

# LTR Pharma Advances Multi-Market Strategy with FDA Milestone and Roxus<sup>®</sup> Launch Pathway

## Commercial Update and Regulatory Progress

26 March 2025

### Highlights

- FDA provides clearly defined path to approval for SPONTAN<sup>®</sup> following pre-IND meeting
- LTR to launch new product Roxus<sup>®</sup> to accelerate US market entry via personalised healthcare
- Strong prescriber growth in Australia demonstrates increasing clinical adoption
- Distribution expanding via pharmacy and telehealth partnerships
- SPONTAN<sup>®</sup> receives scientific acclaim for 470% faster absorption vs. oral tablet
- Investor Webinar to be held on Thursday 27 March 2025 at 10:30 am AEDT / 7:30 am AWST

LTR Pharma Limited (ASX:LTP) (“LTR Pharma” or “the Company”) is pleased to provide an update on its regulatory and commercial progress across multiple markets for SPONTAN<sup>®</sup>, its innovative intranasal spray for erectile dysfunction (ED).

### Regulatory Milestone Achieved: FDA Pre-IND Meeting

LTR Pharma has completed a successful pre-Investigational New Drug (pre-IND) meeting with the US Food and Drug Administration (FDA), marking a critical step in the SPONTAN development program. The FDA broadly endorsed LTR's non-clinical (toxicology) and CMC (Chemistry, Manufacturing and Controls) development plans.

The meeting resulted in alignment on a streamlined clinical development path, including one pivotal safety and efficacy trial and a multi-dose pharmacokinetic (PK) study which will reinforce SPONTAN's labelling and commercial positioning providing LTR with a clear guideline to gain approval in the US.

LTR Pharma's experienced team will work closely with Aptar Pharma and other CROs to leverage their extensive expertise and established FDA relationships to efficiently complete the required studies ahead of the planned New Drug Application (NDA) submission.

The team also plans to investigate the ability to use additional clinical trial data for the US with other regulatory submissions in key global markets.

### Accelerating U.S. Market Entry with Roxus<sup>®</sup>

LTR Pharma is advancing a dual-track US market strategy with the introduction of our new product, Roxus<sup>®</sup>, a vardenafil-based nasal spray targeting the growing personalised healthcare sector. Roxus will be delivered via the

503(a)-compounding pharmacy pathway, part of the broader US compounding pharmacy market—currently valued at over US\$6 billion and projected to reach US\$10 billion by 2033.\*

This strategic initiative enables early market entry while SPONTAN progresses through FDA approval. Roxus is being developed with a pharmaceutical partner in Australia, with testing underway to establish stability and shelf-life. Completion is expected in the coming two quarters, with a potential US release in the first half of 2026CY.

This approach provides LTR with valuable patient and prescriber insights, informs pricing strategy, and builds early commercial traction in the world's largest healthcare market.

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### Australian Market Expansion

LTR continues to experience strong clinical outcomes in Australia under the country's early access schemes. The number of prescribers under the **Special Access Scheme (SAS)** and **Authorised Prescriber Scheme (APS)** continues to grow, highlighting clinical enthusiasm for SPONTAN as a differentiated treatment option.

The Company's joint venture with **Restorative Sexual Health Clinic (RSHC)** launched its online telehealth platform in December 2024. Patient satisfaction and treatment success have been highly positive, further validating SPONTAN's value in the market.

Additionally, LTR has commenced collaboration with **Men's Health Downunder**, Australia's largest men's health pharmacy network, where active prescribing is now underway. The Company is also preparing for broader pharmacy distribution through **Symbion's** national pharmacy network, expected to begin in Q2 CY25.

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### Scientific Recognition at USANZ

SPONTAN received prominent attention at the **Urological Society of Australia and New Zealand (USANZ)** Annual Scientific Meeting. **Chief Scientific and Clinical Adviser Professor Eric Chung** was awarded the **BAUS Trophy**—the event's highest honour—for his presentation showcasing SPONTAN's breakthrough clinical results.

The data revealed that SPONTAN achieves **470% faster absorption** than traditional oral ED tablets. The recognition by an independent panel of experts underscores the growing acceptance of nasal delivery technology in urology.

LTR is now collaborating with leading clinicians to publish real-world case series in peer-reviewed journals, highlighting the safety, efficacy, and clinical utility of SPONTAN in routine care settings.

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### Leadership Commentary

**LTR Pharma Executive Chairman, Lee Rodne, said:**

*"Our positive FDA pre-IND meeting has provided regulatory clarity while unlocking immediate and mid-term commercial opportunities in the US. As SPONTAN moves through the formal FDA process, Roxus offers a fast-track pathway to serve patients through personalised care channels."*

*“Nearly 50% of men discontinue oral ED medications due to lack of personalisation. Our approach focuses on clinical collaboration, not just convenience. By empowering healthcare professionals to guide treatment, we offer patients a holistic experience grounded in real care.*

*“The response to SPONTAN, both clinically and scientifically, affirms the value of our innovative delivery method. We’re building a robust, multi-market commercial model that maximises short-term returns and long-term potential. First US sales are targeted for early 2026, with a strong foundation already in place.”*

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## Looking Ahead

LTR anticipates a pre-submission meeting with Australia’s **Therapeutic Goods Administration (TGA)** in Q2 CY25. The Company will continue to update the market on regulatory progress, prescriber growth, and strategic partnerships as it advances SPONTAN toward commercialisation across global markets.

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

## Investor Webinar

LTR is pleased to invite shareholders and investors to attend a webinar where Executive Chairman, Lee Rodne will provide a Company update and engage in a Q&A session. The webinar will be hosted via Zoom on Thursday, 27 March 2025, at 10:30 am AEDT / 7:30 am AWST.

### Details of the event are as follows:

**Event:** LTR Pharma Limited Investor Webinar

**Date and Time:** Thursday 27 March 2025, 10:30 am AEDT / 7:30 am AWST

**Where:** Zoom Webinar – details to be provided upon registration

To register your interest for the webinar please click through to the link below:

[https://janemorganmanagement-au.zoom.us/webinar/register/WN\\_6z1q3Ta7SX2FdJZY93QSw](https://janemorganmanagement-au.zoom.us/webinar/register/WN_6z1q3Ta7SX2FdJZY93QSw)

After registering your interest, you will receive a confirmation email with information about joining the webinar. Participants will be able to submit questions via the panel throughout the presentation, however we encourage shareholders and investors to send through questions via email beforehand to:

[jm@janemorganmanagement.com.au](mailto:jm@janemorganmanagement.com.au)

- ENDS -

This announcement has been approved by the Board of Directors.

## 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.

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