ASX Announcement

Friday, 18 October 2024

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

30 September 2024 - Tissue Repair Limited (ASX:TRP, TR or the Company) is pleased to update the market on its progress in the September 2024 quarter and attaches its Appendix 4C Quarterly Cashflow Report for the period.

Key Highlights and Update

TR987® for chronic wounds

- First patient screening is anticipated by the end of October for the BG002 study with first patient randomisation expected shortly thereafter
- Clinical trial supply of TR987® has been completed and the product has been labelled at the US depot, and an allocation ready to ship to Australia for the BG003 study.
- The quality agreement for an additional five development batches of the Glucoprime® API is nearing finalization with production expected to commence before the end of the year, to ensure supply for TR Pro+ continued growth
- Cell culture and animal studies done by the University of South Australia have confirmed that the Glucoprime® API can modulate the level of inflammation and speed up entry to the proliferative healing phase, thus accelerating healing.

TR Pro+® for cosmetic and medical procedures

- TR Pro+® sales exceed the Q3 target and increased by 27% over Q2.
- TR Pro+® has been ordered by more than 240 clinics and a high number of repeat orders are being received suggesting sustained market acceptance.
- A number of local pilot studies have been initiated to support a growing range of indications for acute wounds.

Corporate and Financial Summary

The Company's cash position was $15.9 million as at 30 September 2024. During the September 2024 quarter total net cash operating outflows were approximately $289,000, largely attributed to expenses associated with the development of TR-987 and commercialisation of TR Pro+® offset by interest income and FY2023 research and development tax incentive received.

A summary of the operating cash flow for the period 7 October 2021 to 30 September 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 30 June 2024
Working capital and overheads[1]	300,000[1]	3,827,000[1]
Offer costs	2,300,000	1,849,000
Development of Chronic Wound Drug	3,700,000	7,496,000
Phase III Clinical Trials	13,600,000	1,672,000
Commercialisation of Aesthetic Product	2,100,000	2,179,000
Interest received	-	(1,245,000)
R&D tax incentive refund	-	(1,783,000)
TR Pro+ ™ Sales receipts	-	(258,000)
Total	**22,000,000**	**13,737,000**

[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 $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 quality agreement for the additional development batches of the Glucoprime® API is nearing completion which will pave the way for production to commence. This work should be initiated in Q4 2024 and will provide additional in-process information and ensure supply of TGA listed medicine product.

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. • 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.	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 Q4 2024

1.2 Analytical Update

The FDA Investigational New Drug (IND) file has been updated with additional stability data for the drug substance and drug product sections.

Board approval has been given for funding to establish a new cell bank to be used for the ongoing bioassay which is the primary efficacy assessment for the Glucoprime® API.

1.3 Phase 3 VLU Trial Update

Finalised protocols for the US (BG002) and AUS/US (BG003) studies were filed with the FDA and no further feedback was received from the Agency over the following 30-day period which has enabled the study to formally commence. Clinical trial product has been transferred to the US depot for labelling, and an allocation prepared for shipment to Australia.

Studies BG002 and BG003 have 17 and 9 clinical sites selected, respectively, with the BG002 sites allocated in the US and the BG003 sites in Australia and the US.

Patient screening for BG002 at the first US site is expected to commence by late October with most other sites expected to commence throughout November. First patient randomisation is anticipated to take place in early November

The sites for BG003 study will commence screening once final feedback from the Human Research Ethics Committee (HREC) has been received.

A request for Waiver of Paediatric Studies is also being prepared for filing with the FDA.

1.4 Toxicology Program

A detailed protocol for a 28-day repeat dose study in minipigs has been drafted and will be submitted to the FDA during the next quarter.

1.5 Mode of Action Studies

Over the past 12 months Tissue Repair has partnered with Professor Allison Cowin's lab at the University of South Australia to investigate the Glucoprime® API mode of action in more detail. The results from these cell culture and animal studies indicate that the Glucoprime® API can modulate the level of inflammation during the healing process, and this is achieved in part by the production of additional M2 macrophages. It appears that the Glucoprime® API can reduce the inflammatory phase of healing allowing earlier progression to the proliferative phase. This observation aligns comfortably with the real-world experience where clinicians and patients are reporting accelerated healing and reduced downtime. We expect these results to be published in due course.

Next Quarter Activities

- Filing of the 28-day repeat dose toxicology program with the FDA.
- Further refinement of the bioassay using a newly established cell bank.
- Production of additional development batches of Glucoprime® API to optimize the manufacturing process.
- First patient randomisation in Phase 3 trials in the US (BG002) and AUS/US (BG003).

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

2.1 Commercial launch of TR Pro+®

TR Pro+® sales continue to increase with the Q3 target being exceeded (106%) and quarter-on-quarter growth of 27%. Orders have been received from more than 240 clinics, and around half of the monthly orders are repeat orders, indicating sustained market acceptance. The focus continues to be on growing distribution with two new Specialist Territory Managers recruited for VIC and QLD.

Several local pilot studies have been initiated as we continue to expand the range of indications. Applications to assist healing post-surgery, post actinic keratosis treatment, and in controlling eczema flare ups show early promise and are actively being investigated further.

The team is continuing to hold discussions with potential distribution partners and is targeting to realise one or more of these distribution arrangements before the calendar year end.

Regulatory work has commenced to allow TR Pro+® entry into other geographical markets.

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.

Tissue Repair Ltd
Level 10, 255 Pitt Street, Sydney, NSW 2000
ACN: 158 411 566

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 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	90	90
1.2	Payments for		
	(a) research and development	(690)	(690)
	(b) product manufacturing and operating costs	(5)	(5)
	(c) advertising and marketing	(62)	(62)
	(d) leased assets	-	-
	(e) staff costs	(636)	(636)
	(f) administration and corporate costs	(254)	(254)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	103	103
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	1,090	1,090
1.8	Other (provide details if material)	75	75
1.9	**Net cash from / (used in) operating activities**	**(289)**	**(289)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(7)	(7)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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)**	**(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	16,441	16,441
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(289)	(289)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(7)	(7)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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	(234)	(234)
4.6	**Cash and cash equivalents at end of period**	**15,911**	**15,911**

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	10,105	9,635
5.2	Call deposits	5,806	6,806
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)**	**15,911**	**16,441**

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, 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 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)	(289)
8.2	Cash and cash equivalents at quarter end (item 4.6)	15,911
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	15,911
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**55.1**

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.

18 October 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.