

March 2024 Quarterly Activities Report and Appendix 4C

29 April 2024

LTR Pharma Limited (ASX:LTP) ("LTR Pharma", "the Company"), a company focused on improving men's health through the clinical development and commercialisation of an innovative nasal spray treatment for Erectile Dysfunction ("ED"), SPONTAN[®], is pleased to provide its Appendix 4C for the quarter ended 31 March 2024.

Highlights:

- Pivotal clinical study of SPONTAN[®] fully recruited and completed dosing of all participants.
- SPONTAN achieved key manufacturing validation and first commercial batch production.
- SPONTAN is designed to be a world-first, fast-acting, on-demand Nasal Spray treatment for Erectile Dysfunction (ED).
- As at 31 March 2024, the Company held a cash balance of \$5.28 million, strongly positioning LTR Pharma to meet its upcoming milestones.

Corporate Update

LTR Pharma continued its drive to bring SPONTAN to market during the Quarter by preparing and commencing SPONTAN's pivotal bioequivalence clinical study, preparing for the early access scheme in Australia, and conducting a community outreach program to erectile dysfunction interest groups.

In March, the Company undertook a non-deal investor roadshow across Australia, meeting with new and existing investors ([Investor Presentation](#)). The purpose of the roadshow was to provide an update that the Company is on track to meet its milestones as laid out in its IPO prospectus and outline the key milestones still to come in 2024.

LTR Pharma Chairman, Lee Rodne, said: "We are pleased to share that LTR Pharma has made significant strides towards bringing SPONTAN to market this quarter. We completed the dosing phase of the pivotal study and met critical FDA requirements for manufacturing validation. We remain on track with a strong cash position to achieve our milestones and revolutionise the global erectile dysfunction treatment landscape."

Bioequivalence Study Progression

LTR Pharma commenced recruitment for its pivotal study of SPONTAN on 19 February 2024, which was a short process due to the high demand for participation. The Company reported on 25 March that recruitment was successfully completed, and all participants had received their final dosing as part of the study.

The study has entered the data evaluation phase, with results anticipated mid-2024. The study represents a critical milestone for the Company as it is designed to show that SPONTAN can disrupt the global PDE5 (Viagra, etc.) marketplace. The final data from the study is also expected to support the early access scheme in Australia and aid in pre-submission meetings with the FDA and TGA.

With the final study results expected in mid-2024, LTR Pharma is optimistic about SPONTAN's ability to impact the global erectile dysfunction treatment landscape significantly.

SPONTAN Commercial Manufacturing Validation

LTR Pharma completed critical manufacturing validation steps in preparation for SPONTAN's pivotal study. In collaboration with its Contract Manufacturing Organisation (CMO), the Company successfully met essential U.S. Food and Drug Administration (FDA) requirements by conducting stability testing, quality control checks, product purity assessments and packaging integrity evaluations. A portion of the initial commercial batch of SPONTAN was used in the bioequivalence study. This achievement signifies LTR Pharma's commitment to the highest product quality standards and regulatory compliance.

Financial Update

Expenditure

Net cash used for operations in the quarter was \$0.74m, with the expenditure program is on track to meet its objectives regarding the use of funds, as stated in the Prospectus. LTR Pharma's expenditures have been focused on completing its pivotal study and preparations for early access in Australia. The Company's cash balance was \$5.28 million as at 31 March 2024, and the Company remains in a strong position to meet its upcoming milestones.

Comparison to IPO prospectus

A summary of the operating cashflows for the period since the listing date of 11 December 2023 ending 31 March 2024 compared to the proposed use of funds (2-year period) of LTP's Prospectus dated 7 December 2023 is outlined below.

During the period ending 31 March 2024, overall spending remained broadly in line with the estimated use of funds as set out in the Prospectus. The Company expects R&D expenditures to increase in the coming quarters as it completes its pivotal bioequivalence study per the Use of Funds in the table below.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of Appendix 4C was A\$138,750 and included Director fees, salary, and superannuation for the Executive Chairman and Non-Executive Directors.

Use of Funds / Expenditure Program*	\$	
	Expenditure allocated under prospectus (2-year period)	Actual expenditure to date 31-March-24**
Regulatory	\$350,000	\$5,224
CMC (chemistry, manufacturing, and control/packaging for sales)	\$320,000	\$75,453
Non-clinical studies	\$140,000	\$20,225
Bioequivalence trial	\$1,350,000	\$289,308
Sales & Marketing	\$810,000	\$79,035
Payment (SDS License Agreement)	\$475,097	-
Working Capital	\$2,635,337	\$514,218
Expenses of the Offer	\$811,939	\$689,786
Total	\$6,892,373	\$1,673,249

* This table is a statement of current intentions of the Company. Actual use of funds may differ from the budgeted use of funds based on changes in clinical trials budgets or formulation development expenses. The Board may alter the way funds are applied in the future.

** The Company incurred cash outflows before 11 December 2023 which have been added into this table to reflect the use of funds more accurately in relation to the IPO prospectus.

About LTR Pharma

LTR Pharma is focused on improving men's health, physically and mentally, through the commercialisation of an innovative nasal spray treatment for Erectile Dysfunction. ED is a pressing health issue for millions of men that can negatively impact self-esteem and relationships across multiple age brackets. LTR Pharma's lead product, SPONTAN[®], is set apart from existing ED therapies by its mechanism of action – intranasal delivery technology of a PDE5 inhibitor. The nasal cavity is a highly vascular part of the body, supporting even and rapid absorption of the drug, empowering it to work within 10 minutes or less. LTR Pharma is proudly aiming to restore greater control over the timing, spontaneity, and enjoyment of sexual experiences.

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Appendix 4C

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

Name of entity

LTR Pharma, LTR Pharma Inc

ABN
Quarter ended ("current quarter")

March 2024

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(289,835)	(1,468,843)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(79,035)	(215,669)
(d) leased assets	-	-
(e) staff costs	(198,913)	(459,763)
(f) administration and corporate costs	(215,836)	(845,477)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	139	230
1.5 Interest and other costs of finance paid	(338)	(401)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	44,547	44,547
1.9 Net cash from / (used in) operating activities	(739,271)	(2,954,376)
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 (9 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)	-	6,506,035
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	-	6,506,035
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	6,019,672	1,728,742
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(739,271)	(2,954,376)
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 (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	6,506,035
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	5,280,401	5,280,401

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	5,280,401	6,019,672
5.2	Call deposits	-	-
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)	5,280,401	6,019,672

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	-
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>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.</i>		
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)	(739,271)
8.2 Cash and cash equivalents at quarter end (item 4.6)	5,280,401
8.3 Unused finance facilities available at quarter end (item 7.5)	
8.4 Total available funding (item 8.2 + item 8.3)	5,280,401
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	7
<i>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.</i>	
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:	
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:	
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:	
<i>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.</i>	

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.

Date: 29 April 2024

Authorised by: By the Board
(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.