

## ASX Announcement 29 October 2025

Tissue Repair ("TRP") SEPTEMBER 2025 APPENDIX 4C

29 October - Tissue Repair Limited (ASX:TRP, TR or the Company) is pleased to update the market on its progress in the September 2025 quarter and attaches its Appendix 4C Quarterly Cashflow Report for the period.

#### **Key Highlights and Update**

#### TR987® for treatment of chronic wounds -Phase 3 Trial

- Forty-six clinical sites have been selected for the BG002 (U.S.) and BG003 (U.S./Australia) studies; 33 sites initiated and 24 activated to date.
- A turn around in randomizations has occurred with around 35 patients randomized across the two trials; around 30 in BGOO2 (the US trial) and 5 patients in BG003 (the Australian trial).
   The company is prioritizing the completion of BG002.
- 5 large institutions are expected to be online and screening in Q3 and Q4 FY2026 where a meaningful increase in randomization should occur.
- Progress toward the 510(k) submission and CE mark Class 1 and Class 2 for TR Pro+® remains on track, with ongoing development of the technical package to support U.S, Asian and European market entry for chronic wounds and dermatology indications.
- The FDA has confirmed the product will remain classified as a drug, following its decision not to designate it as a biologic under CDER's immunological product category.

#### TR Pro+® for aesthetic and medical procedures

- The partnership with Advanced Cosmeceuticals Pty Ltd (AC) commenced on 15 September 2025, with stage 1 existing TR clinics transitioning to AC. The company expects meaningful sales to commence when all SKUs are available in February/March 2026 through the AC network, (including 10g, 30g and 200g professional use pump packs).
- A major TR Pro+® production campaign is planned for February 2026, covering all tube formats (3g, 10g, 30g, 50g, and 200g) and marking the first manufacturing of the TGAapproved product.
- Internal R&D has commenced working on two new products and formulations to expand the Company's presence in procedure-related and aesthetic channels and general acute and hard to heal wounds called (TR-med), as well as a next generation silicon product TR-S.
- The company is exploring its commercialization strategy for Tr-med including exploring discussions with pharmaceutical distributors for this product. Discussions are ongoing with AC regarding distribution of this product under the existing distribution agreement.
- A launch occurred in August 2025 with Dr Steven Liew a prominent Sydney plastic surgeon presenting the use of TR Pro in his clinic https://youtu.be/cKuAjFivMWc.



#### **Corporate and Financial Summary**

The Company's cash position as at 30 September 2025 was \$10.3 million. During the September 2025 quarter, net operating cash outflows totalled approximately \$\$1.97 million primarily due to R&D expenditure amounting to \$1.13 million. Revenue received for the quarter for TR Pro + sales was \$202,000, up from \$140,000 in the previous quarter with an additional \$23,000 received as interest income from cash and term deposit investments.

A summary of operating cash flows for the period ended 30 September 2025, compared with the intended use of funds outlined in the Company's Prospectus dated 7 October 2021, is provided below:

	Use of Funds under Prospectus	Actual use of funds for the period ending 30 September 2025
Working capital and overheads <sup>1</sup>	300,000 <sup>1</sup>	5,845,000 <sup>1</sup>
Offer costs	2,300,000	1,849,000
Development of Chronic Wound Drug	3,700,000	10,655,000
Phase III Clinical Trials	13,600,000	3,035,000
Commercialisation of Aesthetic Product	2,100,000	3,425,000
Interest received	-	(1,576,000)
R&D tax incentive refund	-	(2,861,000)
TR Pro+ ™ Sales receipts	-	(799,000)
Total	22,000,000	19,573,000

<sup>&</sup>lt;sup>1</sup>The Company raised \$7.5million via a convertible note in April 2021 (pre-IPO) which has been allocated to fund a significant portion of the working capital and overheads of the Company. The working capital and overhead cash outflows are broadly in line with the forecast budget. The Company believes the working capital outflows are consistent with the requirements for an ASX listed biotech Company of its size.

In Accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of the Appendix 4C was \$75,000. This includes payments for remuneration of director fees to executive and non-executive directors in the normal course of business at commercial rates including superannuation, excluding reimbursements of out-of-pocket expenses.

#### **KEY OPERATIONAL UPDATES**

#### 1. TR987® - for treatment of chronic wounds

## **1.1 Manufacturing, Development, and Analytical Update** Manufacturing

Four batches of the Glucoprime® API were produced and all are now complete, with the final two awaiting drying and sterilization to ensure continuity of supply with another major production run of TR Pro SKUs occurring in Feb/March 2026.

A commercial scale-up proposal has been received from a contract manufacturer in France. Additional proposals are being pursued with Australian CMOs.

Work has commenced on the validation summary report which is a requirement to produce TGA-approved TR Pro+®.





#### Analytical

Stability testing is ongoing for both the Glucoprime® API and TR987® finished gel product, including the batch used in the Phase 3 clinical trial. Current trends continue to demonstrate stability across both materials.

Validation and bridging studies to qualify a new test kit for Beta-Glucan content determination have been successfully completed. All future testing will now be conducted using the qualified kit.

Release and stability testing of Glucoprime® API batches manufactured in the U.S. is ongoing, with finalisation of the stability protocols expected shortly.

#### Product development

As part of our next-generation product development program, the team have been working with an Australian-based contract manufacturer to advance formulation design. This work will lay the foundation for a differentiated product portfolio and supports our broader strategy to expand the portfolio with high-impact and locally manufactured therapeutic products. Four products are being reviewed:

Aesthetics	Stage	Description
Tr Pro	Formulated and commercialized TGA listed medicine approved	Existing post-produce aesthetic product designed to accelerate healing and improve skin quality form underlying aesthetic and cosmetic products
		Target Market – Global
Tr – Serum	Formulated – First product in market March 2026 Path for TGA listing expected in February 2026	Rejuvenating serum with hyaluronic acid and Glucoprime® for use post TR Pro – to provide additional dosing of Glucoprime® to accelerate healing and skin quality post TR Pro
		Target Market – Global
Medical and Wounds		
Tr Med	Exploring Formulation Expected first Production March 2026	New gel formulation with anti-bacterial and infection agent to provide a dual use product that controls infection and targets bio-film with Glucoprime® to accelerate healing
		Target Market – Global
Tr S	Exploring Formulation  Expected first Production March 2026	Next generation silicon product targeting the global market for silicon of cUS2b-US3b market
		Target Market - Global
TRF	Scoping stage	New gel formulation targeting bruising with Glucopime® and an anti-bruising agent
		Target Market – Global



#### 1.2 Phase 3 VLU Trial Update

Underperforming sites have been removed from the study and replaced with high potential sites. There are now forty-six sites selected for the BG002 (US) and BG003 (US/Australia) studies, with 33 initiated and 24 activated. Thirty-three patients are currently randomised.

Patient randomisations have started to accelerate as the large institutional sites and university hospitals come on board.

Around 35 patients have been randomised to date, 30 patients in the US trial and 5 patients in the Australian trial

#### 1.3 Additional US 510K and CE Mark Class I and II Device Application for TR Pro+®

Work toward the 510(k) and CE mark Class I and II device submission for TR Pro+® remains on track, with the program continuing to build the technical package required for U.S. market entry under the chronic wound and dermatology indications.

Biocompatibility assessments are underway, and preliminary data are shaping the design of the remaining studies to complete the testing matrix. The submission strategy continues to leverage established predicate devices, streamlining the pathway to clearance.

Overall, the program is advancing steadily through the regulatory preparation phase, positioning TR Pro+® as the lead candidate for U.S. market access ahead of full drug registration and Phase 3 data.

#### 1.4 Regulatory Update

The FDA has confirmed that the product will remain classified as a drug, following the agency's decision not to designate it as a biologic under CDER's immunological product category.

Amended Phase 3 protocols and an updated Data and Safety Monitoring Board (DSMB) charter have been submitted to the FDA, incorporating feedback from the agency's review of the original design. The DSMB convened its initial organisational meeting in July 2025.

Quotations have been received from NAMSA for ISO 10993 biocompatibility testing to support the CE submission, with testing scheduled to commence in Q4 2025. In parallel, chemical characterization and transport testing quotations are being finalised to strengthen the European regulatory package.

This next phase of testing will generate the pivotal data set required for CE Class I and II device submissions and future U.S. 510(k) applications.

Preparations are also underway for the Medsafe submission for New Zealand, with a target filing in Q4 2025. Work is focused on compiling supporting documentation and aligning product data to meet New Zealand regulatory requirements for an efficient review.

#### **Next Quarter Activities**

- Completion of five Glucoprime® API batches, enabling optimisation of the manufacturing process and supply for the TGA-approved TR Pro+® product.
- Ongoing progression of the 510(k) and CE Class I and II device applications to support US and EU market entry.
- Accelerated patient enrolment in the BG002 Phase 3 trial (US) and the BG003 trial (AUS/US).



#### 2. TR Pro+® for the treatment of acute wounds (medical and aesthetic)

#### 2.1 Sales of TR Pro+® in Australia

Q2 receipt from customer growth over Q1 was 44% with revenue growing from \$140,000 to \$202,000.

The transition of the aesthetic business to Advanced Cosmeceuticals is expected to drive renewed sales growth in Q4, supported by access to a broader clinic network.

Meaningful sales growth will not occur through the AC network until all SKUs are available with formal launch occurring through the AC network in March 2026.

A major TR Pro+® production campaign is scheduled for February 2026, covering all tube formats — 3 g, 10 g, 30 g, 50 g and 200 g. Discussions are underway to determine which SKUs will launch through the pharmacy channel and which will remain exclusive to clinics, with the 200 g unit positioned as a professional in-clinic format.

This campaign will consist of three manufacturing batches and marks the first production of the TGA-approved TR Pro+® product.

#### 2.2 Distribution of TR Pro+® in the Aesthetic Channel (Australia)

The partnership with Advanced Cosmeceuticals Pty Ltd (AC) officially commenced on 15 September, with Stage 1 occurring with existing TR clinics transitioning over to the AC network.

AC will expand upon the ~400 clinics previously serviced directly by Tissue Repair, leveraging its network of over 2,500 clinics and strong B2C and online retail capabilities to accelerate market reach from February 2026.

#### **Next Quarter Activities**

- Continue to support Advanced Cosmeceuticals in the promotion and distribution of TR Pro+® in the aesthetic channel.
- Continue to pursue U.S. 510(k) and CE mark applications to support international market expansion.
- Continued development of the expanded product portfolio
- Ongoing efforts to identify and engage distribution partners for overseas markets.
- Production of the first TGA-approved product in all formats.

**ENDS** 

## For further information, please contact: Darryl Reed

darryl.reed@trtherapeutics.com +61 419 557 663

This announcement has been approved for release by the Board of Tissue Repair Limited.



#### **About Tissue Repair**

Tissue Repair Limited (ASX: TRP) is a Phase 3 biotechnology company developing second-generation wound healing agents. The company is advancing its lead drug candidate *TR987*° for chronic wounds and commercialising *TR Pro+*°, a topical treatment designed to accelerate healing and improve skin quality following cosmetic or medical procedures. Its proprietary *Glucoprime*° API underpins a growing pipeline of therapeutic solutions.

### **Appendix 4C**

# Quarterly cash flow report for entities subject to Listing Rule 4.7B

#### Name of entity

Tissue Repair Limited		
ABN	Quarter ended ("current quarter")	

20 158 411 566 30 September 2025

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	202	202
1.2	Payments for		
	(a) research and development	(1,137)	(1,137)
	(b) product manufacturing and operating costs	(191)	(191)
	(c) advertising and marketing	(62)	(62)
	(d) leased assets	-	-
	(e) staff costs	(342)	(342)
	(f) administration and corporate costs	(468)	(468)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	23	23
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)		
1.9	Net cash from / (used in) operating activities	(1,976)	(1,976)

2.	Cas	sh flows from investing activities	
2.1	Pay	ments to acquire or for:	
	(a)	entities	-
	(b)	businesses	-
	(c)	property, plant and equipment	-
	(d)	investments	-
	(e)	intellectual property	-
	(f)	other non-current assets	-

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Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	-	-

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	-	-

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	12,319	12,319
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,976)	(1,976)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	(23)	(23)
4.6	Cash and cash equivalents at end of period	10,320	10,320

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	5,968	7,966
5.2	Call deposits	4,352	4,352
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	10,320	12,319

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000	
6.1	Aggregate amount of payments to related parties and their associates included in item 1	75	
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-	
	Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.		

The amount at 6.1 includes Director fees (including superannuation) for directors, Executive Director fees and related parties.

7.	Financing facilities  Note: the term "facility' includes all forms of financing arrangements available to the entity.  Add notes as necessary for an understanding of the sources of finance available to the entity.	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	Total financing facilities	-	-
7.5	Unused financing facilities available at qu	arter end	-
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		itional financing

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,976)
8.2	Cash and cash equivalents at quarter end (item 4.6)	10,320
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	10,320
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	5.2
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.	

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A

Has the entity taken any steps, or does it propose to take any steps, to raise further 8.6.2 cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

#### **Compliance statement**

- This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

	29 October 2025
Date:	
	The Board
Authorised by:	(Name of body or officer authorising release – see note 4)

#### Notes

- 1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
- If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, AASB 107: Statement of Cash Flows apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
- 3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
- 4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
- If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.