



September 2024 Quarterly Activities Report and Appendix 4C

28 October 2024

LTR Pharma Limited (ASX:LTP) ("**LTR Pharma**", "**the Company**"), a Company focused on improving men's health through 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 30 September 2024.

Highlights:

- **SPONTAN[®] prescribed to first patients under the Therapeutic Goods Administration's (TGA) Special Access Scheme (SAS) and Authorised Prescriber Scheme (APS).**
- **Secured global Co-Development Agreement with Aptar Pharma for SPONTAN for global markets.**
- **As at 30 September 2024, the Company held a cash balance of \$12.05 million.**
- **Subsequent to quarter end, LTR Pharma released SPONTAN's final clinical study results showing it achieves 470% faster absorption than oral PDE5 tablets (Viagra, etc.), positioning SPONTAN as a potential market disruptor in the global ED market.**

Corporate Update

During the quarter, LTR Pharma achieved several significant milestones in its R&D and commercial operations, positioning the Company for accelerated growth and market development.

World first prescriptions of a PDE5 (Viagra, etc) nasal spray

SPONTAN has been prescribed under the Therapeutic Goods Administration (TGA) early access schemes for unmet medical needs - for the first time, globally - marking a significant leap forward in the treatment landscape for ED. This has been facilitated via the following pathways:

- **Special Access Scheme (SAS):** In early August, select patients received SPONTAN via the SAS, allowing for case-by-case prescriptions.
- **Authorised Prescriber Scheme (APS):** On 16 August, SPONTAN was prescribed to the first patients under the APS. This scheme allows registered medical practitioners to prescribe SPONTAN to a broader class of patients with erectile dysfunction, streamlining access for those who may benefit from this innovative treatment.

The involvement of key opinion leaders (KOLs), including internationally renowned men's health experts such as LTR Pharma's Scientific Advisor and consultant urological surgeon, Professor Eric Chung, underscores the growing recognition of SPONTAN's potential for addressing unmet needs in ED treatment.

The TGA's early access scheme facilitates invaluable, real-world clinical access and experience for SPONTAN. It enables medical practitioners to focus on initial patient use and clinical outcomes, and to gather patient feedback with real-world data on how patients use the product, amongst other data. Prescribers are reporting excellent feedback from patients, further validating SPONTAN's potential. This clinical experience builds a foundation for future medical publications and supports the Company's partnering and licensing discussions, and regulatory meetings.

Over the coming quarters, LTR Pharma will continue to build on these clinical cases, enhancing SPONTAN's product profile in real-world scenarios to improve the treatment landscape for ED and to support SPONTAN's regulatory strategy and market positioning.

Global Co-Development Agreement

On 13 August 2024, LTR Pharma secured a global Co-Development Agreement ("the Agreement") with Aptar Pharma, a global leader in nasal spray technology. This strategic partnership supports SPONTAN's commercialisation in key markets, including the US. The Agreement combines LTR Pharma's pharmaceutical development capabilities with Aptar Pharma's expertise in nasal spray technology.

Preparation has commenced in the quarter to initiate the following activities to support a streamlined regulatory pathway and market access for SPONTAN:

- Extractable and leachable (E&L) studies to further validate SPONTAN's compliance with FDA standards.
- Human Factors studies to assess how well users can follow instructions for use.
- Production of FDA-compliant instructional videos to ensure proper product usage.
- Development of dedicated medical education and product supply chain technology infrastructure.

These efforts are vital in preparing for future regulatory meetings and advancing SPONTAN's development pathway towards broader market access.

Manufacturing

To support the Company's R&D and commercial objectives, LTR Pharma has initiated a scale-up of its manufacturing processes. This includes ongoing stability studies to extend SPONTAN's shelf life and to facilitate anticipated patient demand in 2025.

Financial Update

In July, the Company completed a capital raise of \$10.5 million (before costs), complemented by a \$0.4 million R&D tax incentive inflow for the FY23 financial year. As of 30 September 2024, LTR Pharma's cash balance stood at \$12.05 million. This provides a strong foundation for advancing the Company's key strategic objectives over the coming year, including ongoing development, regulatory preparations, and further product commercialisation efforts.

During the quarter, LTR Pharma completed its pivotal clinical study and spent \$536,650 in research and development, mainly comprising of its clinical study.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of Appendix 4C totalled 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 30-September-24**
Regulatory	\$350,000	\$158,074
CMC (chemistry, manufacturing and control / packaging for sales)	\$320,000	\$174,322
Non-clinical studies	\$140,000	\$177,354
Bioequivalence trial	\$1,350,000	\$1,514,487
Sales & Marketing	\$810,000	\$484,494
Payment (SDS License Agreement)	\$475,097	\$461,816
Working Capital	\$2,635,337	\$1,479,986
Expenses of the Offer	\$811,939	\$689,786
Total	\$6,892,373	\$5,140,319

* 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.

Outlook

LTR Pharma is building on its research and development success to advance its strategic objectives across multiple fronts.

After completing its successful clinical trial, the Company's primary commercial focus has been getting real-world feedback from clinicians prescribing SPONTAN through the TGA's early access schemes. This will remain a key focus in the quarter ahead. The Company is receiving positive feedback from medical practitioners and expects this data to be valuable to our regulatory meetings and partnering discussions with global pharmaceutical companies. Building on the success of our pivotal clinical study, the Company is prioritising the publication of our comprehensive clinical data package, complemented by real-world evidence from key opinion leaders' early prescribing experience. This dual approach of robust clinical data and real-world validation remains a central strategic priority for the quarters ahead, positioning SPONTAN's unique advantages in the global ED market.

The Company will also actively progress its regulatory strategy to achieve broader market access for SPONTAN. In line with this, LTR Pharma retained a global regulatory and market access firm in the last quarter to provide a strategic regulatory access plan in key markets. LTR Pharma expects to receive this strategic review in the coming quarter and proceed with initiating regulatory review meetings with the FDA and TGA.

The Company remains committed to improving men's health and looks forward to updating shareholders on its progress in these key areas in the coming months.

This announcement has been approved by the Board of Directors.



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")

September 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	12,400	12,400
1.2 Payments for		
(a) research and development	(536,650)	(536,650)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(199,296)	(199,296)
(d) leased assets	-	-
(e) staff costs	(206,798)	(206,798)
(f) administration and corporate costs	(345,817)	(345,817)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	234	234
1.5 Interest and other costs of finance paid	(695)	(695)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	388,178	388,178
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(888,443)	(888,443)

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
	(c) property, plant and equipment	(4,068)	(4,068)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
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	(4,068)	(4,068)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	9,844,535	9,844,535
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	9,844,535	9,844,535

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
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4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	3,102,323	3,102,323
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(888,443)	(888,443)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(4,068)	(4,068)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	9,844,535	9,844,535
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	12,054,347	12,054,347

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	12,054,347	12,054,347
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)	12,053,160	12,053,160

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	-

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.

7.	Financing facilities <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>	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)	(888,443)
8.2	Cash and cash equivalents at quarter end (item 4.6)	12,054,347
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	12,054,347
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	13.6
	<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:

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.

Date: 28 October 2024

Authorised by: The Board of Directors

(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.