ASX Announcement
Friday 28 April 2023

Tissue Repair ("TRP") MARCH 2023 APPENDIX 4C

31 March 2023 - Tissue Repair Limited (ASX TRP, TR or the Company) is pleased to update the market on its progress in the March 2023 quarter and attaches its Appendix 4C Quarterly Cashflow Report for the period.

Key Highlights and Update

TR-987® for chronic wounds on track for Phase 3 commencement subject to FDA approval

- The Company filed a request for a Type B End of Phase 2 (EOP2) meeting with the FDA on 8 March 2023 and the Agency has scheduled a virtual meeting at the end of May 2023. Subject to a favourable response the Company expects to obtain Phase 3 approval and commence its planned Phase 3 program in the US and Australia by the end of the year.
- The development phase to prepare active pharmaceutical ingredients (API) for the Phase 3 clinical trial is complete and the process is now being executed to generate API. The first of the three GMP batches is in production, and the next two batches will proceed immediately on completion of this initial batch.
- **NEW DATA:** A meta-analysis was done which combined the results from two Phase 2 VLU trials (n=137) using a consistent endpoint. **This analysis confirmed a 60.2% mean reduction in wound size over the placebo control at 12 weeks following treatment with TR-987® (p=0.031) (ITT cohort, VLU 2-12cm^2).** This represents the additional decrease in wound area over above placebo attributable to the Active Group. This strong signal of efficacy is clinically and statistically significant across all 137 patients and provides additional confidence in achieving a successful Phase 3 outcome.
- Work has commenced with the University of South Australia aimed at further elucidating the mechanism of action of the Glucoprime® active ingredient and investigating potential next generation drug products that are based on the Company's Glucoprime® technology platform.
- The Company's AusIndustry Overseas Findings Certificates have been independently reviewed and are expected to provide additional funding to cash on hand from the 43.5% R&D rebate on eligible R&D expenditure.

TR Pro+™ for cosmetic and medical procedures - Commercial Launch

- The commercial batch of TR Pro+™, comprising 10g tubes and 3g sample sachets, has been completed and is within specification.
- The product will be released shortly and be available for purchase via the TR Pro+™ website from early May 2023.
- The pre-launch activity has involved contact with more than 160 clinics who have shown interest in trialling TR Pro+™.

Corporate

- The Company maintains its strong funding position with cash of $21.8m as of 31 March 2023.
- After reviewing its budget, management remains confident that the costs of the adjusted program of work required by the FDA for TR-987® can be fully funded from its current cash reserves and expected R&D rebates to deliver a Phase 3 outcome, whist concomitantly funding the launch of TR Pro+™.

Corporate and Financial Summary

The Company's cash position was $21.8 million as at 31 March 2023. During the March 2023 quarter total cash operating outflows were approximately $1.117 million, largely attributed to expenses associated with the development of TR-987® and commercialisation of TR Pro+™ offset by interest income.

A summary of the operating cash flow for the period 7 October 2021 to 31 March 2023 is shown below:

	Actual use of funds for the period ending 31 March 2023
Working capital and overheads[1]	2,287,000[1]
Offer costs	1,849,000
Development of Chronic Wound Drug	3,383,000
Phase 3 Clinical Trials	191,000
Commercialisation of Aesthetic Product	847,000
Interest received	(194,000)
R&D tax incentive refund	(293,000)
Total	8,070,000

The Company expects future favourable variances of the R&D Tax incentive inflows for FY2022 – FY2023 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 e a contingency should additional expenditure be needed to meet the Company's objectives for TR-987® and TR Pro+™.

During the period the company commissioned a review of the Overseas Certificates awarded to the TR-987 project by AusIndustry. These overseas certificates provide a pre-approval of R&D expenditure for both Australian and overseas expenditure associated with the development of TR-987. These certificates were considered to be active for the activities the company was undertaking.

During the period ending 31 March 2023, overall spend was lower than estimated in the use of funds as set out in the Prospectus largely due to timing differences associated with commissioning of key work streams including chemistry manufacturing and control (CMC) work for the Company's drug candidate TR-897, and development work streams associated with commercialisation of TR Pro+™.

The Company anticipates cash outflows in future quarters will increase in line with the acceleration of the chronic wound drug clinical program, and commercialisation of the aesthetic product.

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 $95,000. 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.

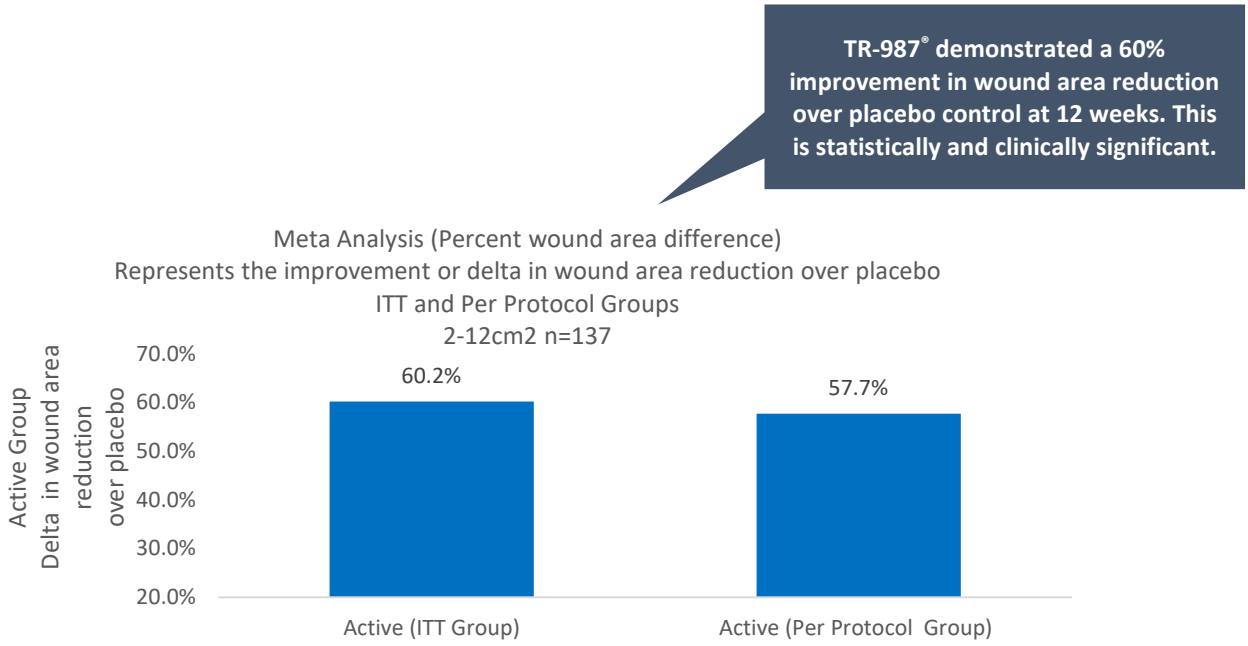
KEY OPERATIONAL UPDATES

1. NEW EFFICACY DATA

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

Analysis of results from 137 patients from both trials confirmed a strong signal of efficacy, with the active group demonstrating a 60% improvement in reduction in wound size over the placebo group (p=0.03).

This represents a positive data point and provides further confidence on the likelihood of a successful Phase 3 outcome which is both clinically and statistically significant.



2. TR987® DEVELOPMENT (for chronic wounds)

2.1 Manufacturing Update

The process development phase to prepare materials for the Phase 3 program is complete and the developed process is now being executed to generate API. The first of the three GMP batches is in production at the CMO, and the next two batches will proceed immediately on completion of this initial batch. The first batch of GMP API is expected to be available in June 2023.

The Company's 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. • Production scheduled with the necessary equipment ordered. • Batch record finalised and an agreement reached with contract manufacturer. • Terminal sterilization scheduled	Completed Expected completion Q2/Q3 2023 (validation completed by Q3 2023)
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.	Expected completion Q3 2023
Stage 4 Production of API into finished gel (10-gram tubes) for Phase 3 clinical supply	• Formulation of API material into gel and filling into 10-gram tubes for the Phase 3 trial • Contract manufacturer has been appointed and is preparing pilot filling of gel product into tubes.	Expected completion early Q4 2023

2.2 Analytical Update

The method validation work has continued through the quarter and will support the development of a comprehensive dossier for the FDA which describes the characterisation of the Glucoprime® API in detail. Our preliminary testing indicates that the Glucoprime® API to be used in the Phase 3 study will comfortably meet these specifications.

2.3 CMO Update

Five contract manufacturers (US and Canada) have now been engaged to produce the Glucoprime® API and produce the TR-987® finished gel for validation and the phase 3 clinical study.

2.4 Regulatory Update

The Company filed a request for a Type B End of Phase 2 (EOP2) meeting with the FDA on 8 March 2023 and submitted the briefing package containing the proposed Phase 3 protocol shortly thereafter. The EOP2 meeting will provide an opportunity to present the proposed Phase 3 protocol to the FDA, and pending a favourable response, will enable the Company to commence the Phase 3 studies planned for the US and Australia. The FDA has acknowledged the request and agreed to meet virtually at the end of May 2023.

2.5 Phase 3 VLU Trial CRO Cost Estimate (RFI)

Study cost estimates for two 300-patient trials in the US and Australia are close to being finalised and the Company is currently assessing the optimal model to move forward with. A final decision on the trial management structure is expected in Q2 2023.

2.6 Scientific Advisory Board (SAB)

The Scientific Advisory Board (SAB) has been heavily involved in refining the phase 3 protocol which was submitted to the FDA as part of the End of Phase 2 meeting request. Several of the SAB members will be present for the EOP2 meeting in May.

2.7 Preclinical work on the mechanism of action

Professor Cowin's lab (UniSA) have received the necessary approvals and have commenced work aimed at further elucidating the efficacy and mechanism of action of the Glucoprime® active ingredient. These outcomes will support our FDA application for TR-987®, assist with the local launch activities of TR Pro+™, and will contribute to the evaluation of potential next generation drug products that are based on the Company's Glucoprime® technology platform.

2.8 Next Quarter Activities

- Further development of the analytical methods required to characterise the Glucoprime® API and TR-987® hydrogel product.
- Virtual meeting with the FDA for the EOP2 meeting scheduled for late May 2023.
- Progress completion of Phase 3 clinical supplies of TR-987®.
- Finalisation of the clinical trial management strategy and continued outreach to clinical sites.

3. TR Pro+TM COMMERCIALISATION (for aesthetic and medical procedures)

3.1 Commercial launch of TR Pro+TM

An Australian-based contract manufacturer has been appointed to manufacture initial batch of TR Pro+™ comprising 10g tubes and 3g sample sachets. Tests on both the prototype and the production batch were within specifications. We expect the 10g tubes to be available for sale from early May via the e-commerce platform on the TR Pro+™ website.
Pre-launch activity has involved sponsorship at several dermatology and cosmetic conferences, including the Australasian Society of Cosmetic Dermatologists (ASCD) and the Advanced Skin Surgery Workshop. The sales team have been active making direct calls on clinics. To date, more than 160 clinics have expressed interest in receiving samples of TR Pro+™.

3.2 Next Quarter Activities

- Commercial launch of TR Pro+™

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 an advanced biotechnology company developing second generation wound healing agents. The Company's core focus is entering a Phase 3 program in chronic wounds for its lead drug candidate TR-987®, 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. 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 March 2023

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	-	-
1.2	Payments for		
	(a) research and development	(339)	(2,053)
	(b) product manufacturing and operating costs	(227)	(243)
	(c) advertising and marketing	(20)	(106)
	(d) leased assets	-	-
	(e) staff costs	(375)	(892)
	(f) administration and corporate costs	(258)	(968)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	60	184
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	150
1.8	Other (provide details if material)	42	101
1.9	**Net cash from / (used in) operating activities**	**(1,117)**	**(3,827)**

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

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 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**	**-**	**(2)**

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	22,813	25,455
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,117)	(3,827)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(2)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 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	96	166
4.6	**Cash and cash equivalents at end of period**	**21,792**	**21,792**

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	6,042	2,118
5.2	Call deposits	15,750	20,695
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)**	**21,792**	**22,813**

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	95
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 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 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)	(1,117)
8.2	Cash and cash equivalents at quarter end (item 4.6)	21,792
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	21,792
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**19.5**

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.

28 April 2023

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.