOLS to be break-through efficacy.

TR Pro+™ has been launched - commercialising the technology in aesthetics and acute wounds and laying the foundations for scaling. The Company has started generating revenue in Australia for its first product, which it believes has a strong growth opportunity as a global product.

The majority of its considerable cash reserves of cAUD\$17m and an additional c\$8m in OS certificate R&D grants is being utilised to complete the Phase 3 trial program.

The Company has no plans for any additional raises and is fully funded.

The Company is a rare genuine Phase 3 asset fully funded to complete pivotal trials in significant global addressable markets.



TR Pro+™ - Initial Technology Commercialisation

Real world Feedback that includes more than 50 testimonials from clinicians, doctors, cosmetic nurses and dermal therapists

Dr Olivia Fox
General Practitioner
Wylah Skin Aesthetics

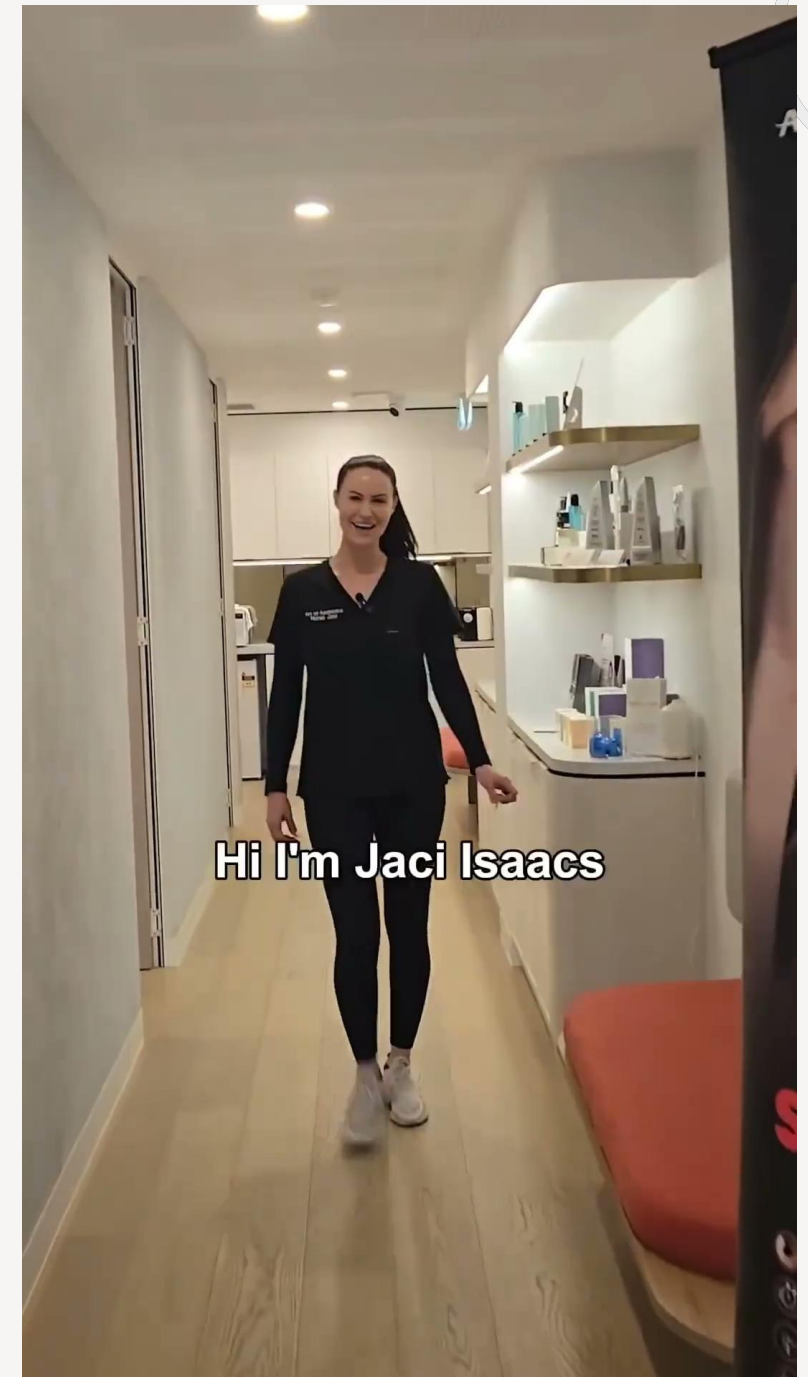


Dermatologist
Dr David Scott
Your Skin Clinic

Dr David Scott
MBBS FRACGP
Diploma Dermatology

Hi, I'm Dr.

Jaci Issacs
Registered Nurse
Clinical Director Art of
Aesthetics

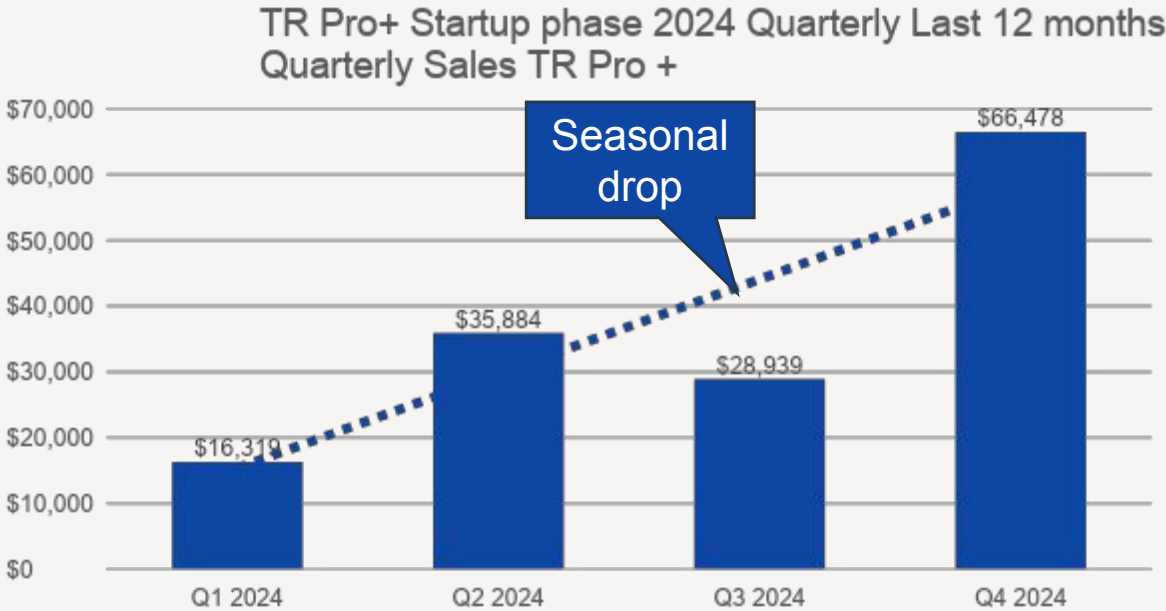
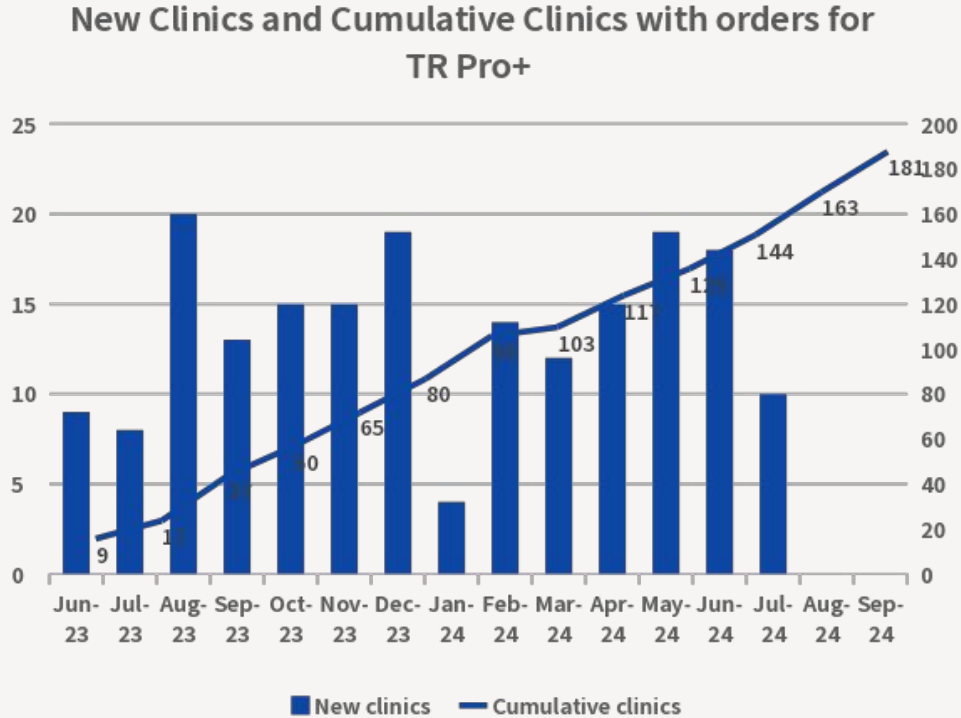




We have been laying foundations to scale

Last quarter sales up over 100% in the Quarter (150-200 clinics)

- The priority is preparing for scaling via partners and less about sales growth -> primary focus is clinic distribution.
- Still small numbers given very limited investment, but management believe **proof of product market fit for a global product opportunity has been achieved.**
- Current sales growth likely to be inconsistent as foundation work continues, but we believe strong growth will be achieved over the medium term.
- Growth is with only c1.2FTE sales reps in NSW. Currently recruiting for two additional reps in QLD and VIC.
- Pursuing a number of exciting distribution/partner opportunities.



TR Pro+™ has been approved as a TGA listed medicine . . . a significant development

The TGA Listing allows Tissue Repair to expand into a broad range of additional dermatology and aesthetic indications

Existing aesthetic applications

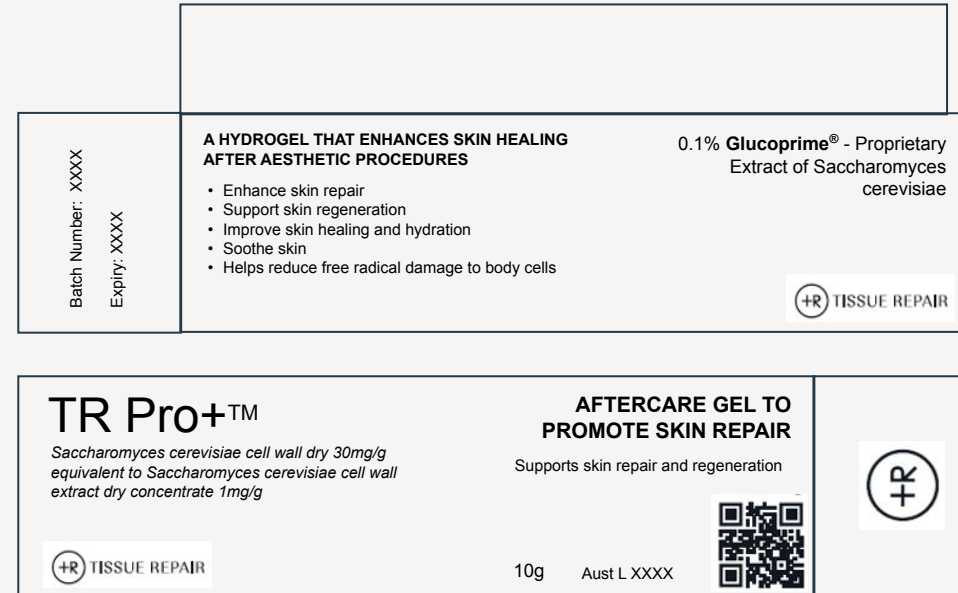
Skin needling
Non-ablative laser
Ablative laser
Sclerotherapy/vascular laser
Body sculpting / cellulite
Laser tattoo removal
Platelet rich plasma

Existing medical applications

Biopsy
Excisions (including skin cancer excisions)
Cryotherapy and serial curettage excision
Removal of skin lesions
Scar revision

Additional medical applications

Solar Keratoses
Burns
Surgical acute wounds
Cuts and abrasions



- TR Pro+™ now has claims around improvements in healing
- Able to attach and communicate comprehensive data package which could not be done as a cosmetic
- The Company is in discussions with a number of global and domestic businesses for distribution rights for TR Pro+™ which can now be stocked in pharmacy off the back of the TGA listing

Some examples . . . Fractional laser skin resurfacing



A split face procedure shows the profound impact of TR Pro+™ at **18 hours** where the skin is significantly less red and does not have the raised circles from the laser.

The patient could not believe the impact following application compared to their usual healing.



Morpheus8 (RF skin needling)

The effects of TR Pro+™ were apparent in as little as **one hour**, with less visible redness. The patient reported almost instantaneous cooling and soothing that reduced the pain and tingling compared to prior procedures.



Chemical peel

At **18 hours**, and after the application of TR Pro+™, the skin was significantly less flaky and there was little evidence of the peel procedure the day before. As well as reduced redness and irritation, TR Pro+™ was able to significantly reduce the patient downtime without compromising the benefits of the peel.



Hard to heal sore - BCC removal (basal cell carcinoma)

Elderly man had a BCC removed
from his lower leg.

After **5 days** the previously
infected wound appeared healthy
and close to healed.

Patient indicated this healing was
significantly quicker and less
painful than previous removals.



Wounded skin

Minor headwound impact.

After **48 hours**, this head wound was noticeably smaller and by 7 days there was virtually no sign of the damaged skin.



Superficial burn



After **5 days** without using TR Pro+™ this burned skin still appeared red and painful.
Three days of treatment with TR Pro+ cooled and soothed the wound and left the skin looking healthy.

TR Pro+™ used as the glide solution during needling

TR Pro+™ was infused during the needling procedure on the right-hand side of the face while the other side was untreated.

The treated side is clearly less red and according to the client had less pain and irritation.



Lipoma excision

The TR Pro+™ was applied
from **day 3**, three times a
day with a clean cotton tip.

There was no post heal
itching, inflammation or
sensitivity.





TGA listed version of TR Pro+™ has the potential of to be a \$10m- \$50m revenue business in Australia alone, assuming a 10% - 20% market penetration rate (illustrative only)

Tissue Repair may not enter these markets on its own would look to partner off the back of a TGA product

Procedure	Customer							1% Penetration		5% Penetration		10% Penetration		20% Penetration		Reference	
	GP - Aestheti	GP - Skin	Dermatol ogist	Cosmeti c	Nurse	Plastic Surgeon	Dermal Therapi	Total	Units	Revenue	Units	Revenue	Units	Revenue	Units		Revenue
Aesthetic																	
Skin needling	2,520		1,064	769	11,340	-	48,127	63,820	957	36,377	4,787	181,887	9,573	363,774		Fifty Five Five Market Research December 2021	
Non-ablative laser	2599		3,559	1,308	22,050	5,314	18,630	53,460	802	30,472	4,010	152,361	8,019	304,722			
Ablative laser	1496		1,636	1,538	18,270	429	9,315	32,685	490	18,630	2,451	93,152	4,903	186,305			
Sclerotherapy / vascular laser	2599		3,436	2,000	12,600	429	1,552	22,616	339	12,891	1,696	64,456	3,392	128,911			
Body sculpting / cellulite	2205		164	2,038	11,340	3,686	3,105	22,538	338	12,847	1,690	64,233	3,381	128,467			
Laser tattoo removal	2992		82	1,423	13,860	257	1,552	20,167	303	11,495	1,513	57,476	3,025	114,952			
Platelet rich plasma	630		286	231	14,490	86	-	15,723	236	8,962	1,179	44,811	2,358	89,621			
Total	15041		10,227	9,307	103,950	10,201	82,281	231,009	3,465	131,675	17,326	658,376	34,651	1,316,751	69,303		2,633,503
Biopsy, excisions etc																	
Skin cancer excisions			45,650					45,650	685	26,021	3,424	130,103	20,543	780,615	41,085	1,561,230	Medicare Statistics June 2022 to July 2023 Items 31377, 31378, 31379, 31380, 31381, 31382 or 31383 30071, 30072, 30078, 30081, 30084, 30087, 30090, 3009, 30094, 30820 31356, 31357, 31358, 31359, 31360, 31361, 31362, 3136 3, 31364, 31365, 31366, 31367, 31368, 31369, 31 270, 21271, 21272, 21273, 21274, 21275, 21276, 45510, 45512, 45515, 45518
Biopsy for diagnostic purposes			1,645,548					1,645,548	24,683	937,962	123,416	4,689,812	246,832	9,379,624	493,664	18,759,247	
Cryotherapy and serial curettage excision			285,995					285,995	4,290	163,017	21,450	815,086	42,899	1,630,172	85,799	3,260,343	
Removal of skin lesions			1,316,657					1,316,657	19,750	750,494	98,749	3,752,472	197,499	7,504,945	394,997	15,009,890	
Scar revision			8,880					8,880	133	5,062	666	25,308	1,332	50,616	2,664	101,232	
Total			3,302,730					3,302,730	49,541	1,882,556	247,705	9,412,781	509,105	19,345,971	1,018,209	38,691,942	
Solar Keratoses																	
Treatment of SK (units of product)			308,684					308,684	3,087	175,950	15,434	879,749	30,868	1,759,499	61,737	3,518,998	IMS data (2020) includes Efudix, Aldara, Picanto, Solaraze plus generics
Total			308,684					308,684	3,087	175,950	15,434	879,749	30,868	1,759,499	61,737	3,518,998	
Scar Treatment																	
Total										2,190,181		10,950,906		22,422,221		44,844,442	

Excludes bites stings cuts and abrasions and other acute wounds

TR 987 Phase 3 Drug Trial Initiation

**First patient randomisation
scheduled for
30 September 2024**



CLINICAL TRIAL PROTOCOL

Protocol Title: TRIVIA Study (Tissue Repair Gel in Venous Leg Ulcers in AU/US). A Phase 3 Randomized, Parallel Group, Double-Blind, study to Evaluate the Efficacy, Tolerability, and Safety of TR987® 0.1% gel versus Standard of Care in the treatment of Chronic Venous Insufficiency Leg Ulcers (VLU)

Protocol Number:	BG002
Version Number:	2.0, Amendment 1.0
Version Date	08-Jul-2024
IND#:	073122
Indication:	Chronic venous insufficiency leg ulcer (VLU)
Development Phase:	Phase 3
Investigational Drug:	TR987® 0.1% gel
Comparator:	Standard of Care (SoC)
Sponsor:	TR Therapeutics, Inc. 1717 Pennsylvania Ave NW, Suite 1025, Washington, DC 20006

TR987® Phase 3 trial update

Key trial numbers

- 2x Phase 3 trials
- BG002 (US) 300 patient trial
- BG003 (Primarily Australia) 300 patient trial
- 20 sites participating in the US and 5 major hospitals in Australia
- Professor Robert Kirsner, Principal Investigator for the US trial, a prominent KOL in VLUs and was PI on their VLU drug trial (Smith and Nephew HP 802-247)

First patient targeted to be randomised by 30 September (screening in mid-September)

Trial recruitment period of 18 months from initiation

Interim analysis point for futility to be advised at 25% recruitment c6 months from initiation

Significant amount of work for the NDA (new drug application) has been completed (e.g. majority of the method validations etc.)

Some delays but prospectus objectives are being met within the funding envelope



Additional work on the protocol and optimizing trial design

- Control arm will be standard-of-care and not vehicle gel, to support reimbursement and health economics application
- Saved US\$5m in potential toxicology animal work (FDA cleared)
- Significant and unexpected FDA feedback on protocol and Chemistry, Manufacturing and Controls (CMC) all of which had to be accounted for and funded

CMC unforeseen challenges

- Manufacturer partner had a serious incident in their production facility
- Incident resulted in a 6-month delay and lost 300 grams of clinical material which was planned for the clinical trial stock
- Notwithstanding the above, a complete Module 3 was updated to the FDA IND file

Trial cost blow outs have meant we have internalised CRO with considerable savings

- Per patient costs doubled, FDA sought additional patients than forecast
- Pivoted from outsourced CRO to an internal CRO team, (now a staff of 7FTE to save considerable funds to allow us to progress within our funding envelope)

- *The Phase 3 trial is fully funded despite the challenges*
- *Management has stayed the course with a venture style and founder-led ethos to pivot and solve challenges effectively*
- *Ensure we can meet our objectives without a dilutive raise*

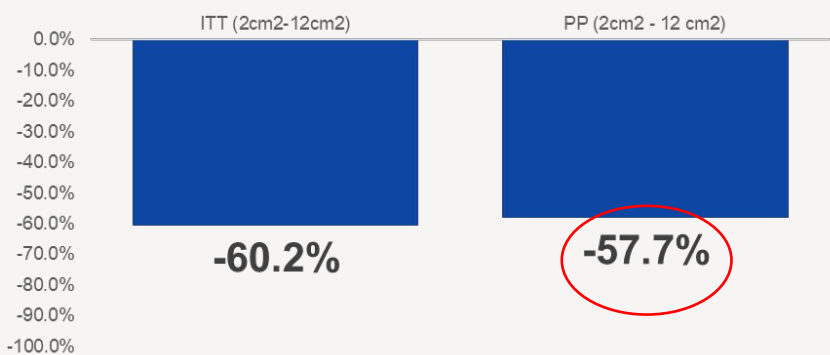


The Phase 3 opportunity is exciting because a 20% delta in VLUs in pivotal trials has not previously been demonstrated

Per protocol Phase 2B dataset

At least 50% reduction in VLU area	19.1%	OR 4.86 (1.17, 20.2) 89.2% vs 63.1% p=0.030
At least 70% reduction in VLU area	27.0%	OR 3.23 (1.03, 10.1) 74.7% vs 47.7% p=0.044
At least 90% reduction in VLU area	29.6%	OR 3.39 (1.08, 10.6) 65.1% vs 35.5% p=0.036
At least 95% reduction in VLU area	29.3%	OR 3.51 (1.06, 11.6) 55.8% vs 26.5% p=0.039
Achieved 100% re- epithelialized	24.2%	OR 2.82 (0.84, 9.46) 51.5% vs 27.3% p=0.093
Percent change in ulcer area	34.0%	34.0% reduction (-58.7, -9.3), p=0.007

Meta-analysis of all Phase 2 patients
Mean wound reduction change between placebo and active
in VLU 2-12cm² n=147



Protocol and optimized trial design

- Control arm will be standard-of-care and not vehicle gel, to support reimbursement and health economics application
- Use of a MolecuLight phosphorescent camera to detect bacteria and control for infection -> patients with a large bacteria load are excluded. Controlling for infections will enhance efficacy.
- Trial inclusion criteria set at 2-12cm² -> larger wounds are harder to heal
- Increased treatment period to 16 weeks to provide more time to detect a difference. In Phase 2, patients with 90% or 95% healed wounds had superior efficacy at 12 weeks compared to patients that were 100% healed

Improved trial design to improve our prospects to replicate the Phase 2 delta in Phase 3

New analysis on mechanism of action at the University of South Australia (UniSA)

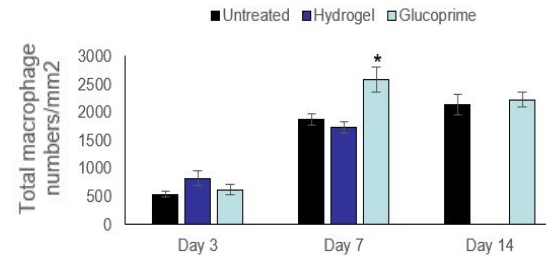
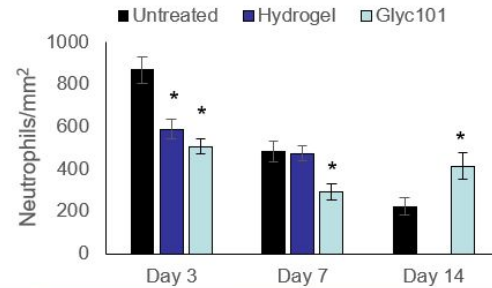
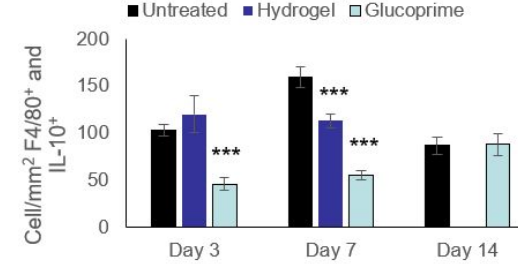
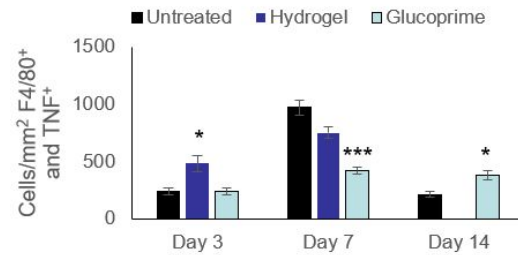
Research by UniSA demonstrates how Glucoprime® can modulate the balance between pro- and anti-inflammatory stages during healing

At day 1 we know there is a spike of TNF α

1.

Reduced levels of TNF α at the wound site....

Macrophage (F4/80) and cytokines



Fewer neutrophils required because there is less inflammation at day 7

2.

....and less neutrophils required

Lower IL-10 at day 7 means less inflammation

3.

....less IL-10 is needed to manage the inflammation....

4.

....but a greater number of macrophages are present.

Almost double the number of macrophages at day 7 to assist with tissue regeneration



University of South Australia

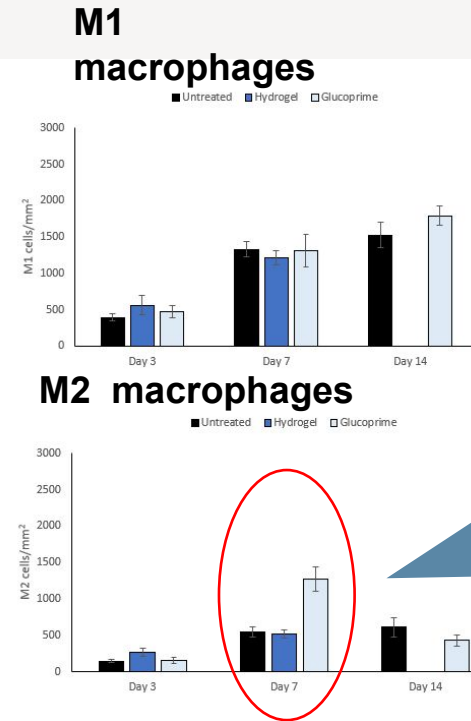
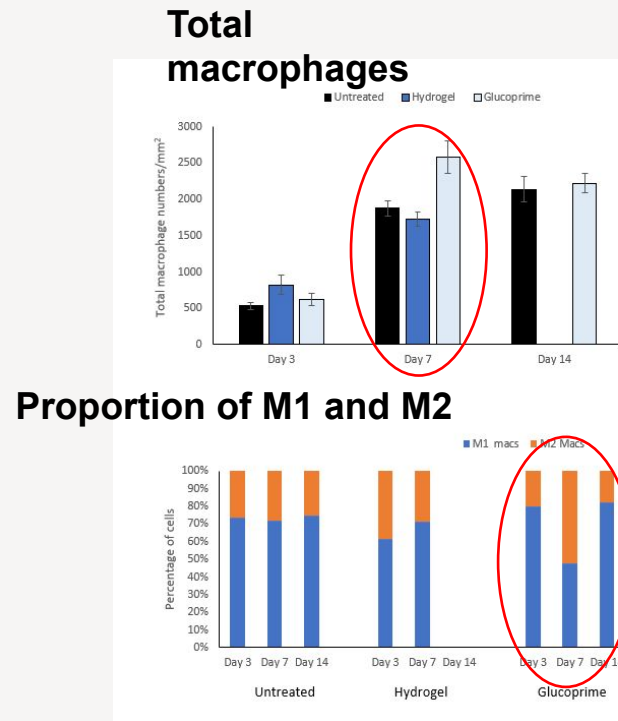
- F4/80 - mouse macrophage
- TNF – tumour necrosis factor
- IL-10 – Interleukin 10
- YM-1 – M2 macrophage

- Wound analysis on mice following a 10mm punch biopsy.
- One application of TR Pro+ was applied immediately after the procedure.

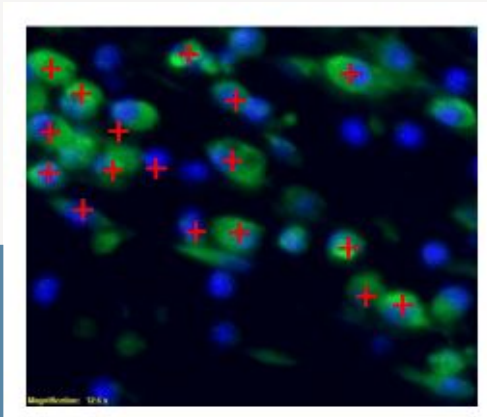
* Data on file. University of South Australia and Tissue Repair Ltd.

TR Pro+™ facilitates the transition of M1 to M2 macrophages*

This MoA is powerful and has application to a significant number of wound types and dermatologic indications



Over double the number of M2-type macrophages at day 7 (anti-inflammatory impact)



Macrophage (F4/80) / TNF dual staining



- Preliminary data indicates a higher proportion of M2-type macrophages compared to the untreated and hydrogel-only samples.
- M2-type macrophages support the regeneration of damaged skin, leading to accelerated healing and superior quality.

A case study: Oneness Biotech's primary product is Fespixon currently in trials in the USA at Phase 3 in DFUS with a US2.2b market capitalisation. . . TR is trading below cash backing.



Shares on Issue 60,464,843

Options on issue 21,954,292

Most options grants made pre-ipo and all post IPO grants made at IPO price

Cash as of 30 June 2024 \$18m

R&D (Aus industry certificates) \$8m

Total effective cash \$26m

Cash backing per share **\$0.43**

Share price as at 25 July \$0.22

Market Capitalisation **\$13.1m**

Discount to cash backing **c42%**





Market ascribed a valuation of US\$2.2b down from recent highs of cUS\$4b

- Based on Chinese herbal extracts
- Oneness Biotech (Taiwan) listed company. Primary product is Fespixon (but does have other products in its pipeline) Fespixon is the most advanced product
- Chronic wound gel to accelerate healing in diabetic foot ulcers
- Limited revenues
- Approval in Taiwan and currently in Phase 3 in DFUS)





In summary Tissue Repair has a significant opportunity ahead with a track record of achieving goals and navigating challenges

TR Pro+™ Medical and aesthetic wounds incl. burns	Australian TAM +AUD100M Global TAM +AUD1.5b	Generated revenue now with strong growth TGA approved with marketing commencing Q1 2025 Exploring approvals in China, UK and US Q1 2025 Exploring a significant number of third-party distribution opportunities
TR987® Device VLU	 Global TAM +US2b	Device approval targeted Q1 2025. Ability to entry chronic wound market with reimbursement
TR987® Drug VLU		Phase 3 Trial initiation Sept 2024
Drug other chronic wounds	Global TAM +US20b	Exploring ability to undertake additional truncated trials (e.g. DFUs pressure ulcers) to support other indications

Founder strategy has not changed and prospectus objectives remain in sight

Opportunity is still clear and real with Global Phase 3 assets trading at significant premiums to TR

(even with similar end markets, indications)

Dedicated founding team with significant venture, operations experience delivering growth outcomes in healthcare and highly regulated areas:

- o **Track record in delivering significant growth outcomes** Myself and my co-founder founded Mable, Australia's largest healthcare delivery platform, delivering over 600,000 hours of care and support per month and a 75% CAGR over the preceding five years. The group processes +1B in healthcare funds. Over 20m hours of care and support delivered to date.
- o **Management team has a depth of experience** COO, VP of Clinical, VP of Regulatory and CMC team, have depth of experience in sales and marketing, product development regulatory, clinical and analytical chemistry and manufacturing.
- o **Co-founding team clear understanding of the science and MOA and trial design** having been heavily involved in all operations across the Phase 2 program as well as authoring 3 recent patents as co-inventors.

Small highly experienced seasoned team of executors

Tony Charara
Co founder and Executive Director

Tony is a co-founder of Tissue Repair. He has been actively involved in the Company's clinical development program, across its two-phase 2B trials, commercialisation strategy, IP, manufacturing, analytical development and overall operations. Tony holds patents in the company's proprietary technology platform Glucoprime®. Tony is an investment banker by background and has extensive experience across early-stage venture assets and in advising technology companies at JPMorgan Tony is also a co-founder of Mable Australia's largest online health technology platform operating in the health services and aged care and disability sectors. Tony was named one of Australia's top 100 innovators by the Australian in 2022 and is a finalist in EY entrepreneur of year 2024

Dr Darryl Reed
Chief Operations Officer

With over 25 years' experience in the pharmaceutical industry, Dr Reed has worked across research, Government and the private sector. At the completion of his melanoma research fellowship in Lausanne, Switzerland, Darryl relocated back to Australia where he joined the Therapeutic Goods Administration (Dept. of Health) and represented the Government on several joint industry committees. Moving to the private sector, Darryl has worked in a variety of senior roles with both Roche and Bayer, spanning regulatory and scientific affairs, medical and clinical support, product development, and sales and marketing.

AnhThu Nguyen
VP Clinical

AnhThu is a seasoned professional with broad therapeutic experience in pharmaceutical, medical device and health technology. Previous leadership roles include Executive Director of Clinical Operations at 9 Meters Biopharma working across the gastrointestinal and rare disease space, Senior Director of Clinical Operations at Synergy Biopharma serving an integral role in the FDA approval of Trulance®, and while at AbbVie (Forest Laboratories) supported the sNDA approval of Vraylar® in Major Depressive Disorder. AnhThu is also a co-founder at Veuu, a revenue cycle management platform, that adjudicates, and discharges health insurance claims using Artificial Intelligence (AI) to reduce medical coding errors and calculate insurance payment risk.

William Bost
VP Manufacturing

Bill is a chemical operations and process specialist with extensive experience advising pharmaceutical manufacturers in drug development and manufacture, with a focus on topicals. Bill has direct specific experience in approved wound topicals including the only topical drug approved for chronic wounds over the last 30 years. Bill led the technical manufacturing transfer of the

Dr Pramod Nedoor
VP Chemistry and Analytics

Dr Nednoor has held leadership roles at a number of pharmaceutical companies undertaking drug development and manufacturing activities. He has extensive experience assisting small and medium size pharma companies in identifying, evaluating and selecting CDMOs, contract analytical and microbiology labs to support drug development for IND/NDA/ANDA submissions. Dr. Nednoor also has expertise in creating and maintaining detailed CMC project plans, timelines, budget and managing multiple CMC programs. He played a key role in the development, production and quality control testing of Tissue Repair's TR-987 Gel product to support the Phase IIB clinical study. He is currently leading the CMC activities to support Phase III clinical studies. He is also actively involved in the preparation of CMC documentation to the FDA.

Dr Jur Strobos
Regulatory, Quality Medical

Dr. Jur Strobos has spent more than 30 years providing legal, regulatory, strategic development, management, and policy advice to life science companies that manufacture, import, or sell medical products (drugs, devices, biologics, cell and gene therapy, human tissues), foods, cosmetics, tobacco regulated by the US Food and Drug Administration (FDA) or comparable international authorities. Dr. Strobos is a medical doctor and a credentialed federal law enforcement officer. He previously served as a legal, regulatory, and policy official in the Commissioner's Office at FDA.

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