ASX Announcement

Friday, 31 January 2025

Tissue Repair ("TRP") DECEMBER 2024 APPENDIX 4C

**31 January 2025 - Tissue Repair Limited (ASX:TRP, TR or the Company) is pleased to update the market on its progress in the December 2024 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***

- First patient randomisation has occurred. US storms and fires and a request from the FDA requiring some protocol changes (which have required a formal protocol amendment) have hindered enrollment in key sites over the previous several weeks. The protocol amendment is in process, and we expect enrollment to ramp up over the coming months.
- More than 30 sites across the US and Australia have been selected and qualified, with 18 initiated and 10 sites activated.
- Pre-clinical work has progressed on a US device application for TR987®. We are targeting US device approval within 12-18 months which would allow entry into the US chronic wound market ahead of the Phase 3 drug approval. Under the current regime the expected reimbursement could be orders of magnitude above the current TR Pro+® pricing, affording excellent unit economics.

***TR Pro+® for cosmetic and medical procedures***

- TR Pro+® sales (unaudited) in Q4 were 35% higher than for the prior quarter with monthly sales peaking at 45k per month in December 2024. TR Pro+® is evidencing a strong track record of growth and uptake in the Australian market which is expected to continue.
- TR Pro+® has been ordered by more than 270 clinics and a quick uptake of a test promotion of the 30g tubes validates market appetite for larger units at a much higher cost point.
- The Company is in advanced discussions with a distributor for the aesthetics channel in Australia and New Zealand and is exploring a number of options with parties for a second Australian distributor or partnership for medical applications (being acute wounds and other wound types) in Australia and New Zealand) which would see TR Pro+® enter the pharmacy channel.
- To support expected distribution relationships globally the Company has approved investment of an additional US$1M to go towards additional API manufacturing, with the dual aim of also obtaining additional analytics data to support TR987® and to optimize efficiencies in the production process for both the drug and TR Pro+® applications. The Company expects to recoup this investment with expected continuous growth in TR Pro+® sales.

**Corporate and Financial Summary**

The Company's cash position was $14.4 million as at 31 December 2024. During the December 2024 quarter total net cash operating outflows were approximately $2.149million largely attributed to expenses associated with the development of TR-987 and commercialisation of TR Pro+ offset by TR Pro+ cash sales and interest income.

A summary of the operating cash flow for the period 7 October 2021 to 31 December 2024 compared with the proposed use of funds in the Company's Prospectus dated 7 October 2021 is shown below:

| | Use of Funds under Prospectus | Actual use of funds for the period ending 31 December 2024 |
|---|---|---|
| Working capital and overheads[1] | 300,000[1] | 4,220,000[1] |
| Offer costs | 2,300,000 | 1,849,000 |
| Development of Chronic Wound Drug | 3,700,000 | 8,546,000 |
| Phase III Clinical Trials | 13,600,000 | 2,281,000 |
| Commercialisation of Aesthetic Product | 2,100,000 | 2,472,000 |
| Interest received | - | (1,323,000) |
| R&D tax incentive refund | - | (1,783,000) |
| TR Pro+ ™ Sales receipts | - | (376,000) |
| **Total** | **22,000,000** | **15,886,000** |

[1]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.

The Company expects future favourable variances of the R&D Tax incentive inflows for FY2024 and beyond, which were not included in the use of funds statement in the Prospectus. Such R&D tax incentive refunds will further extend the Company's cash runway, assisting with execution of the Company's strategy and providing a contingency should additional expenditure be needed to meet the Company's objectives for TR987® and TR Pro+™.

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 $104,000. 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**

An additional US$1M has been invested in manufacturing additional Glucoprime® API to allow sufficient inventory for expected domestic and potential international distributors. With the additional aim of securing additional analytical data for manufacturing which will be used to support the NDA application.

Potential testing laboratories in Australia are being identified and screened in the lead up to production, and an audit of the Australian-based CMO producing the finished hydrogel product is planned for February 2025 prior to the supply of the TGA labelled product.

Stability studies for the Glucoprime® API and the finished product are ongoing and to date have confirmed all measures to be with specifications.

The Company is also undertaking a global search to secure an ongoing commercial scale manufacturer for TR Pro+® and TR987®.

The Company's recent manufacturing status is summarised in the table below:

| Stage | Update | Status |
|---|---|---|
| **Stage 1** Laboratory scale API | • Successful production of 3 laboratory scale batches | Completed |
| **Stage 2** Engineering API | • Successful production of 3 scaled-up engineering batches.<br>• Production scheduled with the necessary equipment ordered.<br>• Batch record finalised and an agreement reached with contract manufacturer.<br>• Terminal sterilization processing | Completed |
| **Stage 3** GMP API | • Partial production of 3 GMP batches has been completed with the final stages in the manufacturing process to be completed following successful production of the engineering batches. | Completed |
| **Stage 4** Production of API into finished gel (6-gram tubes) for Phase 3 clinical supply | • Formulation of API material into gel and filling into 6-gram tubes for the Phase 3 trial<br>• Contract manufacturer has been appointed and is preparing pilot filling of gel product into tubes. | Completed |
| **Stage 5** Optimization of the API manufacturing process and supply of TGA listed medicine product | • Production of multiple batches to assess process changes aimed at reducing manufacturing costs and also ensure supply of TGA listed medicine product | Expected completion Q2 2025 |

### 1.2 Phase 3 VLU Trial Update

There are 30 sites selected for the US study (BG002) with 18 initiated and 10 activated. A small number of patients have been screened, and the first patient randomisation has occurred.

Recruitment has been delayed due to the recent adverse weather events in the US. Further, some amendments have been made to the trial protocol in response to our FDA consultation feedback and learnings from early screened patients., These changes are expected to be approved by the relevant ethics committees in the next few weeks which would allow enrolment to progress as initially forecast.

A request for Waiver of Paediatric Studies has been drafted and will be filed with the FDA in Q1 2025.

### 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. Minor additional work is needed, requiring additional biocompatibility data to

support the application. A vendor screening process to identify laboratories capable of this work has already commenced.

This device application will provide an additional pathway to commercialise TR987® for chronic wounds and dermatology indications in the US. Key milestones include:

- 510K device application within 12-18 months;
- Ability to utilize an existing reimbursement code which will allow TR987® 10 gram tubes to be reimbursed to achieve attractive unit economics

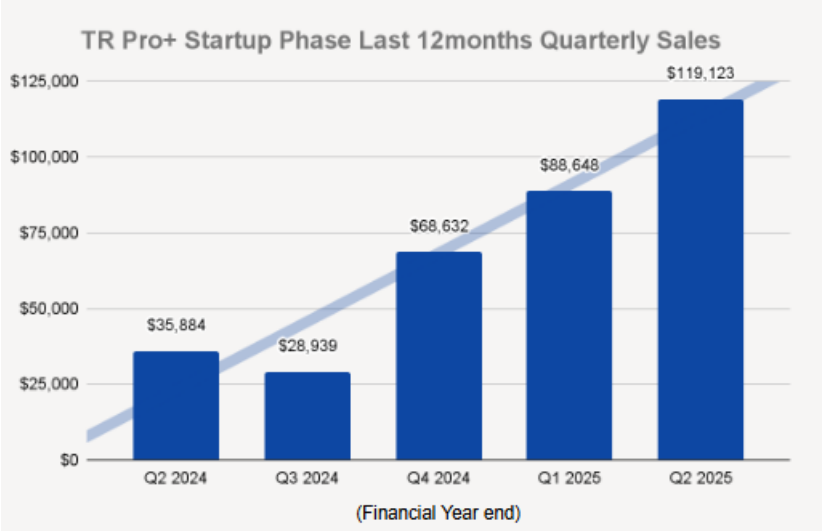
**Next Quarter Activities**

- Production of additional development batches of Glucoprime® API to optimize 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.

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

### 2.1 Commercial launch of TR Pro+® in Australia

TR Pro+® sales (unaudited) have continued to grow with Q4 up 35% on the prior quarter demonstrating very strong growth at increasing scale. November and December were particularly strong with more than $40,000 in revenue in each month, characterised by a high proportion of clinic re-orders compared to prior months. Orders have now been received from more than 270 clinics.




Customers have been vocal about having access to TR Pro+® in tubes larger than the 10g tubes that are currently available. A larger size is required where the surface area being treated is large, or where clinicians decide to use the product as a backbar unit to treat clients in the clinic. To accommodate this, 400 units of the 30g tubes (ex-clinical trial stock) were re-labelled and made available to select clinics. Most of these were sold within 6 weeks prior to Christmas which validates the market appetite for a larger unit, at a much higher price point than the 10 gram tubes.

Discussions are continuing with potential local distributors to manage the medical and aesthetic channels, and we remain optimistic that a distribution agreement will be forthcoming in the next quarter for the aesthetic channel with advanced discussions taking place with an identified preferred partner.

Having proven the business case locally, we are reaching out to potential overseas distributors.

For further information in relation to 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** | **Quarter ended ("current quarter")** |
| 20 158 411 566 | 31 December 2024 |

| **Consolidated statement of cash flows** | | **Current quarter $A'000** | **Year to date (6 months) $A'000** |
|---|---|---|---|
| **1.** | **Cash flows from operating activities** | | |
| 1.1 | Receipts from customers | 118 | 208 |
| 1.2 | Payments for | | |
| | (a) research and development | (1,288) | (1,978) |
| | (b) product manufacturing and operating costs | (25) | (30) |
| | (c) advertising and marketing | (70) | (132) |
| | (d) leased assets | - | - |
| | (e) staff costs | (583) | (1,219) |
| | (f) administration and corporate costs | (367) | (621) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 78 | 181 |
| 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) | (12) | 63 |
| **1.9** | **Net cash from / (used in) operating activities** | **(2,149)** | **(2,438)** |

| | | | |
|---|---|---|---|
| **12.** | **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 | - | - |
| | (f) other non-current assets | - | - |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (6 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** | **-** | **(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** | **-** | **-** |

| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
|---|---|---|---|
| 4.1 | Cash and cash equivalents at beginning of period | 15,911 | 16,441 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (2,149) | (2,438) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | - | (7) |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (6 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 | 671 | 437 |
| **4.6** | **Cash and cash equivalents at end of period** | **14,433** | **14,433** |

| 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 | 10,126 | 10,105 |
| 5.2 | Call deposits | 4,307 | 5,806 |
| 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)** | **14,433** | **15,911** |

| 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 | 104 |
| 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**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*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 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) | (2,149) |
| 8.2 | Cash and cash equivalents at quarter end (item 4.6) | 14,433 |
| 8.3 | Unused finance facilities available at quarter end (item 7.5) | - |
| 8.4 | Total available funding (item 8.2 + item 8.3) | 14,433 |
| 8.5 | **Estimated quarters of funding available (item 8.4 divided by item 8.1)** | **6.7** |

*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:

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 |

*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

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.

31 January 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.