

ASX Announcement

Wednesday, 30 April 2025

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

30 April 2025 - Tissue Repair Limited (ASX:TRP, TR or the Company) is pleased to update the market on its progress in the March 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

- Thirty-four sites have been selected for the BG002 (US) and BG003 (US/Australia) studies, with 19 initiated and 13 activated. The Company targets 30 sites activated over the next three months.
- Some delays were experienced in delivering additional protocol amendments designed to increase enrollment. The protocol amendments have passed ethics approval, and patient screenings are expected to increase.
- The US wound care market is experiencing severe regulatory disruption. Medicare has removed reimbursement for hundreds of devices due to weak clinical evidence. This has caused a significant increase in clinical trials for venous leg ulcers (VLUs) and diabetic foot ulcers (DFUs).
- To date, 4 patients have been randomised. The Company feels it has strategies in place to increase enrollment in the coming months despite the significantly increased demand for patients to participate in trials. The regulatory situation validates our secondary strategy of securing drug approval with high-quality clinical evidence as a major differentiator in this market. The Company understands it is the only drug in Phase 3 trials globally for VLUs.
- The 2024 Annual Report, amendments to the study protocol, and a Request for Designation of TR987® 0.1% gel as a biologic have all been drafted and will be filed with the FDA by mid-May 2025.
- Site qualification visits have been completed at four of the TR987®/TR Pro+® manufacturing sites, and discussions are ongoing with three potential contract manufacturers capable of producing the Glucoprime® at API commercial scale, which is crucial to facilitating long-term global distribution opportunities.

TR Pro+® for aesthetic and medical procedures

- Further manufacturing of the Glucoprime® API is underway. Beta-glucan extraction on the first of five additional batches was completed in April, providing sufficient Glucoprime® API for the next 12 -18 months to supply continued growth in TR Pro+® and potential increased demand from any secured distribution arrangements.
- Sales in the aesthetic market, as expected, were seasonally low in January and February. However, sales for TR Pro+® achieved a record high for 10-gram tubes in March. Orders have now been received from more than 300 clinics. Organic growth is expected to continue in that market.
- Discussions are continuing with local distributors to manage the medical and aesthetic channels. These channels will cover aesthetic indications and have not yet entered markets for medical wounds and hard-to-heal wounds, which are targeted to be sold in pharmacies, through hospitals, and aged care

facilities. The Company is targeting a distribution arrangement by the end of Quarter 4. A Singapore-based consultant is assisting with introductions to potential distributors in the Asia Pacific region.

- A manuscript describing the mode-of-action studies undertaken by the University of South Australia has been drafted; publication is expected in the coming months.

Corporate and Financial Summary

The Company's cash position as at 31 March 2025 was \$12.6 million. During the March 2025 quarter, net operating cash outflows totalled approximately \$1.834 million, primarily driven by expenditure relating to the TR-987 clinical trials and TR Pro+ development activities. Revenue received for the quarter for TR Pro+ sales was \$75,000, with an additional \$198,000 received as interest income from cash and term deposit investments.

A summary of operating cash flows for the period ended 31 March 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 31 March 2025
Working capital and overheads ¹	300,000 ¹	4,668,000 ¹
Offer costs	2,300,000	1,849,000
Development of Chronic Wound Drug	3,700,000	9,580,000
Phase III Clinical Trials	13,600,000	2,651,000
Commercialisation of Aesthetic Product	2,100,000	2,634,000
Interest received	-	(1,521,000)
R&D tax incentive refund	-	(1,783,000)
TR Pro+ TM Sales receipts	-	(358,000)
Total	22,000,000	17,720,000

¹The 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.

The Company has recently lodged its Research and Development (R&D) Tax Incentive claim for the financial year ended 30 June 2024 and anticipates receiving the refund within the next six months.

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 \$69,000. 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

Additional extraction of the Glucoprime® API is required to provide the TGA product and support continued sales growth, as API volumes have been depleted.

Extraction on the first of five Glucoprime® API batches was completed on April 18. The material will be sampled, lyophilised, and tested before being sent for drying, packaging, and sterilisation. As expected, this first lot provided some learning opportunities; however, the team is confident that this Glucoprime® API can produce cosmetic TR Pro+® for sale in Australia.

The next four batches will be manufactured sequentially and are expected to be completed by the end of August. Together, they will provide sufficient Glucoprime® API for at least the next 12 months and support the introduction of the TGA-approved TR Pro+®.

Meetings have been held with three contract manufacturers to explore a commercial partnership for the ongoing manufacture of Glucoprime® API at commercial scale. Two of the three are working on a proposal for a technological review of the process to adapt it to larger volumes. The current process, which relies on decantation and manual handling of the solids concentrate between each process step is not viable at large volumes. Some development work is required before final design and equipment definition for a commercially scaled process. This manufacturing and analytical work will provide additional insights and information to support the final drug application for TR987®.

1.2 Phase 3 VLU Trial Update

Thirty-four sites have been selected for the BG002 (US) and BG003 (US/Australia) studies, with 19 initiated and 13 activated. Due to the recently introduced protocol amendments, the screening commencement for several additional sites has been delayed. This amendment has passed through the ethics approvals, and patient screenings are expected to increase.

Several mitigation strategies have been implemented to boost patient recruitment, including initiating contact with some larger institutional clinics that had not previously been approached. The team is also working on local advertising strategies to drive additional interest.

The recently introduced Medicare requirement for clinical evidence in the form of randomised clinical trials has caused significant disruption to the US wound care market, with hundreds of previously approved products withdrawn from Medicare reimbursement coverage. This has led to many sponsors looking to initiate sponsor-funded trials to support reimbursement applications, increasing the demand for chronic wound patients with venous leg ulcers (VLUS) and diabetic foot ulcers (DFUS). The number of clinical trials being planned or conducted is high.

To date, 4 patients have been randomised across BG002 and BG003. Despite increased patient competition, the Company is aiming to activate 30 sites in the coming months. Additional sites with larger institutions will increase the number of randomised patients.

Payers' significant focus on clinical evidence in the wound care market validates the Company's strategy of securing drug approval with high-quality clinical data as a major differentiator from the devices with lower levels of clinical evidence currently dominating the market.

Tissue Repair is the only sponsor with a product in Phase 3 trials for VLUs.

1.3 Additional US 510K Device Application for TR Pro+®

There is an opportunity to introduce TR Pro+® into the US under a 510(k) device classification based on existing predicate devices. Initial biocompatibility studies have commenced, and these results will

determine what additional testing will be required. This device application will provide an additional pathway to commercialise TR987® for US chronic wounds and dermatology indications.

1.4 Regulatory Update

- All documents for the 2024 Annual Report have been completed, and the filing will be made at the end of April 2025.
- Following feedback from the FDA on the study protocol, several amendments were made to the extent that the Company believes reasonable. The ethics committees have filed and approved the revised protocols, and enrollment is in progress. We also anticipate notifying the FDA of the changes made due to their comments in the next week.
- The Request for Designation of TR987 0.1% gel as a biologic was filed electronically on April 15, 2025, and is to be reviewed by CDER with the primary focus being immunological activity. FDA has until April 22 to perform a preliminary review and, if they deem the filing incomplete, to “not file.” While this is FDA’s usual practice with first or second filings, we expect this second filing will be ‘filed.’ In that event, a response is due by June 13.

Next Quarter Activities

- Production of additional development batches of Glucoprime® API to optimise the manufacturing process and support the TGA-approved product.
- Progression of 510(k) device application.
- Increased enrollment in Phase 3 trials in the US (BG002) and AUS/US (BG003) studies.
- Ongoing negotiations with a potential distribution partner for Australia and New Zealand for TR Pro+®.

2. TR Pro+® for cosmetic and medical procedures – COMMERCIALISATION

2.1 Commercial launch of TR Pro+® in Australia

Sales across the aesthetic market are typically low in January and February, and TR Pro+® revenue reflected this before bouncing back to a record high in March. Orders have now been received from more than 300 clinics.

The demand for TR Pro+® is significantly constrained by the unavailability of larger (30-gram) tubes.

Sales peaked in December, when a small production run of 30-gram tubes was made available to test the market. These test tubes sold out in a matter of weeks, validating the demand for this larger format.

The product line is being expanded to 10g, 30g and 50-gram tubes by the end of the calendar year and a premium 30mL serum, comprising a synergistic formulation with the Glucoprime® API for anti-ageing applications.

A manuscript describing the mode-of-action studies undertaken by the University of South Australia has been drafted; publication is expected in the coming months. Tissue Repair has been invited to present these results at the Non-Surgical Symposium (Gold Coast) in June, Australasia’s premier event for non-surgical aesthetics. The Company will also be at the BioKorea Conference (Seoul) as part of the Austrade/NSW Investment stand.

Discussions are continuing with local distributors to manage the medical and aesthetic channels, and a Singapore-based consultant is assisting with introductions to potential distributors in the Asia Pacific region. We remain optimistic that a distribution agreement for the aesthetic channel in Australia will be forthcoming in the next quarter, with advanced discussions with an identified preferred partner.

For further information concerning this release, please contact Darryl Reed at darryl.reed@trtherapeutics.com

0419 557 663.



This announcement has been approved for release by TRP's board

--ENDS--

About Tissue Repair

Tissue Repair Limited (ASX:TRP) is a Phase 3 advanced biotechnology company developing second generation wound healing agents. The Company's core focus is entering Phase 3 clinical trials in chronic wounds for its lead drug candidate TR987[®], with a secondary focus on commercialising TR Pro+[®] a post procedure topical gel to accelerate healing and improve skin quality following cosmetic and medical procedures, as well as other acute wound products in its pipeline. The Company's longer-term strategy is to commercialise its propriety Glucoprime[®] API to treat a variety of wounds and skin conditions.

Appendix 4C

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

Name of entity

Tissue Repair Limited

ABN

20 158 411 566

Quarter ended ("current quarter")

31 March 2025

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	75	283
1.2 Payments for		
(a) research and development	(906)	(2,884)
(b) product manufacturing and operating costs	(24)	(54)
(c) advertising and marketing	(68)	(200)
(d) leased assets	-	-
(e) staff costs	(886)	(2,105)
(f) administration and corporate costs	(223)	(844)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	198	379
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives		1,090
1.8 Other (provide details if material)		63
1.9 Net cash from / (used in) operating activities	(1,834)	(4,272)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment		(7)
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
	(f) other non-current assets	-	-
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	-	(7)

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	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	14,433	16,441
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,834)	(4,272)
4.3	Net cash from / (used in) investing activities (item 2.6 above)		(7)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	(30)	407
4.6	Cash and cash equivalents at end of period	12,569	12,569

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	8,271	10,126
5.2	Call deposits	4,300	4,307
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)	12,571	14,433

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	69
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		

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

7.	Financing facilities <i>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.</i>	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 quarter 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.		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,834)
8.2	Cash and cash equivalents at quarter end (item 4.6)	12,571
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	12,571
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	6.9
<i>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.</i>		

8.6	If item 8.5 is less than 2 quarters, please provide answers to the following questions:
8.6.1	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
8.6.2	Has the entity taken any steps, or does it propose to take any steps, to raise further 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
<i>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.</i>	

Compliance statement

- 1 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.

30 April 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.
2. 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".
5. 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.