

29 July 2025

# **Quarterly Activities Report & Appendix 4C**

# For the Period Ending 30 June 2025

# Highlights

- **SPONTAN® pharmacy distribution commenced** through the Symbion network.
- **ROXUS® development milestones achieved** with stability testing progressing well, on track for US market launch H1 CY2026.
- **OROFLOW®** collaborative development agreement signed with Strategic Drug Solutions (SDS) for novel intranasal treatment targeting Oesophageal Motility Disorders, addressing the \$4.5 billion global market.
- **Clinical trial protocols finalised** following FDA guidance, with Phase II pharmacokinetic study preparations underway.
- **Clinical capabilities strengthened** with A/Prof. Darren Katz's appointment.

**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<sup>®</sup> and ROXUS<sup>®</sup>, is pleased to provide its Appendix 4C and an overview of its activities for the period ended 30 June 2025 (the "Reporting Period" or the "Quarter").

# Commenting on the activity for the Quarter, Executive Chairman, Lee Rodne, stated:

"This quarter marked a pivotal step for LTR Pharma, with SPONTAN becoming available in nationwide pharmacies under Special Access. We advanced the development of ROXUS for the US personalised healthcare market and initiated our OROFLOW development program, expanding our platform into gastrointestinal disorders. Backed by strong clinical leadership, these milestones reflect the growing recognition of our nasal spray technology and our potential to transform care in high-need therapeutic areas."

# **Corporate & Operational Update**

During the Quarter, LTR Pharma achieved significant milestones across commercial distribution, product development, and clinical advancement.





# **Commercial Distribution Launch**

A significant commercial step was achieved through the start of the Symbion pharmacy distribution network in May 2025:

- Initial pharmacy orders and prescriber feedback have been encouraging, supporting broader market uptake in future quarters.
- Patients can now have SPONTAN prescriptions filled at pharmacies across Symbion's 3,900-location network.
- Pharmacy training programme delivered to pharmacists nationwide on SPONTAN's unique benefits and patient counselling.
- Initial orders received from both metropolitan and regional pharmacies.

# **Clinical Leadership Strengthened**

Distinguished urologist A/Prof. Darren Katz was appointed to the Scientific Advisory Board in May 2025:

- Brings extensive ED treatment expertise as Medical Director of Men's Health Melbourne and Immediate Past Leader of USANZ Andrology Special Advisory Group.
- Appointment strengthens clinical capabilities and prescriber network expansion.

# **ROXUS Development Progress**

The Company advanced ROXUS product development and market entry preparation during the Quarter:

- Development of a scalable, GMP-compliant manufacturing process is being progressed in collaboration with our Australian pharmaceutical partner.
- Key formulation milestones achieved, bringing the product closer to market readiness ahead of the planned US launch in H1 CY2026.
- Manufacturing optimisation underway.

# **Pipeline Expansion – OROFLOW Development**

A strategic milestone was achieved with the signing of a collaborative development agreement with Strategic Drug Solutions (SDS) in May 2025:

- OROFLOW development initiated for Oesophageal Motility Disorders, a debilitating group of conditions affecting swallowing function.
- Programme leverages LTR's proven intranasal delivery platform and patent rights from SPONTAN and ROXUS.
- Targeting rapid symptom relief for patients with swallowing difficulties, potentially offering a non-invasive alternative to current treatments.
- Addresses a \$4.5 billion global market projected to reach \$8.1 billion by 2034.1
- Proof-of-Concept testing preparations underway.





# **Clinical Programme Advancement**

Following guidance from the FDA pre-IND meeting, the Company progressed its clinical development during the Quarter:

- LTR Pharma has selected experienced Clinical Research Organisations (CROs) and clinical sites for its Phase II pharmacokinetic study.
- Patient enrolment expected in Q1 CY2026.

#### **Financial Update**

LTR Pharma maintained a robust financial position during the Quarter, with a strong cash balance of \$31.8 million as at 30 June 2025, providing substantial runway to execute strategic objectives across multiple markets.

The Company's disciplined capital allocation during the Period focused on advancing key development programmes and commercial initiatives. Research and development activities represented a key investment area, with approximately \$1.0 million directed towards the programme.

The Company received R&D tax incentives totalling \$1.0 million during the Quarter. Interest income of \$0.3 million further contributed to the Company's financial position, reflecting prudent cash management.

Receipts of \$30,000 represent SPONTAN prescriptions under the TGA's Special Access Scheme (SAS), which provides controlled access for patients with unmet medical needs, particularly those who have unsatisfactory outcomes with PDE5 inhibitors such as Viagra (sildenafil) or Cialis (tadalafil). These early-stage receipts are consistent with typical pre-commercial biotech pathways.

Feedback from prescribers accessing SPONTAN through the SAS has been encouraging, with reports that the product is delivering meaningful therapeutic benefit and addressing a significant clinical gap. The Company is collecting these prescriber insights to help define its commercial rollout strategy once fully approved.

LTR Pharma maintained a disciplined burn rate, with net operating outflows of \$0.9 million in the quarter. With \$31.8 million in cash, the Company is well-capitalised to execute on clinical and commercial milestones.

As disclosed on <u>29 April 2025</u>, all expenditure outlined in the LTR Pharma Limited IPO has now been completed.

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\$132,406 and included Director fees, salary, and superannuation for the Executive Chairman and Non-Executive Directors.

The Company's solid financial position provides confidence in executing its planned activities, including the completion of ROXUS development, commencement of clinical trials, progression of OROFLOW development, and continued commercial expansion of SPONTAN through pharmacy networks.





# **Looking Ahead**

Building on the progress achieved during the quarter, LTR Pharma is focused on several key priorities for the remainder of 2025:

#### **US Market Preparation**

- Complete ROXUS development and prepare for launch through personalised healthcare channels with first sales in the H1 CY2026.
- Finalise regulatory compliance for streamlined market access and establish commercial infrastructure.

#### **Commercial Expansion**

- Continue supporting SPONTAN availability through Symbion, Restorative Health Clinics Joint Venture, Men's Health Down Under, plus additional pharmacy networks.
- Continue regulatory planning for SPONTAN's transition from Special Access Scheme to wider patient access.

#### **SPONTAN Clinical Development**

• Commence the Phase II pharmacokinetic study with patient enrolment in Q1 CY2026.

#### **EU Market Preparation**

• Initiate regulatory engagement with the European Medicines Agency (EMA) in H2 CY2025, including a planned scientific advice meeting to define the regulatory and market access pathway for SPONTAN in the European Union.

#### **Pipeline Advancement**

• Continue to pursue expansion of the nasal spray platform into new therapeutic indications through pipeline evaluation and preclinical research.

The Company remains committed to transforming the treatment landscape for erectile dysfunction through innovative, fast-acting nasal spray solutions that address significant unmet medical needs across multiple therapeutic areas.

#### This announcement has been approved by the Board of Directors.

#### - ENDS –

<sup>1</sup> Fact.MR. "Ineffective Oesophageal Motility Treatment Market Analysis 2034." Fact.MR, 2024.





## **About LTR Pharma**

**LTR Pharma** is an emerging pharmaceutical company committed to developing and commercialising innovative therapies that address significant unmet medical needs. The Company is leveraging its proprietary intranasal drug delivery platform to enable rapid, non-invasive treatment options across multiple therapeutic areas.

LTR's lead products, **SPONTAN**<sup>®</sup> and **ROXUS**<sup>®</sup>, are fast-acting intranasal sprays for the treatment of erectile dysfunction, enabling onset of action in 10 minutes or less. Building on this proven technology, the Company is now advancing **OROFLOW**<sup>®</sup>, a novel intranasal spray under development for the treatment of Oesophageal Motility Disorders (OMD) – a debilitating group of conditions affecting swallowing function.

Through strategic partnerships, LTR Pharma is expanding its pipeline and global footprint to deliver differentiated, patient-centric treatments that enhance quality of life.

Stay informed with LTR Pharma's latest announcements and market updates-visit our Investor Centre.

#### 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 ("curre	nt quarter")
64 644 924 569	June 2025	
Consolidated statement of cash flows	Current quarter \$A	Year to date (12 months) \$A

			\$A
1.	Cash flows from operating activities		
1.1	Receipts from customers	30,000	114,200
1.2	Payments for		
	(a) research and development	(965,824)	(2,536,805)
	(b) product manufacturing and operating costs		-
	(c) advertising and marketing	(207,886)	(730,545)
	(d) leased assets		-
	(e) staff costs	(653,713)	(1,532,511)
	(f) administration and corporate costs	(350,852)	(1,517,820)
1.3	Dividends received (see note 3)		-
1.4	Interest received	303,833	595,221
1.5	Interest and other costs of finance paid	(241)	(46,366)
1.6	Income taxes paid		-
1.7	Government grants and tax incentives	974,445	1,362,623
1.8	Other (provide details if material)		-
1.9	Net cash from / (used in) operating activities	(870,238)	(4,292,002)

2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	(80,000)	(197,735)
	(c) property, plant and equipment	(1,817)	(13,169)
	(d) investments	-	-

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

Con	solidated statement of cash flows	Current quarter \$A	Year to date (12 months) \$A
	(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	(81,817)	(210,905)

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

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

Con	solidated statement of cash flows	Current quarter \$A	Year to date (12 months) \$A
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	32,796,871	3,101,136
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(870,238)	(4,292,002)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(81,817)	(210,905)
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	31,844,816	31,844,816

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	31,844,816	32,796,871
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)	31,844,816	32,796,871

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	132,406
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
	any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a de ion for, such payments.	escription of, and an

#### Appendix 4C

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

7.	FinancingfacilitiesNote: 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	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 qua	arter end	-
7.6	Include in the box below a description of each rate, maturity date and whether it is secured of facilities have been entered into or are proposi include a note providing details of those facilities	or unsecured. If any add sed to be entered into af	itional financing

8.	Estimated cash available for future operating activities	\$A
8.1	Net cash from / (used in) operating activities (item 1.9)	(870,238)
8.2	Cash and cash equivalents at quarter end (item 4.6)	31,844,816
8.3	Unused finance facilities available at quarter end (item 7.5)	
8.4	Total available funding (item 8.2 + item 8.3)	31,844,816
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	37

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?

8.6.2	Has the entity taken any steps, or does it propose to take any steps, to raise furthe cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?
Answe	•

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.

29 July 2025

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.