Tissue Repair Limited
AGM Company Update

- ***Progress on TR987® Phase 3 trials***
- ***Sales commence for TR Pro+™***

October 2023

TR987® - Cleared to enter Phase 3 by the FDA. A core Clinical Operations capability has been established with first patient randomisation planned for early Q2 2024

Glucoprime® - Patented platform technology. Applicable to many types of wound healing in humans and animals. Initial focus on products for the treatment of chronic wounds and the aftercare of aesthetic and minor medical procedures.

Chronic wounds

TR987® cleared for Phase 3. TR987® has the promise of being the first drug approved for venous leg ulcers (VLUs) in 25 years. VLUs represent a significant market with unmet needs.

Aesthetic

TR Pro+™ launched June 2023. A novel cosmeceutical that improves skin quality following procedures where the skin may or may not be broken. Aesthetic and minor medical procedures represent a **significant growing market estimated at AUD1b* market with no clear product leader**

* Management estimate

Key Updates since IPO

- Feedback on the **Phase 3 VLU trial** protocol provided at recent FDA meeting all the key areas of the protocol have been agreed.
- **Chemistry-Manufacturing-Controls and Toxicology programs** have all been accepted by the FDA and are progressing.
- **NEW DATA** A meta-analysis was done on 137 patients from the two Phase 2 VLU trials. Results demonstrated a 60% difference in mean wound area vs placebo (p=0.03). Confirmed a **strong signal of efficacy, providing further confidence to move into Phase 3.**
- **Strong cash balance and expect material R&D tax incentive refunds to provide additional funding**
- **An initial batch of TR Pro+™ was manufactured** for launch in June 2023 supported by 1.5FTE Territory Managers
- Monthly sales growth of 20% per month
- Sold into more than 60 clinics within three months
- Very positive client feedback on healing and skin quality

Despite some delays TR is achieving key milestones . . . within its existing funding envelope

TR987®
Phase 3 trial approval received by FDA

- ✓ Glucoprime® API manufactured to meet reference standards – five batches in total (pilot, engineering, and GMP)
- ✓ Successful scale-up of the immunogenic Glucoprime® API has been achieved
- ✓ Glucoprime® API analytical development and characterisation to FDA standard for Phase 3
- ✓ Successful FDA meeting (Type C) provided clarity on CMC and abridged toxicology program
- ✓ **Cleared for Phase 3 (Type B FDA meeting)**
- ✓ Secured Professor Robert Kirsner as the Principal investigator for the Phase 3 trial. Prof Kirsner is eminently experienced and was the PI on a recent Phase 3 study for a VLU drug candidate product

TR Pro+™
Product launch in May 2023

- ✓ Inventory produced for launch in June 2023 in Australia with potential for global expansion
- ✓ **Real world evidence study. Compelling patient feedback - >80% rating 4/5 and 5/5 on skin quality and perception of healing**
- ✓ Peer reviewed paper published in Dermatologic Surgery demonstrating a significant improvement in skin quality (wrinkling and elastosis; FDA approved Phase 2 trial)
- ✓ **Attractive gross margins when produced at scale based on expected sale price**
- ✓ Estimates by management of market size could be c+1b globally. Market wide open no clear category winner
- ✓ In >85 clinics with growth in sales at c20% per month

Intellectual Property

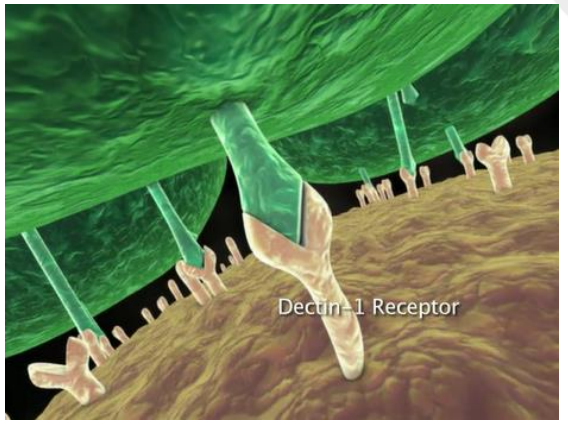
- ✓ First patent published (12 June 2022) to cover manufacturing process (includes 21 years of protection)
- ✓ **Second patent published (23 March 2023) covers use of molecule on any topical skin condition and all forms of healing eg: 21 years of protection for TR987® and TR Pro+™**
- ✓ Regulatory exclusivity maintains for a drug or biologic for 5 years and 12 years, respectively
- ✓ Collaboration established with Prof. Allison Cowin (University of South Australia) on further investigation of the Glucoprime® mechanism of action

Funding

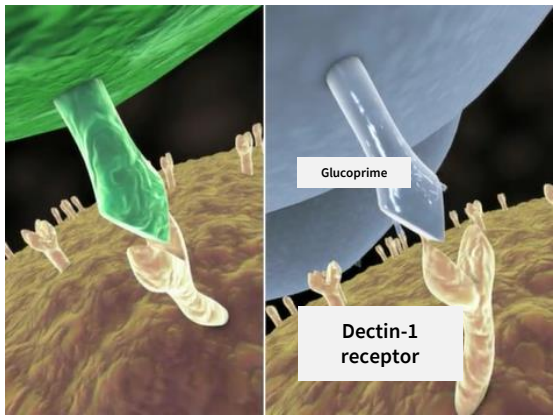
- ✓ Founder led ethos to capital management
- ✓ AusIndustry Overseas Findings Certificates confirmed as valid, providing an additional 43.5% R&D rebate on expected expenditure (up to $7m of additional cash funding)
- ✓ **Strong cash balance and expect material R&D tax incentive refunds to provide additional funding**

TRs technology platform Glucoprime® is applicable for multiple types of wounds in humans and animals

Receptors on macrophages within damaged tissue recognize the Glucoprime® - containing hydrogel. Macrophages are the ‘guard’ cells that protect against invaders.



Two receptors, Dectin-1 and TLR2, are engaged and trick the body into believing there is a yeast infection. Macrophages become activated to express genes that enable phagocytosis, protein synthesis and cytokine release.

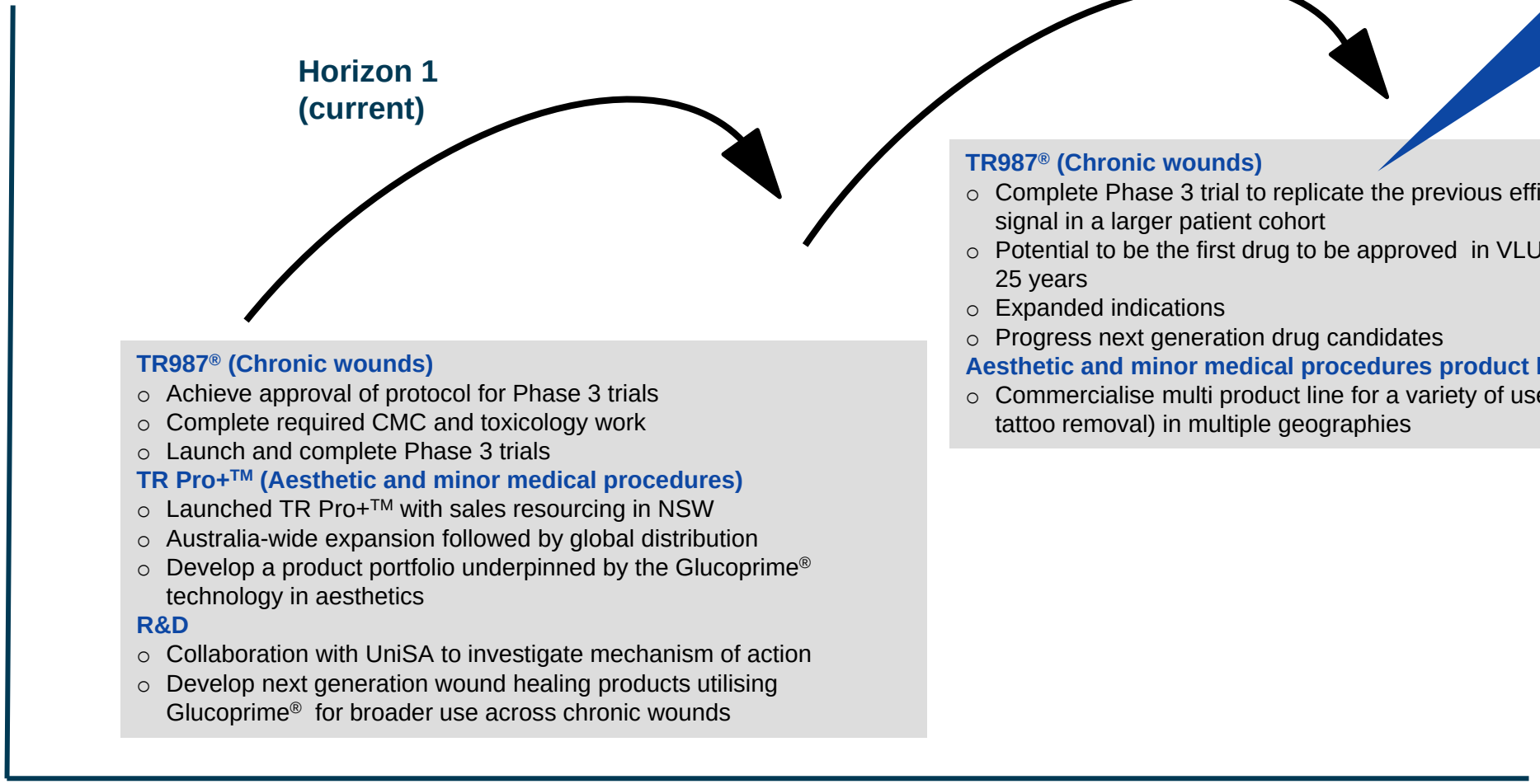


In this way TR987® and TR Pro+™ (with Glucoprime®) initiates a mild innate immune response that attracts more macrophages as well as other immune cells like neutrophils and monocytes.

- In laboratory and clinical studies TR987® and TR Pro+™ have been shown to promote wound healing by activating some genes in macrophages (TNFα and IL-10).
- Macrophages play a key role in re-modelling by releasing growth factors that aid in tissue repair and angiogenesis.
- Current hypothesis suggests that Glucoprime® initiates an initial proinflammatory burst then establishes an extended regenerative phase which allows damaged skin to heal.

The medium-term focus is on commercialisation of two products for two discrete applications, each having significant markets and compelling economics

. . . success in either is a significant value milestone



An FDA-approved label for the treatment of chronic wounds is a highly prized asset

TR987® (Chronic wounds)
- Achieve approval of protocol for Phase 3 trials
- Complete required CMC and toxicology work
- Launch and complete Phase 3 trials

TR Pro+™ (Aesthetic and minor medical procedures)
- Launched TR Pro+™ with sales resourcing in NSW
- Australia-wide expansion followed by global distribution
- Develop a product portfolio underpinned by the Glucoprime® technology in aesthetics

R&D
- Collaboration with UniSA to investigate mechanism of action
- Develop next generation wound healing products utilising Glucoprime® for broader use across chronic wounds

TR987® (Chronic wounds)
- Complete Phase 3 trial to replicate the previous efficacy signal in a larger patient cohort
- Potential to be the first drug to be approved in VLUs in 25 years
- Expanded indications
- Progress next generation drug candidates

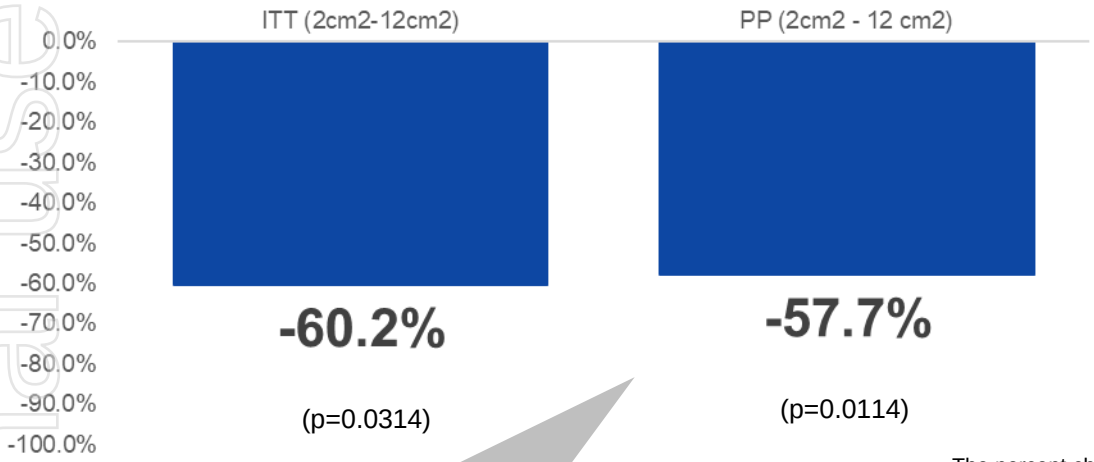
Aesthetic and minor medical procedures product line
- Commercialise multi product line for a variety of uses (eg: tattoo removal) in multiple geographies

TR987®
CHRONIC WOUNDS

NEW DATA A recent meta-analysis on 147 patients from two Phase 2 trials has confirmed a strong signal of efficacy and demonstrated a 60% reduction in wound size vs placebo control (p=0.03). A strong data point, providing further confidence on a successful Phase 3 outcome

In March 2023 an individual patient data (IPD) meta-analysis was conducted across the Phase 2A and Phase 2B studies using consistent endpoints adopted in both studies, namely absolute and percent change in ulcer area.

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



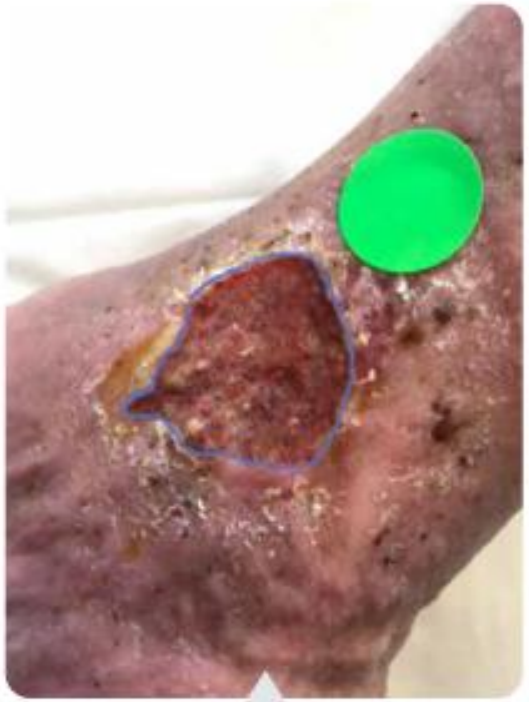
Circa 60% reduction in wound compared to placebo & Standard of Care at 12 weeks (statistically and clinically significant)

Meta-analysis of all phase 2 patients. Mean wound reduction change between placebo and active across a range of cohorts . VLU sizes 2-12cm² and 2-20cm2

Population	Dose TR-987 gel	Wound size	Adjusted difference in mean change (95% CL)	p-value
ITT	Low	2-12cmsq	-55.9 (-113.3, 1.52)	0.0562
ITT	Low	All	-31.6 (-68.60, 5.30)	0.0925
PP	Low	2-12cmsq	-58.0 (-103.0, -13.05)	0.0124
PP	Low	All	-41.6 (-72.41, -10.82)	0.0087
ITT	**All**	**2-12cmsq**	**-60.2 (-114.9, -5.53)**	**0.0314**
ITT	**All**	**All**	**-33.2 (-65.36, -1.12)**	**0.0427**
PP	**All**	**2-12cmsq**	**-57.7 (-101.8, -13.47)**	**0.0114**
PP	**All**	**All**	**-44.3 (-71.16, -17.38)**	**0.0015**

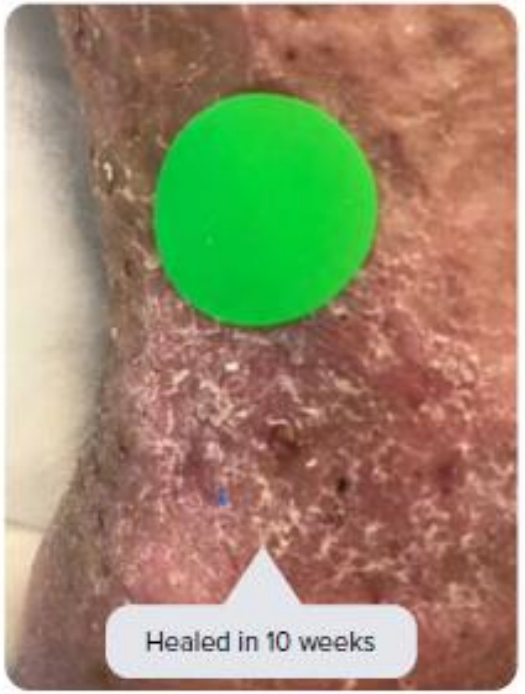
The percent change in ulcer area and actual change in ulcer area (cm2) was analysed using a general linear model with baseline ulcer area and duration of study VLU as covariates. Adjusted treatment effects for TR-987 0.1% gel (low dose) versus placebo and for TR-987 all doses combined (i.e. TR-987 0.1% or 1.0% gel) versus placebo were obtained overall for the ITT and PP populations for all patients from both studies combined and for the subgroup of patients with baseline ulcer area 2-12cm2, the proposed inclusion for the planned Phase 3 trials. Results are presented below in tables E2 (percentage change) and E3 (actual change) and graphically in figures E1 (percentage change) and E2 (actual change).

An example of a closed venous leg ulcer following treatment by TR987® during the Phase 2B trial



7.53cm² at screening (Heidelberg Repatriation Hospital Melbourne)

Ulcer present for 208 weeks (4 years prior to enrollment) patient age was 72 with leg ulcers present from age 57



1. Chronic Wounds (Venus Leg Ulcer)
Atypical example of a VLU wound healed with TR-987 2020 Phase IIB Venus Leg Ulcer trial n=67 (2-12cm2)

TR987® for chronic wounds - key advantages over current products

Strong efficacy signal from well designed trials

- No drug or biologic appears to have been approved in chronic wounds since REGRANEX gel in 1997, and as such a drug label with high quality clinical data drives reimbursement and is highly prized
- Strong signal for efficacy in wound healing (including key FDA accepted endpoints) demonstrated in clinical trials

Aiming to prove superior in-use outcomes over current therapies

- Existing therapies are expensive and require application by healthcare professionals in a hospital setting. Many are costly as derived from human placental tissue, which is the treatment of choice for chronic wounds in the US
- Tissue Repair aims to provide a superior in-use alternative to these therapies, without reliance on harvesting human tissue and the ease of a topical gel in contrast to a complicated patch or scaffold

Positive safety profile

- TR987® has a robust safety profile across its clinical program to date
- TR987® has been tested across different indications on over 240 patients with no significant adverse events attributable to the drug product

Ease of use

- Administered topically onto the wound – no complicated bandages or patches
- Can be used in combination with standard of care products, including compression bandaging
- Capable of being administered by a nurse/caregiver or in the home directly by the patient

Stable over a long shelf life

- TR987® has preliminary stability testing which suggests a three-to-five-year shelf life at room temperature, with no refrigeration or freezing required

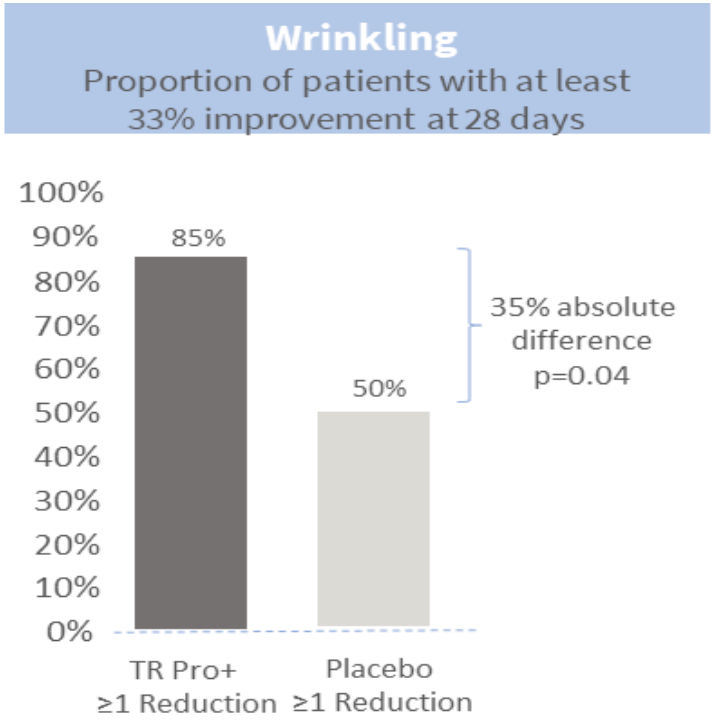
Having a topical gel as the delivery mechanism provides a significant product in use advantage over existing complicated patches and biologics

TR Pro+™ (AESTHETIC AND MINOR MEDICAL PROCEDURES)

The Phase 2B study using laser skin resurfacing showed a statistically significant improvement in skin quality at Day 28

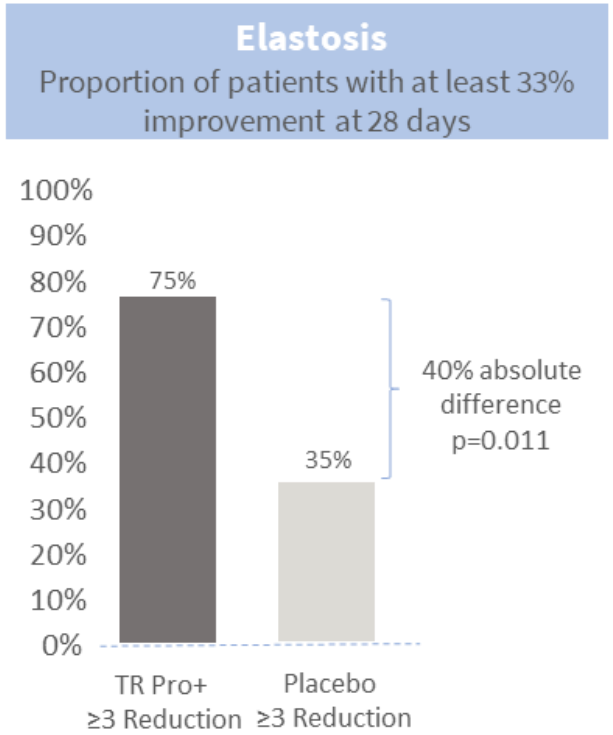
Wrinkling

In this group, 85% of responders in the active group achieved a wrinkling score improvement of at least 33% compared to only 50% of responders in the placebo group.



Elastosis

In this group, 75% of responders in the active group achieved an elastosis score improvement of at least 33% compared to only 35% of responders in the placebo group.



Conclusion

TR's recent Phase 2 trial demonstrated that TR Pro+™ generates additional collagen production and fibrosis, filling out wrinkles and fine lines at an accelerated pace.

The Phase 2B study was recently published in a peer reviewed journal (Wu *et al.* 2022)

Original Article

OPEN

A Novel Macrophage-Activating Gel Improves Healing and Skin Quality After CO_2 Laser Resurfacing of the Chest

Douglas C Wu, MD, PhD, Ramya Kollipara, MD, Marissa J. Carter, PhD, and Mitchel P. Goldman, MD*

BACKGROUND After laser resurfacing, it is imperative that an appropriate postoperative regimen is followed for optimal wound healing. There is currently no consensus about which agents should be used.

OBJECTIVE To evaluate the safety and efficacy of a novel macrophage-activating gel in a Phase 2B trial to be used after fractionated ablative laser resurfacing of the chest.

MATERIALS AND METHODS Forty-two adults who received fractionated CO_2 laser resurfacing of the chest were randomized (active or placebo) for 5 consecutive days after procedure. Skin quality at baseline and follow-up was assessed by a blinded evaluator using the Fitzpatrick–Goldman Wrinkle Scale. Subject satisfaction with skin healing and quality was also assessed.

RESULTS At 28 days according to the Fitzpatrick–Goldman Wrinkle Scale, 85% of subjects achieved an improvement of at least 33% for the active group versus 50% in the placebo group (absolute difference 35%; $p = .04$). Similarly, 75% of subjects achieved an improvement score of at least 33% in elastosis in the active group versus 35% in the placebo group at 28 days (40% absolute difference; $p = .011$).

CONCLUSION This study confirms the potent effects of the novel macrophage-activating gel for optimization of skin healing and quality after laser resurfacing of the chest.

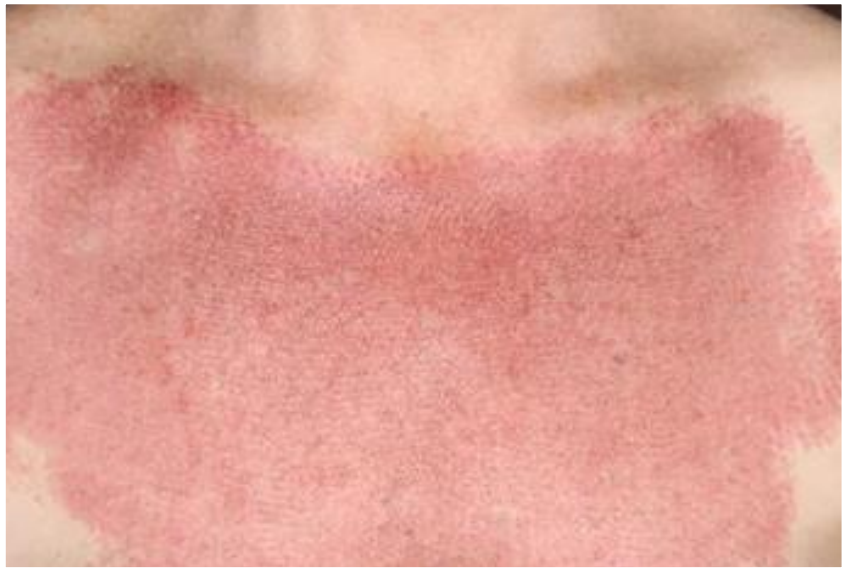
***Study Author's concluded* "In summary, this study demonstrates the potential of TR Pro+™ 0.1% gel to significantly improve skin quality outcomes after fractionated ablative laser resurfacing without any negative side effects, most likely through a unique immunomodulatory mechanism of action"**

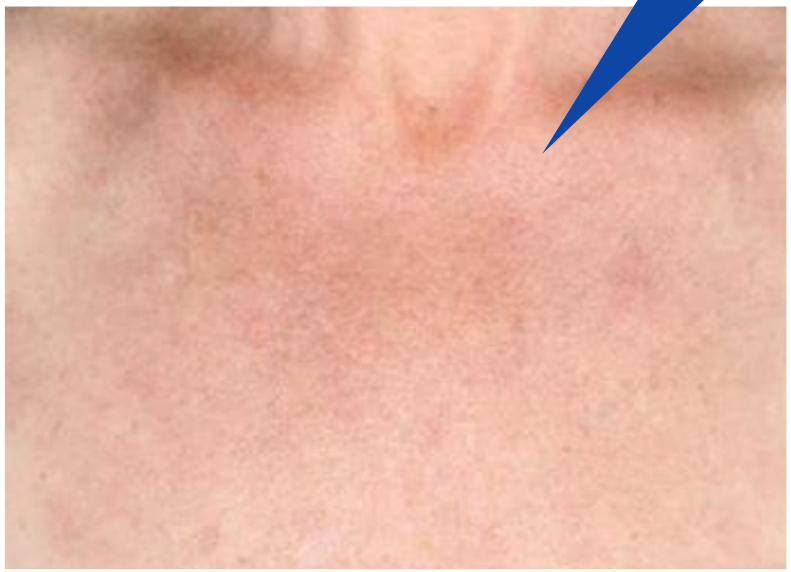
A typical example of redness and irritation following treatment by TR Pro+™ in the Phase 2B laser skin resurfacing study

Days post-procedure

Day 1

Day 28

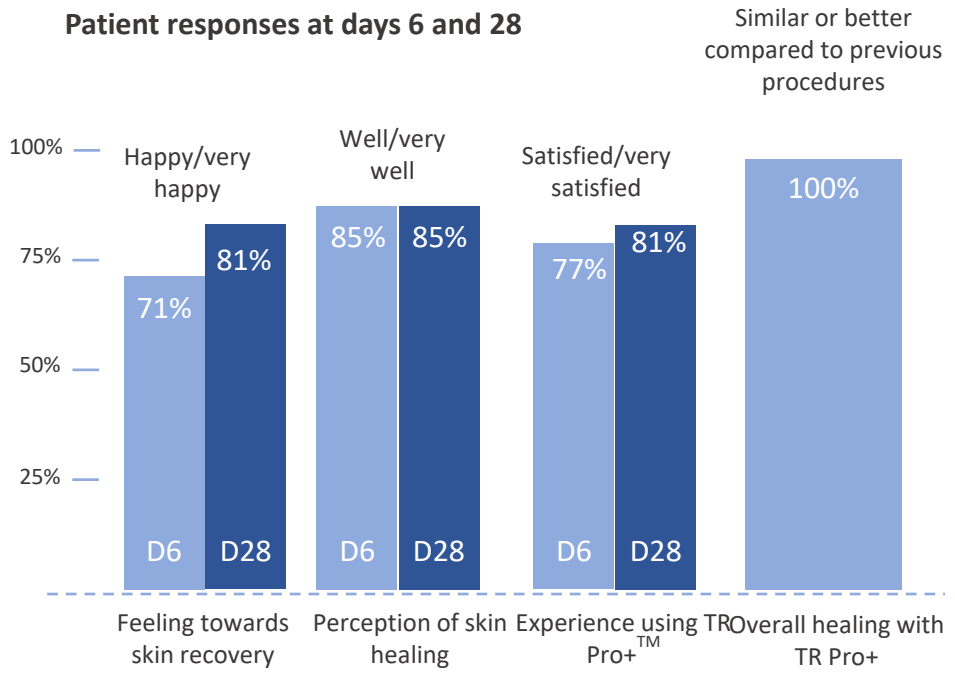


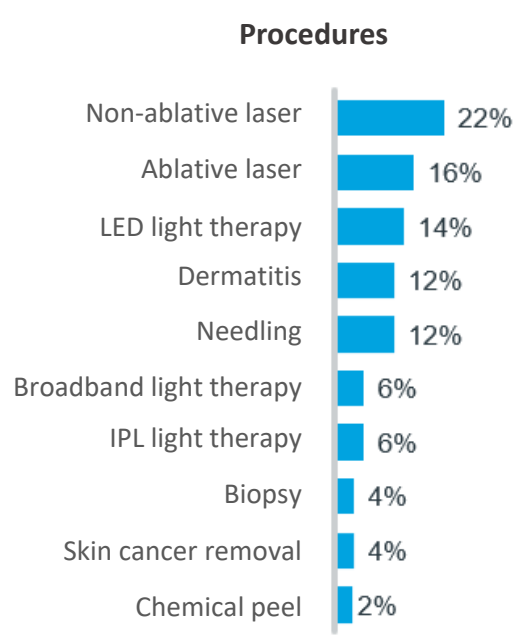


Close to double the improvement in skin quality as measured by elastosis and wrinkling vs standard of care & placebo

In a real-world evidence study (2022), 100% of patients rated TR Pro+™ as good or better than previous post-procedure aftercare product used. . . 85% of patients rated it as 4/5 stars on healing and skin quality

A real-world evidence study[1] with 12 dermatology clinics in Australia in patients (n=48) who had undergone a range of cosmetic and medical procedures. The program was run independently, and patients provided anonymous feedback at day 6 and day 28 following the procedures.





Healthcare professionals who consider TR Pro+™ appealing[1] **86%**

Dermatologists interested in learning more about the Phase 2 laser skin resurfacing trial [2] **84%**

1 FiftyFive5 TR Pro+ Market Research Dec 2021 (n=57)
2 IQVIA Medibus October 2022 (n=31)

TR Pro+™ - an opportunity to deliver on an unmet need in current therapy following aesthetic and minor medical procedures

Launched in June 2023 (10,000 tubes and sample sachets)

The gel has potential application to a range of cosmetic procedures, including:

- Laser skin resurfacing (particularly ablative)
- Skin needling
- IPL treatment
- Chemical peels
- Skin cancer removal
- Biopsy
- Laser tattoo removal

- 1.5 FTE Territory Managers have approached more than 160 clinics since January, with over 85 clinics having placed orders at four months post-launch.

- 58% of orders are wholesale (clinics) with 42% retail (consumers/patients). Wholesale orders represent 93% of volume.

- Key targets include cosmetic dermatologists, laser technicians, dermal therapists, plastic/cosmetic surgeons

- The team have global ambitions for TR Pro+™ following a launch in Sydney with learnings to be applied in other geographic markets

- Additional products under review to develop a portfolio based on the Glucoprime® platform (eg: moisturizer, serum, sunscreen and higher potency aftercare formulation)

The post procedure topical market has no clear product lead, and is potentially a USD1b* market globally

Skincare and cosmetics are significant global markets with strong CAGRs

- Total revenues from the global cosmetics market are set to hit $103.8 billion in 2023
- Skincare was the leading category accounting for about 41 percent of the global market. Revenue is projected to generate roughly 188 billion U.S. dollars in 2026.

Comparable companies are evidencing revenues of circaUS100m focusing on post procedure repair key call outs across the competitive landscape

- Limited number of products lines revenue concentrated only in a handful of SKU's
- Limited focus on improvement of skin quality more focussed on improved healing (i.e. reduced redness, itching faster healing), and improved scaring
- Existing product lines prohibitively expensive with some products costing in the range of c$US100-$US400
- Very limited evidence of efficacy
- No clear product leader or winner with several disparate products recommended by clinicians

Sales Update

- In more than 85 clinics
- Month-on-month sales growth of 20%
- Consistently positive client feedback during first three months in market

TR has an opportunity to create a significant business

- **Focussed on skin quality improvement with a strong data package (underpinned by clinical evidence)**
- **Expand product line - delivering a number of products powered by Glucoprime® with TR Pro+™ as the flagship product**
- **Attractive price points - affording broader adoption**

* Management estimate

Intellectual Property

Glucoprime® meets the FDA criteria of A New Chemical Entity (NCE). There is no drug substance currently approved globally for any indication based on Tissue Repair's engineered molecule. This provides the potential for exclusivity preventing competitors from replicating the technology.

Regulatory exclusivity
5 years in USA
10 years in Europe

- **USA:** The FDA defines a new chemical entity as "a drug that contains no active moiety that has been approved by FDA in any other application submitted under section 505(b) of the Act." The FDA grants exclusivity for New Chemical Entities (NCE). This exclusivity provides the licence holder of an approved new drug application protection from new competition in the marketplace for the innovation represented by its approved drug product.
- **Europe:** A chemical active substance that is not previously authorised in a medicinal product for human use in the European Union and that is from a chemical structure point of view not related to any other authorised substances should be considered as a NAS ("New Active Substance")

If Glucoprime® is classified as a biologic by the FDA, it may be eligible to increase marketing exclusivity from 5 to 12 years in the USA. Whilst the focus for TR987 is as a potential drug approval, the company will also be discussing and considering the classification of Glucoprime® with the FDA as a biologic.

US Divisional Patent
Glucoprime **GRANTED**
Methods of manufacture
Pub No US 11,384,160 Bl
Publication Date Jul. 12, 2022

METHOD OF MAKING A BETAGLUCAN COMPOUND

- The claims allowed cover the methods of extraction of the Glucoprime® API, there are no other know methods to produce the API to the specifications required by the FDA which link directly to potency and efficacy and in turn clinical impact

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US Divisional Patent
Glucoprime **GRANTED**
Composition Claims
Pub. No.: US 2023/0085802 Al
Publication Date 23 March 2023

ISOLATED BIOLOGICAL POLYSACCHARIDE COMPOUND, METHODS OF USE AND METHODS OF MANUFACTURE THEREOF

- The claims allowed are relatively broad in terms of the type of skin treatment that may be treated. The only limitation in terms of treatment is that Glucoprimelink is applied topically to the skin of a wound site. The broadest claim is not restricted in terms of the type of wound and what else the vehicle comprises apart from Glucoprimelink.

US Divisional Patent
Glucoprime **UNDER EXAMINATION**

BIOLOGICAL POLYSACCHARIDE COMPOUND

- The claims sought in this application cover the molecule itself for any application

Tissue Repair. Strategy on a Page

	Market	Product	Strategy	Stage of clinical development	Commercial
Primary focus				Preclinical Ph 1 Ph 2A Ph 2B Ph 3	
#1	Chronic wounds	TR987®	• Achieve FDA and TGA approval as a topical drug for use in venous leg ulcers • Obtain reimbursement in the US and Australia	→ Progression to Ph3 following FDA approval	2024 commence partnering discussions ahead of P3 outcome
#2	Cosmetic and medical procedures	TR Pro+™	• Commercialise as a post-procedure aftercare product • Initially launched as a 'cosmetic' product while seeking TGA approval	→ Product developed for launch leveraging existing phase 2 trials	Launched in June 2023
#3	New indications	Potential for a variety of products	• Invest in the research and development of additional products and extend clinical evidence to a broader range of indications	→ R&D commencing in 2024	

Unique platform technology

Differentiated drug label strategy provides valuable opportunity

TR987®

Phase 3 clinical trials commencing in 2023

Medium-term commercialisation of cosmeceutical post procedure product

Capital Structure Update

Shares on Issue	60,464,843		
Options on issue	21,954,292	$0.49	(Average exercise price)
Cash as at 30 June 2023	$21.4m		
Cash backing per share	**$0.35**		
Share price as at 24 October 2023	$0.275		
Market Capitalisation	$16.6m		
Discount to cash backing	**Circa -22%**		

All seed and founders escrowed for up to 2 years

All options issued pre IPO, did not dilute IPO shareholders

Majority founder and management team held, (significant portion has not vested), options subject to log dated escrow

Cash back excludes significant estimated R&D refunds from pre-approved certificates with AusIndustry

Appendix
Additional clinical data - Phase 2B Trial

Phase 2B ITT Summary Results.

Partial and complete healing metrics.

Table 15 *Summary of key efficacy findings: ITT population*

Subset	Treatment	VLU area reduction by week 12 [a,b,c]	At least 50% reduction in VLU area [c,d,e]	At least 70% reduction in VLU area [c,d,e]	At least 90% reduction in VLU area [c,d,e]	At least 95% reduction in VLU area [c,d,e]	VLU healed by week 12 [d,e,f]
Baseline VLU 2-20cm²	Placebo	-29.8%	46.4%	36.2%	26.5%	19.4%	20.7%
	TR 987 0.1% gel	-42.3%	66.6%	56.7%	47.5%	40.6%	37.1%
	Difference	12.5%	20.2%	20.5%	20.9%	21.2%	16.4%
	(95% CL)	(-17.0%, 41.9%)	(-1.4%, 40.2%)	(-1.3%, 40.4%)	(-0.2%, 40.1%)	(1.0%, 39.5%)	(-3.6%, 35.0%)
	Odds ratio		2.3	2.31	2.5	2.84	2.26
	(95% CL)		(0.87, 6.12)	(0.89, 5.98)	(0.92, 6.82)	(0.96, 8.34)	(0.78, 6.57)
	p-value		0.094	0.085	0.073	0.058	0.134
Baseline VLU 2-12cm²	Placebo	-30.5%	52.1%	40.7%	31.4%	26.5%	27.9%
	TR 987 0.1% gel	-48.3%	74.7%	64.8%	57.1%	49.3%	48.3%
	Difference	17.8%	22.6%	24.1%	25.7%	22.8%	20.4%
	(95% CL)	(-19.1%, 54.7%)	(-0.7%, 44.2%)	(-0.2%, 45.8%)	(1.4%, 47.0%)	(-1.0%, 43.9%)	(-3.4%, 41.8%)
	Odds ratio		2.72	2.68	2.91	2.7	2.42
	(95% CL)		(0.86, 8.64)	(0.85, 8.52)	(0.91, 9.26)	(0.83, 8.80)	(0.77, 7.58)
	p-value		0.09	0.094	0.071	0.1	0.13
Baseline VLU 2-7cm²	Placebo	-25.4%	47.7%	31.7%	27.9%	25.0%	34.4%
	TR 987 0.1% gel	-35.4%	70.1%	62.3%	57.0%	50.7%	49.1%
	Difference	10.0%	22.4%	30.5%	29.1%	25.7%	14.7%
	(95% CL)	(-37.2%, 57.2%)	(-5.9%, 46.9%)	(2.1%, 54.5%)	(1.0%, 53.4%)	(-1.8%, 50.3%)	(-13.0%, 40.8%)
	Odds ratio		2.57	3.55	3.42	3.08	1.84
	(95% CL)		(0.71, 9.30)	(0.94, 13.3)	(0.89, 13.2)	(0.81, 11.8)	(0.55, 6.19)
	p-value		0.15	0.061	0.074	0.1	0.325

LOCF, last observation carried forward.

[a] Adjusted difference in ulcer area reduction and adjusted odds ratio estimates obtained from repeated measures mixed model with percentage change in area as outcome, and treatment group, treatment visit (and interaction), and baseline VLU area as explanatory variables

[b] For testing the null hypothesis that the difference in percentage change in VLU area between the treatment groups is zero

[c] Subjects are classified at Week 12 using LOCF values if no data is recorded at Week 12

[d] Adjusted difference in healing rates and adjusted odds ratio obtained from the logistic model with baseline covariates for age at time of VLU, duration of study VLU, and baseline VLU area

[e] p-value for testing the null hypothesis that the adjusted odds ratio equals 1

[f] Subjects are classified as healed if there is 100% re-epithelialization of the study VLU with no drainage noted. This must be confirmed at a subsequent study visit.

Phase 2B Per Protocol Summary Results.

Partial and complete healing metrics.

Table 16 *Summary of key efficacy findings: PP population*

Subset	Treatment	VLU area reduction by week 12 [a,b,c]	At least 50% reduction in VLU area [c,d,e]	At least 70% reduction in VLU area [c,d,e]	At least 90% reduction in VLU area [c,d,e]	At least 95% reduction in VLU area [c,d,e]	VLU healed by week 12 [d,e,f]
Baseline VLU 2-20cm²	Placebo	-41.8%	63.1%	47.7%	35.5%	26.5%	27.3%
	TR 987 0.1% gel	-75.8%	89.2%	74.7%	65.1%	55.8%	51.5%
	Difference	34.0%	26.2%	27.0%	29.6%	29.4%	24.2%
	(95% CL)	(9.3%, 58.7%)	(5.2%, 46.2%)	(2.6%, 48.6%)	(4.5%, 51.2%)	(4.7%, 50.6%)	(-0.4%, 46.0%)
	Odds ratio		4.86	3.23	3.39	3.51	2.82
	(95% CL)		(1.17, 20.2)	(1.03, 10.1)	(1.08, 10.6)	(1.06, 11.6)	(0.84, 9.46)
	p-value		**0.03**	**0.044**	**0.036**	**0.039**	0.093
Baseline VLU 2-12cm²	Placebo	-43.8%	69.4%	57.8%	45.4%	38.3%	38.2%
	TR 987 0.1% gel	-88.5%	97.1%	86.3%	77.1%	66.7%	66.3%
	Difference	44.7%	27.7%	28.5%	31.7%	28.4%	28.1%
	(95% CL)	(15.1%, 74.4%)	(8.2%, 49.0%)	(3.5%, 51.5%)	(4.2%, 55.1%)	(0.1%, 52.5%)	(-0.2%, 52.3%)
	Odds ratio		14.8	4.62	4.04	3.23	3.18
	(95% CL)		(1.38, 159)	(1.03, 20.7)	(1.05, 15.5)	(0.87, 12.0)	(0.85, 11.9)
	p-value		**0.026**	**0.046**	**0.042**	0.08	0.087
Baseline VLU 2-7cm²	Placebo	-37.8%	66.5%	46.6%	41.8%	37.2%	47.1%
	TR 987 0.1% gel	-88.0%	95.8%	84.1%	78.0%	69.3%	67.4%
	Difference	50.3%	29.3%	37.6%	36.2%	32.1%	20.3%
	(95% CL)	(11.3%, 89.2%)	(2.3%, 52.1%)	(5.3%, 61.9%)	(3.0%, 61.5%)	(-1.5%, 58.9%)	(-12.9%, 48.8%)
	Odds ratio		11.5	6.09	4.94	3.81	2.32
	(95% CL)	(11.3%, 89.2%)	(0.90, 147)	(1.11, 33.5)	(0.95, 25.7)	(0.82, 17.7)	(0.57, 9.51)
	p-value		0.061	**0.038**	**0.057**	0.087	0.241

LOCF, last observation carried forward.

[a] Adjusted difference in ulcer area reduction and adjusted odds ratio estimates obtained from repeated measures mixed model with percentage change in area as outcome, and treatment group, treatment visit (and interaction), and baseline VLU area as explanatory variables

[b] For testing the null hypothesis that the difference in percentage change in VLU area between the treatment groups is zero

[c] Subjects are classified at Week 12 using LOCF values if no data is recorded at Week 12

[d] Adjusted difference in healing rates and adjusted odds ratio obtained from the logistic model with baseline covariates for age at time of VLU, duration of study VLU, and baseline VLU area

[e] p-value for testing the null hypothesis that the adjusted odds ratio equals 1

[f] Subjects are classified as healed if there is 100% re-epithelialization of the study VLU with no drainage noted. This must be confirmed at a subsequent study visit.

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