



29 April 2025

Quarterly Activities Report & Appendix 4C

For the Period Ending 31 March 2025

Highlights

- SPONTAN® receives scientific acclaim for 470% faster absorption than traditional oral tablet, presenting clinical data at USANZ Annual Scientific Meeting and Prof. Eric Chung awarded BAUS Trophy.
- Australian distribution of SPONTAN expands via pharmacy and telehealth partnerships.
- Australian prescriber network continues to grow, expanding with Men's Health Downunder and Restorative Sexual Health Clinic.
- LTR Pharma to launch new product, Roxus®, to accelerate US market entry to personalised healthcare model and market, minimising US import tariff exposure.
- FDA provides clear path to SPONTAN approval following successful pre-IND meeting.

LTR Pharma Limited (ASX:LTP) ("LTR Pharma" or "the Company"), a company focused on improving men's health through clinical development and commercialisation of innovative nasal spray treatments for erectile dysfunction ("ED"), SPONTAN® and ROXUS®, is pleased to provide its Appendix 4C and an overview of its activities for the period ended 31 March 2025 (the "Reporting Period" or the "Quarter").

Commenting on the activity for the Quarter, Executive Chairman, Lee Rodne, stated: *"The first quarter of 2025 delivered significant progress across our regulatory, commercial and scientific objectives. The pre-IND meeting with the FDA has provided us with a clear development pathway, while the launch of our ROXUS programme advances our dual-market strategy to unlock the US personalised healthcare market."*

"Our Australian operations continue to build momentum, with growing prescriber adoption and patient access through the TGA's early access schemes. The scientific recognition at USANZ has further validated the clinical advantages of SPONTAN."

"With our commercial infrastructure taking shape and key regulatory activities underway, we are executing our strategy to transform the treatment landscape for erectile dysfunction."

Corporate & Operational Update

During the Quarter, LTR Pharma achieved significant milestones in regulatory, commercial, and product development initiatives.

Regulatory Progress

In March, the Company held a successful pre-IND meeting with the United States' Food & Drug Administration (FDA). Outcomes included:

- FDA's broad endorsement of LTR's non-clinical (toxicology) and CMC (Chemistry, Manufacturing and Controls) development plans.
- Agreement on a pivotal efficacy/safety study and a multi-dose pharmacokinetic study.
- Clear guidance on the pathway to market through the 505(b)(2) regulatory process.

Post meeting, LTR Pharma has:

- Initiated Chemistry, Manufacturing and Controls (CMC) studies with Aptar Pharma.
- Commenced extractables and leachables studies required for regulatory documentation.
- Developed specific protocols for the upcoming clinical studies.

ROXUS

During the Quarter, the Company announced ROXUS, a new nasal spray targeting the US personalised healthcare sector, representing a significant expansion of the Company's product portfolio. This announcement marked a key milestone in the Company's dual-track US market strategy. Key achievements during the Quarter included:

- ROXUS announced as a strategic initiative to accelerate US market entry.
- Ongoing product development with our Australian pharmaceutical partner.
- Analysis of the US personalised healthcare sector, confirming its current market value of US\$6 billion with projected growth to US\$10 billion by 2033 (5.2% CAGR)*

ROXUS supports the Company's dual-market strategy to establish early revenue in the US market in 1H CY26.

* Source: Nova1Advisor – Compounding Pharmacies Market Size, Share & Trends Analysis.

Commercial Expansion in Australia

The Company expanded its Australian commercial operations during the Quarter through:

- Growing prescriber base, prescribing under the TGA's Special Access Scheme (SAS) and Authorised Prescriber Scheme (APS).
- Continued growth of telehealth operations, with the joint venture with Restorative Health Clinic and other telehealth providers.
- Further distribution preparations made, having completed implementation and planning with Symbion for the Q2 CY25 rollout, which will establish nationwide pharmacy distribution capabilities over the coming quarters.
- Clinical partnerships strengthened, thanks to collaboration with Men's Health Downunder, resulting in increased prescription volumes through their pharmacy network.

Scientific Recognition for SPONTAN

A significant achievement during the Quarter was the recognition of SPONTAN at the Urological Society of Australia and New Zealand's (USANZ) Annual Scientific Meeting.

Chief Scientific & Clinical Adviser, Professor Eric Chung, was awarded the prestigious BAUS Trophy, which is the event's highest honour, for his presentation of SPONTAN's clinical results.

Professor Chung's presentation highlighted the compelling pharmacokinetic and absorption data from SPONTAN's pivotal pharmacokinetic clinical study.

Key clinical results:

- Mean time to peak concentration (Tmax) of 12 minutes (range 9-15 minutes) for SPONTAN, compared to a mean Tmax of 56 minutes for traditional oral tablet treatments (longest time was 180 minutes for oral tablets).
- SPONTAN 5mg intranasal dose delivered 111.8% dose-normalised bioavailability.
- SPONTAN saw a 155.6% higher peak concentration, despite using a lower dose.

This scientific recognition, voted on by a panel of urologists, reinforces SPONTAN as a best-in-class, fast-acting ED therapy, and has attracted strong interest from international urologists and key opinion leaders.

Financial Update

LTR Pharma executed its targeted investment programme during the Quarter, allocating capital to high-value initiatives, while maintaining a strong cash position of \$32.8 million as at 31 March 2025.

Key expenditures during the Period included continued investment in the joint venture with Restorative Health Clinic's telehealth platform, makehardeasy.com.au.

The Company directed approximately \$0.7 million towards research and development activities, encompassing the advancement of regulatory trials, preparatory work for the FDA pre-IND meeting, ROXUS product development, and ongoing stability work to progress product shelf-life extensions across products.

Sales, general, and administrative costs totalled approximately \$0.2 million, and investor relations and marketing activities accounted for an additional \$0.2 million.

The Company also strengthened its development team by adding a new Program Director to support R&D expansion.

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\$243,906 and included Director fees, salary, and superannuation for the Executive Chairman and Non-Executive Directors.

The Company maintains a strong financial position, providing runway to execute its targeted objectives across multiple markets.



Use of Funds / Expenditure Program*	\$	
	Expenditure allocated under prospectus (2-year period)	Actual expenditure to date 31-December-24**
Regulatory	\$350,000	\$326,127
CMC (chemistry, manufacturing and control/packaging for sales)	\$320,000	\$332,613
Non-clinical studies	\$140,000	\$190,699
Bioequivalence trial	\$1,350,000	\$1,514,487
Sales & Marketing	\$810,000	\$807,857
Payment (SDS License Agreement)	\$475,097	\$461,816
Working Capital	\$2,635,337	\$2,568,988
Expenses of the Offer	\$811,939	\$689,786
Total	\$6,892,373	\$6,892,373

*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.

Looking Ahead

Building on the achievements of the Quarter, LTR Pharma will focus on advancing several strategic priorities throughout 2025.

On the regulatory front, the Company will advance CMC and non-clinical studies to support our FDA regulatory pathways. In Australia, we will launch the Symbion distribution network, significantly expanding our reach across 3,900 pharmacy locations, whilst broadening our prescriber education programme and enhancing our telehealth capabilities.

Product innovation remains a core focus, with completion of ROXUS testing to enable early US market entry, advancement of manufacturing scale-up activities, and continued creation of additional SPONTAN derivatives to address various market segments.

The Company remains committed to executing its strategy to bring innovative, fast-acting treatments to the millions of patients worldwide affected by erectile dysfunction.



This announcement has been approved by the Board of Directors.

- ENDS -

About LTR Pharma

LTR Pharma is dedicated to improving men's health—physically and mentally—through the commercialisation of innovative treatments for erectile dysfunction. The Company's lead product, **SPONTAN**[®], delivers a PDE5 inhibitor via a fast-acting intranasal spray, enabling onset of action in 10 minutes or less. This unique delivery method offers men greater control, spontaneity, and confidence, distinguishing SPONTAN from conventional oral therapies.

LTR Pharma is focused on building a global footprint, leveraging regulatory milestones, strategic partnerships, and medical community engagement to address unmet patient needs.

For further information please contact:

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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 2025

Consolidated statement of cash flows		Current quarter \$A	Year to date (9 months) \$A
1. Cash flows from operating activities			
1.1 Receipts from customers		31,400	84,200
1.2 Payments for			
(a) research and development		(719,875)	(1,570,981)
(b) product manufacturing and operating costs			-
(c) advertising and marketing		(176,734)	(522,658)
(d) leased assets			-
(e) staff costs		(394,034)	(878,799)
(f) administration and corporate costs		(204,252)	(1,166,968)
1.3 Dividends received (see note 3)			-
1.4 Interest received		290,835	291,389
1.5 Interest and other costs of finance paid		(429)	(46,125)
1.6 Income taxes paid			-
1.7 Government grants and tax incentives		-	388,178
1.8 Other (provide details if material)			-
1.9 Net cash from / (used in) operating activities		(1,173,089)	(3,421,764)
2. Cash flows from investing activities			
2.1 Payments to acquire or for:			
(a) entities		-	-
(b) businesses		(94,335)	(117,735)
(c) property, plant and equipment		(2,688)	(11,352)
(d) investments		-	-
(e) intellectual property		-	-
(f) other non-current assets		-	-

Consolidated statement of cash flows		Current quarter \$A	Year to date (9 months) \$A
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	(97,024)	(129,088)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	33,246,587
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	-	33,246,587

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	34,066,984	3,101,136
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,173,089)	(3,421,764)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(97,024)	(129,088)

Consolidated statement of cash flows		Current quarter \$A	Year to date (9 months) \$A
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	33,246,587
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	32,796,871	32,796,871

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	32,796,871	34,066,984
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)	32,796,871	34,066,984

6.	Payments to related parties of the entity and their associates	Current quarter \$A
6.1	Aggregate amount of payments to related parties and their associates included in item 1	243,906
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>		

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

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	Amount drawn at quarter end \$A
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
8.1 Net cash from / (used in) operating activities (item 1.9)	(1,173,089)
8.2 Cash and cash equivalents at quarter end (item 4.6)	32,796,871
8.3 Unused finance facilities available at quarter end (item 7.5)	
8.4 Total available funding (item 8.2 + item 8.3)	32,796,871
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	28
<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: 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	
<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.

29 April 2025

Date:

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.