

LTR Pharma 2025 Full-Year Results

29 August 2025

Highlights:

- SPONTAN[®] achieved 470% faster absorption rate than oral vardenafil tablets, with time-to-peak concentration in as little as 9 minutes.
- Successfully commenced patient treatment under TGA early access schemes with growing prescriber network.
- Secured global Co-Development Agreement with Aptar Pharma to support FDA regulatory pathway.
- Expanded product development portfolio with ROXUS[®] targeting US personalised medicine market and OROFLOW[®] for oesophageal motility disorders.
- Established national distribution through Symbion and agreement with Men's Health Downunder.
- As of 30 June 2025, the Company held a cash balance of \$31.8 million.

LTR Pharma Limited (ASX:LTP) ("LTR Pharma", "the Company") is pleased to provide an update on its full-year results for the year ended 30 June 2025 (FY25). During FY25, LTR Pharma achieved significant clinical and commercial milestones, establishing multiple pathways to market while advancing its proprietary nasal spray platform across an expanded therapeutic portfolio.

Financial Highlights

As of 30 June 2025, the Company maintained a robust cash balance of \$31.8 million, providing sufficient cash reserves to support key regulatory milestones and commercial initiatives through FY26. Total revenue and other income increased to \$2.1 million (FY24: \$49,331), primarily driven by R&D tax incentive receipts of \$1.4 million.

The Company's expenditure remained aligned with projections, with the loss after tax improving to \$5.6 million (FY24: \$7.0 million), reflecting disciplined cost management while advancing multiple development programmes.

Operational Highlights

Clinical

In October 2024, LTR Pharma announced final results from its pivotal pharmacokinetic study of SPONTAN[®], confirming 470% faster absorption compared to oral vardenafil tablets, with peak concentration (Tmax) achieved in a mean time of 12 minutes (range 9-15 minutes) versus 56 minutes for oral tablets. The study demonstrated comparable efficacy at half the oral dose (5mg vs 10mg) with a favourable safety profile and no serious adverse events.

In June 2025, the Company completed the extractables study for SPONTAN, a critical safety and compliance milestone required for the Food and Drug Administration (FDA) 505(b)(2) regulatory submission. Conducted in partnership with Aptar Pharma, the study confirmed all compounds were within safe thresholds, keeping the FDA submission timeline on track with the leachables phase now underway.

Market Access Achievements

The Company successfully initiated patient treatment under Australia's Therapeutic Goods Administration (TGA) Special Access Scheme (SAS) and Authorised Prescriber Scheme (APS). Prescriptions are now being fulfilled through our partnership with Men's Health Downunder, Australia's largest men's health pharmacy, and our national distribution agreement with Symbion covering 3,900+ pharmacies, including TerryWhite Chemmart's 600-pharmacy network. Additionally, we have established a joint venture with Restorative Health Clinic for the telehealth platform [MakeHardEasy.com.au](https://www.MakeHardEasy.com.au).

Strategic Partnerships

The global Co-Development Agreement with Aptar Pharma provides critical support for FDA 505(b)(2) regulatory submission, including access to VP7 nasal spray system expertise and specialised analytical services. This partnership significantly de-risks the US regulatory pathway while accelerating time to market.

Development Portfolio Expansion

LTR Pharma strategically expanded its nasal spray platform with ROXUS[®], targeting the US\$6+ billion personalised medicine market¹, and OROFLOW[®], addressing the US\$8.1 billion oesophageal motility disorders market² through collaboration with Strategic Drug Solutions.

Matters Subsequent to the end of the financial year

No matter or circumstance has arisen since the end of the financial period and the date of this report that has significantly affected, or may significantly affect the Company's operations, the results of those operations, or the Company's state of affairs in future financial years.

LTR Pharma Chairman, Lee Rodne said: *"The 2025 financial year has been transformative for LTR Pharma, marked by exceptional clinical validation of SPONTAN and the establishment of comprehensive distribution networks. The 470% faster absorption rate demonstrated by SPONTAN represents a paradigm shift in ED treatment, offering men the spontaneity they desire. Our expanded portfolio with ROXUS and OROFLOW, combined with strategic partnerships like Aptar Pharma, positions us to capture significant value across multiple high-growth markets. I thank our shareholders, clinical partners, and the growing number of patients benefiting from our innovations for their continued support as we advance toward global commercialisation."*

¹ Source: Nova1Advisor. Compounding Pharmacies Market Size, Share & Trends Analysis

² Source: Fact.MR. "Ineffective Oesophageal Motility Treatment Market Analysis | 2034." Fact.MR, 2024.

-Ends-

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'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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