ASX Announcement
Monday, 31 July 2023

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

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

- Process development of the Glucoprime® active pharmaceutical ingredient (API) has been delayed slightly due to a incident at its US-based Contract Manufacturer (CMO) GMP facility, the Company still has access to batches of API these will be processed at the R&D site of the CMO for use in the Phase 3 clinical trials.
- The pre-validation work has been completed with final validation expected to be completed over the next few weeks. We remain confident that the Glucoprime® API to be used in the Phase 3 study will comfortably meet the specifications.
- A CMO has been engaged to manufacture the TR987® gel, and an initial pilot batch has been produced for tests on terminal sterilisation and analytical validation.
- The End-of-Phase 2 (EOP2) meeting held with the FDA in May provided clearance for the Company to progress into a Phase 3 program, subject to some modifications to the study protocol. The Company is amending the protocol and expects to submit to the FDA in Q3 2023 for final review, however the FDA has already provided feedback on all substantive matters for the Phase 3 trial design which the company has adopted.
- The Company has established an in-house clinical operations team to develop and manage the Phase 3 program. The immediate focus is on site outreach and preparing the necessary quality framework and documents to support the program, with a view to commence patient enrolment in Q1 2024.
- The toxicology pilot study has been cleared to commence following identification of an assay to measure systemic concentrations of beta-glucan.

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

- An initial batch of TR Pro+ 10g tubes (10,000) and 3g sample sachets (18,000) has been completed and released.
- First sales of TR Pro+™ have been achieved with overwhelmingly positive feedback from clinicians and patients from the use of the product.
- Promotional activity has been driven predominantly by virtual and face-to-face calls on dermatology and cosmetic clinics and complemented by healthcare professional conference sponsorships.

- Early signs post-launch are positive with neither clinicians nor patients highlighting any barriers to the usage of TR Pro+ (eg: price, efficacy, format etc), confirming that the main growth strategy will be focused on changing clinician behaviour to incorporate the product into cosmetic and medical procedures.

Corporate and financial

The Company's cash position was $21.4million as at 30 June 2023. During the June 2023 quarter total cash operating outflows were approximately $427,000, largely attributed to expenses associated with the development of TR-987 and commercialisation of TR Pro+ offset by interest income and receipt of FY22 R&D tax incentive.

A summary of the operating cash flow for the period 7 October 2021 to 30 June 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 30 June 2023
Working capital and overheads[1]	300,000[1]	2,490,000[1]
Offer costs	2,300,000	1,849,000
Development of Chronic Wound Drug	3,700,000	4,095,000
Phase III Clinical Trials	13,600,000	213,000
Commercialisation of Aesthetic Product	2,100,000	975,000
Interest received	-	(429,000)
R&D tax incentive refund	-	(693,000)
TR Pro+ ™ Sales receipts	-	(3,000)
Total	**22,000,000**	**8,497,000**

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

During the period ending 30 June 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 $56,000. 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

Process development of the active pharmaceutical ingredient (API) has been delayed due to an incident at the US-based CMO GMP facility. The processing of API batches however is continuing and will be completed in the R&D site of the CMO. These API batches are currently being processed will be used for the Phase 3 clinical trial supplies.

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 Expected completion 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 Q4 2023/Q1 2024
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 Q4 2023

1.2 Analytical Update

There are more than 20 tests used to characterise the Glucoprime® API. As a result of the incident at the CMO, some of these methods have been outsourced to alternate laboratories. While the interruption in Glucoprime® API production has led to a slight delay in test validation, the pre-validation work has been completed with final validation expected to be completed over the next few weeks. We remain confident that the Glucoprime® API to be used in the Phase 3 study will comfortably meet the specifications.

1.3 CMO Update

A US-based CMO has been engaged to manufacture the TR987® gel, and the production of a test 50kg batch has been completed.

An End-of-Phase 2 (EOP2) meeting was held with the FDA in May to discuss the updated TR987® dossier and proposed Phase 3 protocol. The response from the FDA provided clearance for the Company to progress into a Phase 3 program, subject to some modifications to the study protocol. The Company is amending the protocol and expects to submit it to the FDA in Q3 2023 for a final review.

1.4 Phase 3 VLU Trial Management

Following the EOP2 meeting, the Company has established an in-house clinical operations team to develop and manage the Phase 3 program. The team is currently US-based but there are plans to add an Australian arm shortly. The immediate focus is on preparing the necessary quality framework and documentation to support the clinical program. Given the delay in production of the Glucoprime® API, we anticipate patient enrolment to commence in Q1 2024. More than 15 sites have been approached and indicated a strong level of engagement and commitment to participate in the trial.

1.5 Pre-clinical work on the mechanism of action

Work progresses at the University of South Australia on investigations into the mechanism of action of the Glucoprime ® API. Initial work has validated the 0.1% concentration as being superior to higher doses. Over the coming months we expect to gain a more complete understanding of the temporal effects on cytokines and growth factors as well as insights into on collagen production and scar formation.

1.6 Conferences

Dr Darryl Reed (COO) attended the recent 25th World Congress of Dermatology (Singapore) and presented on the *'Efficacy of TR987®, beta-1,3-1,6-D-glucan, in the treatment of chronic venous insufficiency ulcers: a two-arm, double-blind, placebo-controlled, randomized controlled Phase 2B trial'*. He delivered a poster (summary of study and outcomes) on *'A Patient Experiential Program to assess the effectiveness of a novel wound healing hydrogel, TR Pro+™ (beta-1,3-1,6-D-glucan) as an aftercare treatment for cosmetic and medical procedures'*.

1.7 Next Quarter Activities

- Further validation of the analytical methods required to characterise the Glucoprime® API and TR987® hydrogel.
- Production of Phase 3 clinical supplies of TR987®.
- Submission of the revised Phase 3 protocol to the FDA.
- Continued outreach to clinical sites and development of documentation to support the clinical program.
- Advancement of the toxicology program and preclinical mechanism of action studies.

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

2.1 Commercial launch of TR Pro+™

The number of 10g tubes (10,000) and 3g sachets (18,000) produced for TR Pro+™ was less than expected due to some technical challenges associated with filling the viscous hydrogel into sachets, something which had not been done before. Consequently, the products were released in early June, slightly later than planned.

First sales of TR Pro+ have been achieved with overwhelmingly positive feedback being received from clinicians and patients from in field use.

Promotional activity has been driven predominantly by virtual and face-to-face calls on dermatology and cosmetic clinics, complemented by healthcare professional conference sponsorships. While a steady run of orders is being received, this initial uptake of TR Pro+ is highly dependent upon field force activity. Importantly, neither clinicians nor patients have highlighted any barriers to the usage of TR Pro+ (eg: price, efficacy, format etc), confirming that the main growth strategy will focus on changing clinician behaviour. The immediate goal is to establish a group of clinics willing to integrate the aftercare product into their procedures and demonstrate consistently re-ordering. Confirmation of this positive signal of market uptake will prompt the team to identify further channels to scale up activity and accelerate growth.

2.2 Next Quarter Activities

- Continued promotion of TR Pro+™
- Exploration of potential partnerships and growth opportunities

For further information in relation to this release please contact Darryl Reed at
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0419 557 663.

This announcement has been approved for release by TRP's board.

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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 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	30 June 2023

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	3	3
1.2	Payments for		
	(a) research and development	(459)	(2,512)
	(b) product manufacturing and operating costs	(21)	(264)
	(c) advertising and marketing	(24)	(130)
	(d) leased assets	-	-
	(e) staff costs	(386)	(1,278)
	(f) administration and corporate costs	(223)	(1,191)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	235	419
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	400	550
1.8	Other (provide details if material)	48	149
1.9	**Net cash from / (used in) operating activities**	**(427)**	**(4,254)**

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 (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**	**-**	**(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	21,792	25,455
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(427)	(4,254)
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 (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	31	197
4.6	**Cash and cash equivalents at end of period**	**21,396**	**21,396**

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	7,646	6,042
5.2	Call deposits	13,750	15,750
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)**	**21,396**	**21,792**

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	56
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)	(427)
8.2	Cash and cash equivalents at quarter end (item 4.6)	21,396
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	21,396
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**50.1**

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.

31 July 2023

Date: .....

The Board of Directors

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.