ASX Announcement

Tuesday, 30 January 2024

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

31 December 2023 - Tissue Repair Limited (ASX:TRP, TR or the Company) is pleased to update the market on its progress in the December 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

- Glucoprime® API manufacturing has been completed for Phase 3 clinical supplies.
- Release testing samples from the two Phase 3 Glucoprime® API batches have been shipped to all the respective labs for testing with a full CoA expected in Q1 2024.
- The first scale up batch of the finished gel has been completed and is being used to finalise the remaining test methods for release and stability testing of the Phase 3 drug product. A second batch to be used for the Phase 3 program is scheduled for production in February.
- The clinical operations team have 10 sites in the United States with approved budgets and a further 12 sites that are still in preliminary discussions. Two Australian sites have committed to the study with a further eight sites at various stages of discussion. First patient enrolment is expected mid-Q2 2024.
- The Phase 3 protocol is expected to be filed with the FDA in March following advice on a study design question submitted as part of a Type C meeting.

TR Pro+™ for cosmetic and medical procedures – Early success following product launch

- The clinical evidence that underpins TR Pro+™ has been effectively leveraged during the launch period and has expanded the use of the gel to other procedures aside from laser skin resurfacing.

Corporate and Financial Summary

The Company's cash position was $19.3 million as at 31 December 2023. During the December 2023 quarter total cash operating outflows were approximately $990,000, largely attributed to expenses associated with the development of TR-987 and commercialisation of TR Pro+™ offset by TR Pro+™ sales and interest income.

A summary of the operating cash flow for the period 7 October 2021 to 31 December 2023 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 2023
Working capital and overheads[1]	300,000[1]	3,070,000[1]
Offer costs	2,300,000	1,849,000
Development of Chronic Wound Drug	3,700,000	5,342,000
Phase 3 Clinical Trials	13,600,000	473,000
Commercialisation of Aesthetic Product	2,100,000	1,345,000
Interest received	-	(814,000)
R&D tax incentive refund	-	(693,000)
TR Pro+ ™ Sales receipts	-	(67,000)
Total	**22,000,000**	**10,505,000**

[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 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 a contingency should additional expenditure be needed to meet the Company's objectives for TR987® and TR Pro+™.

During the period ending 31 December 2023, overall spend was lower than estimated in the use of funds as set out in the Prospectus. This was 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 TR987®, commencement of Phase 3 trials 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 $58,000. 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® DEVELOPMENT (for chronic wounds)

1.1 Manufacturing Update

The laboratory and pilot work has been completed with current efforts focused on the summary of the purification process development and outlining areas that may require further development prior to moving to NDA development and validation runs.

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 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 • Contract manufacturer has been appointed and is preparing pilot filling of gel product into tubes.	Expected completion Q1 2024

1.2 Analytical Update

Release testing samples from the two Phase 3 Glucoprime® API batches have been shipped to all the respective labs for testing which is expected to be completed by mid-February 2024. A full CoA is expected to be issued shortly thereafter.

Stability studies have commenced on the engineering batch Glucoprime® API with a final report expected in January.

1.3 CMO Update

The first scale up batch of TR987® has been completed and is being used to finalise the remaining test methods for release and stability testing of the Phase 3 drug product. A second batch to be used for the Phase 3 program is scheduled for production in February.

1.4 Phase 3 VLU Trial Update

The clinical operations team have 10 sites in the US with approved budgets and having their site qualification visit either completed or scheduled. A further 12 sites are still in preliminary discussions. Site outreach in Australia is also progressing well with two sites having committed to the trial and a further eight sites at various stages of discussion. The quality framework and documentation to support the clinical program are proceeding and we anticipate first patient enrolment mid-Q2 2024.

The Phase 3 protocol was submitted to the FDA in mid-December as part of a Type C meeting request which was necessary to clarify one particular aspect of the study design. The written FDA response is expected in the first week of March and we expect to formally submit the protocol shortly thereafter.

1.5 Pre-clinical work on the mechanism of action

Preliminary results from the collaboration with Dr Allison Cowin at the University of South Australia has provided additional insights into the mechanism of action of the Glucoprime® API and are suggestive of immunomodulation via the M2-type population of macrophages. Additional tests to confirm this are ongoing.

1.6 Next Quarter Activities

- Final validation of the analytical methods required to characterise the Glucoprime® API and TR987® hydrogel.
- Production and characterization of the Phase 3 batch of TR987®.
- Submission of the final Phase 3 protocol to the FDA.
- Continued outreach and qualification of clinical sites in Australia and the US.
- Commencement of the pilot toxicology program and continued work on the preclinical mechanism of action studies.

2. TR Pro+™ COMMERCIALISATION (for cosmetic and medical procedures)

2.1 Commercial launch of TR Pro+™

The clinical evidence which differentiates TR Pro+™ from other aftercare products is particularly relevant to healthcare professionals and consequently our launch strategy has been focussed on a range of practitioners.

At six months post-launch TR Pro+™ had been ordered by around 100 clinics and the feedback provided from online orders and our sales team has indicated that the gel is being used more broadly than just post-laser procedures. This aligns with our knowledge about the mechanism of action which suggests that TR Pro+™ can benefit healing in virtually any circumstance where the skin has been damaged or wounded.

Insights and case studies generated during the launch period have enabled us to fine tune our messaging and tailor communication to a broad range of clinicians and therapists. Over the next six months the Company will sponsor a number of annual conferences and scientific meetings which will continue to drive product awareness and adoption.

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. 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 2023

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	37	64
1.2	Payments for		
	(a) research and development	(375)	(861)
	(b) product manufacturing and operating costs	(67)	(115)
	(c) advertising and marketing	(30)	(80)
	(d) leased assets	-	-
	(e) staff costs	(449)	(856)
	(f) administration and corporate costs	(361)	(636)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	203	385
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)	52	91
1.9	**Net cash from / (used in) operating activities**	**(990)**	**(2,008)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(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**	**-**	**-**

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	20,543	21,396
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(990)	(2,008)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

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	(289)	(124)
4.6	**Cash and cash equivalents at end of period**	**19,264**	**19,264**

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	6,021	7,427
5.2	Call deposits	13,243	13,116
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)**	**19,264**	**20,543**

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	58
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)	(990)
8.2	Cash and cash equivalents at quarter end (item 4.6)	19,264
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	19,264

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.

30 January 2024

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.