

SPONTAN® Strengthens Commercial Position with 18-Month Shelf Life Achievement

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Highlights

- SPONTAN® achieves 18-month shelf life under ICH conditions, surpassing current commercial distribution requirements.
- Confirms commercial-scale manufacturing and distribution capabilities across Australia.
- Supports strategic discussions with leading pharmaceutical partners.
- Ongoing stability studies provide a clear regulatory pathway for further shelf-life extensions.

LTR Pharma Limited (ASX:LTP) (“LTR Pharma” or “the Company”) today announced that SPONTAN® has achieved an 18-month shelf life under international pharmaceutical stability standards, a key milestone that strengthens the product's commercial potential in the global erectile dysfunction market, forecast to reach US\$6.0 billion by 2028¹.

This achievement demonstrates the robustness of SPONTAN's formulation, delivery device, and packaging system under standard storage conditions. The 18-month shelf life exceeds current requirements for the Company's growing Australian pharmacy network and provides the stability foundation essential for international market entry and partnership discussions.

Technical and Competitive Significance

Achieving extended shelf life is a major technical milestone for a liquid nasal spray formulation. Unlike oral PDE5 tablets (e.g., Viagra, Cialis), liquid formulations must maintain active ingredient stability in solution whilst ensuring consistent device performance throughout the shelf life. SPONTAN has demonstrated both chemical stability and device reliability across the full 18 months under [International Council for Harmonisation](#) (ICH) conditions.

This stability data strengthens SPONTAN's Chemistry, Manufacturing, and Controls (CMC) package, an essential component for regulatory submissions in the US, Europe and Asia. It positions SPONTAN competitively against oral PDE5 inhibitors while preserving its key advantage – rapid onset of action within 10 minutes compared to 60+ minutes for tablets.

Regulatory and Commercial Pathway

LTR Pharma's ongoing stability program will continue through 24 months and beyond, with interim data potentially supporting further shelf-life extensions. Under established regulatory guidelines, manufacturers can extend expiry dates as new stability data becomes available, creating additional commercial flexibility.

LTR Pharma Executive Chairman, Lee Rodne, said:

"This 18-month stability achievement marks a pivotal step in SPONTAN's global commercial journey. We have proven that our innovative intranasal formulation can meet international distribution standards. This milestone validates our manufacturing strength and positions SPONTAN as a commercially viable alternative to traditional ED treatments. With our Australian footprint expanding and a stability profile that meets global expectations, we are on track to transform ED treatment worldwide."

¹Source: Frost and Sullivan Report, The Erectile Dysfunction Medicines Market, September 2023.

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This announcement has been approved by the Board of Directors.

About LTR Pharma

LTR Pharma is a commercial-stage pharmaceutical company delivering innovative therapies for significant unmet medical needs through its proprietary intranasal drug delivery platform. The Company has successfully commercialised its rapid-acting treatment technology in Australia and is expanding access whilst advancing regulatory pathways in the US and other key markets.

LTR Pharma's lead products, SPONTAN[®] and ROXUS[®], 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[®], 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.

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