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ASX Announcement

Monday, 30 October 2023

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

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

- The final batches of active pharmaceutical ingredient (API) to be used in the Phase 3 trial are in the last stages of drying and sterilization. Recent development work has provided information essential to the completion of this process design stage to enable an FDA-approved commercial drug product.
- The majority of the 20-plus tests used to characterise the API have been, or are close to, validation.
- An initial 50kg pilot batch of the TR987® gel has been manufactured with two larger scale-up batches scheduled for November 2023 and January 2024.
- The Company's in-house clinical operations team has been established and has continued site outreach activities in both Australia and the US, with 20 sites in the US now having shown a high level of interest. First patient recruitment is expected in Q2 2024.
- Major hospitals in Australian including Royal North Shore Hospital (Sydney) are actively engaged in considering participation in the Phase 3 program.
- The Phase 3 protocol is nearing finalization and is expected to be filed with the FDA in early Q4 2023.

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

- TR Pro+™ was launched in early June and has demonstrated positive early signals with sales increasing month-on-month. The focus remains on establishing a sizable distribution network.
- A number of sales channels are being tested and initiated to build on the initial positive momentum established in the early period of the launch of the product.

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

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Corporate and Financial Summary

- The Company's cash position was $20.5 million as at 30 September 2023. During the September 2023 quarter total cash operating outflows were approximately $1,018,000, 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 September 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 September 2023
Working capital and overheads[1]	300,000[1]	2,730,000[1]
Offer costs	2,300,000	1,849,000
Development of Chronic Wound Drug	3,700,000	4,740,000
Phase III Clinical Trials	13,600,000	360,000
Commercialisation of Aesthetic Product	2,100,000	1,170,000
Interest received	-	(611,000)
R&D tax incentive refund	-	(693,000)
TR Pro+ ™ Sales receipts	-	(30,000)
Total	22,000,000	9,515,000

- [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 September 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 TR987®, 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 were $52,000. 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 final batches of active pharmaceutical ingredient (API) to be used in the Phase 3 trial are in the last stages of drying and sterilization. Recent development work has provided information essential to the completion of this process design stage to enable an FDA-approved commercial drug product.

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.	Expected completion Q4 2023/Q1 2024
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

The majority of the 20-plus tests used to characterise the API have been, or are close to, validation. Some technical challenges exist on one assay which management is confident of solving.

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1.3 CMO Update

Following the successful production of a 50kg pilot batch, preparations are underway for two larger scale-up batches at the contract manufacturer (CMO).

1.4 Phase 3 VLU Trial Update

The core clinical operations team based in the US have continued to identify potential sites with 20 US-based sites having completed CDAs indicating a high level of interest in participating. Site outreach in Australia is also underway, with almost 10 sites having been contacted to date. The necessary quality framework and documentation to support the clinical program are proceeding and we anticipate first patient enrolment in early Q2 2024.

The Phase 3 protocol is nearing finalization and is expected to be filed with the FDA in early Q4 2023.

1.5 Pre-clinical work on the mechanism of action

Our collaboration with Dr Allison Cowin at the University of South Australia continues to shed light on the mechanism of action of the beta glucan API. Future experiments aim to define the temporal expression of some key cytokines and growth factors involved in wound healing following multiple applications of the hydrogel. Examination of collagen expression and some markers involved in scar formation should also yield interesting results which can bolster our preclinical package for the FDA and healthcare professional communications in Australia.

1.6 Next Quarter Activities

- Further validation of the analytical methods required to characterise the API and TR987® hydrogel.
- Production and characterization of scale up batches 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.
- Advances to 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+™

TR Pro+™ was officially launched in the second week of June following some manufacturing delays. There are several early signals that indicate positive uptake by the market, supporting the market research and real-world-evidence study. Sales have increased steadily by about 20% month-on-month. Orders from clinics (wholesale) account for 93% of the sales volume with the other 7% being retail (consumer/patient) orders.

The Company is focussed on establishing a footprint of distribution in the early stages of the launch [as opposed to a focus on aggressive sales growth]. The Company is pleased with the number of clinics accepting an initial order of TR Pro+™ and the consistent positive feedback on clinical impact following cosmetic procedures.

The main procedures utilising the TR Pro+™ aftercare gel are skin needling, laser skin resurfacing, and scar management.

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A number of sales channels are being tested to build on the initial positive momentum in the early stages of the products launch.

2.1 Conferences

The Company sponsored several key conferences over the past three months including Aesthetics 2023, SkinCon 2023 and the Beauty Expo. Delegates at all conferences showed a high level of interest in 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 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.

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Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

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Name of entity	
Tissue Repair Limited	
ABN	**Quarter ended ("current quarter")**
20 158 411 566	30 September 2023

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	27	27
1.2	Payments for		
	(a) research and development	(486)	(486)
	(b) product manufacturing and operating costs	(48)	(48)
	(c) advertising and marketing	(50)	(50)
	(d) leased assets	-	-
	(e) staff costs	(407)	(407)
	(f) administration and corporate costs	(275)	(275)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	182	182
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)	39	39
1.9	**Net cash from / (used in) operating activities**	**(1,018)**	**(1,018)**

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	-	-

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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**	**-**	**-**

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	21,396	21,396
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,018)	(1,018)
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 (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	165	165
4.6	**Cash and cash equivalents at end of period**	**20,543**	**20,543**

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	7,427	7,646
5.2	Call deposits	13,116	13,750
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)**	**20,543**	**21,396**

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	52
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.

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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)	(1,018)
8.2	Cash and cash equivalents at quarter end (item 4.6)	20,543
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	20,543
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**20.2**

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.

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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 October 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.

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