ASX Announcement

Wednesday, 31 July 2024

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

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

Key Highlights and Update

TR987® for chronic wounds - On track for Phase 3 commencement

- First patient randomisation to occur prior to 30 September.
- Validation work has been completed for most of the analytical tests and stability testing of the engineering and clinical batches continues.
- Batch manufacturing and release testing of the Phase 3 lot has been completed, and updated protocols for the US (BG002) and AUS/US (BG003) studies which incorporate FDA feedback have been finalised.
- First patient enrolment in the US study (BG002) is expected at the end of September with enrolment in the AUS/US study (BG003) to commence shortly thereafter.
- Investigations have confirmed that the Glucoprime® API effects an increase in the number of M2-type macrophages, which modulate the immune response and facilitate the repair of damaged tissue. This has relevance for both TR987® and TR Pro+™.

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

- TR Pro+ sales in June reached a new high with Q3 revenue showing 130% growth over the prior quarter. Growing distribution is the primary focus.
- TR Pro+ ™ has been approved by the TGA as an AustL product which will enable the team to leverage the science and clinical information more broadly.

Corporate and Financial Summary

The Company's cash position was $16.4 million as at 30 June 2024. During the June 2024 quarter total net cash operating outflows were approximately $1,549,000, largely attributed to expenses associated with the development of TR987® and commercialisation of TR Pro+™ offset by interest income.

A summary of the operating cash flow for the period 7 October 2021 to 30 June 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]	3,601,000[1]
Offer costs	2,300,000	1,849,000
Development of Chronic Wound Drug	3,700,000	6,979,000
Phase 3 Clinical Trials	13,600,000	1,068,000
Commercialisation of Aesthetic Product	2,100,000	1,954,000
Interest received	-	(1,142,000)
R&D tax incentive refund	-	(693,000)
TR Pro+ ™ Sales receipts	-	(168,000)
Total	**22,000,000**	**13,448,000**

[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 30 June 2024, 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 TR897® and Phase 3 preparation. 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 totalled $133,000. 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

Additional development batches are being planned to optimize the production process and reduce costs with this work expected to be completed by the end of the year. Efforts are also being made to identify a CMO capable of producing the Glucoprime® API in commercial quantities.

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	• Production of four development batches to assess process changes aimed at reducing manufacturing costs	Expected completion Q4 2024

1.2 Analytical Update

Validation work has been completed for most of the analytical tests and stability testing of the engineering and clinical batches continues to be ongoing.

Module 3 of the eCTD (electronic common technical document) which describes the chemistry, manufacturing and controls associated with the drug substance (Glucoprime® API) and drug product (TR987®) has been finalised and filed with the FDA.

1.3 CMO Update

Batch manufacturing and release testing of the Phase 3 lot was completed. The slight delay to product release was due to an outstanding test requirement, however the TR987® 6g tubes have been shipped under quarantine and are expected at the depot late July 2024 for labelling and packaging for distribution to around 25 planned clinical trial sites.

1.4 Phase 3 VLU Trial Update

Updated protocols for the US (BG002) and AUS/US (BG003) studies which incorporate FDA feedback from the Type C meeting held in Q1 2024 have been finalised and are expected to be filed with the FDA mid-Q3 2024. Based on the detailed feedback received to date it is unlikely that the Agency will require any further significant changes once the study commences. The electronic trial database has commenced user acceptance testing with the eTMF expected to go live in mid-August. Five US trial sites will be ready to enrol subjects by the end of September 2024. A total of 20 US sites and five Australian sites will initially participate in the two planned trials.

Clinical trial site outreach is continuing in Australia with three sites qualified to initiate early patient enrolment.

1.5 Toxicology Program

The pilot toxicology study has been completed and will enable drafting of a detailed protocol for the 28-day repeat dose study. Documentation for both studies will be filed with the FDA for review in Q3 2024.

Next Quarter Activities

- Lot release of 6g tubes of TR987® for the Phase 3 program.
- Production of additional development batches of Glucoprime® API to optimize the manufacturing process.
- First patient enrolment in Phase 3 trials in the US (BG002) and AUS/US (BG003).
- Drafting of the 28-day repeat dose study protocol and review by the FDA.

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

2.1 Commercial launch of TR Pro+™

TR Pro+™ sales in June reached a new high with Q3 revenue showing 130% growth over the prior quarter. Sales continue to come from a mix of existing and new accounts with more than 160 clinics having now ordered product. While numbers are still relatively small, the focus is on growing distribution, and in line with this the sales resource will be expanded to include specialist territory managers in QLD and VIC.

Our range of case studies continues to expand and supports a growing list of indications for both medical and aesthetic procedures. Testimonials from healthcare professionals reinforce the HCP-driven strategy and a strong brand presence at key educational meetings allows the dissemination of the science that underpins TR Pro+™. Discussions have commenced with a range of potential distributors in Australia and abroad.

A TGA application to market TR Pro+ ™ as an AustL product has been approved. The TGA listing will enable the team to promote the science and clinical data more broadly. It will also increase the credibility of the product with a wider range of users and user types.

Marketing of TR Pro+ ™ should also benefit from the recently completed University of South Australia investigations into the mechanism of action of the Glucoprime® API which have confirmed how TR Pro+™-treated wounds enable skin to heal optimally.

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	30 June 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	67	165
1.2	Payments for		
	(a) research and development	(596)	(2,287)
	(b) product manufacturing and operating costs	(5)	(290)
	(c) advertising and marketing	(71)	(203)
	(d) leased assets	-	-
	(e) staff costs	(858)	(2,099)
	(f) administration and corporate costs	(261)	(1,132)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	132	713
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)	43	182
1.9	**Net cash from / (used in) operating activities**	**(1,549)**	**(4,951)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(3)	(3)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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)**	**(3)**

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	18,082	21,396
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,549)	(4,951)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(3)	(3)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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	(89)	(1)
4.6	**Cash and cash equivalents at end of period**	**16,441**	**16,441**

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	9,635	6,776
5.2	Call deposits	6,806	11,306
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)**	**16,441**	**18,082**

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	133
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)	(1,549)
8.2	Cash and cash equivalents at quarter end (item 4.6)	16,441
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	16,441
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**10.6**

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 July 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.