LTR Pharma 2026 Full-Year Results

28 August 2026

Highlights

- **Strong balance sheet maintained,** with A$19.7 million in cash and no debt at 30 June 2026.
- **US commercial pathway established for ROXUS®,** with definitive agreements executed with Shed Holdings and Strive Pharmacy following year-end, completing the two commercial pillars required for the planned US launch.
- **SPONTAN® Phase II programme advanced the FDA pathway,** with interim data demonstrating median time to peak plasma concentration of approximately 10 minutes for a 5 mg intranasal dose compared with approximately 60 minutes for 20 mg oral vardenafil.
- **Phase II recruitment completed,** including participants aged 65 years and over, addressing an important FDA Pre-IND requirement, with no evidence of drug accumulation and no serious or severe treatment-emergent adverse events reported in the interim analysis.
- **More than 1,000 SPONTAN prescriptions issued in Australia** through the TGA Special Access Scheme and Authorised Prescriber pathways, supported by repeat prescribing and a growing prescriber base.
- **OROFLOW® received ethics approval for its first clinical study,** extending LTR Pharma's intranasal platform beyond erectile dysfunction into oesophageal motility disorders.

LTR Pharma Limited (ASX:LTP) ("LTR Pharma" or "the **Company")** is pleased to provide its full-year results for the year ended 30 June 2026 ("FY26").

FY26 marked an important transition for LTR Pharma from clinical development towards commercial execution. During the year, the Company advanced SPONTAN® through Phase II development, expanded its Australian real-world prescribing footprint, established a contracted commercial pathway for ROXUS® in the United States and progressed the first clinical programme extending its intranasal platform beyond erectile dysfunction.

Financial Highlights

LTR Pharma ended FY26 with **A$19.7 million in cash and no debt,** compared with A$31.8 million at 30 June 2025.

Net operating cash outflow for the year was approximately **A$10.8 million,** reflecting increased investment across clinical development, regulatory activities and preparation for commercial execution. Research and development expenditure increased to approximately **A$6.7 million,** with a significant proportion directed towards the SPONTAN Phase II programme and related development activities.

Revenue and other income for FY26 was approximately **A$1.6 million,** compared with A$2.1 million in FY25. The reduction primarily reflected a lower Research and Development Tax Incentive rebate as a greater proportion of development expenditure was incurred outside Australia and was therefore not eligible for the Australian R&D Tax Incentive.

The statutory loss after tax for FY26 was approximately **A$14.2 million,** compared with A$5.6 million in FY25. The FY26 result included approximately **A$3.1 million of non-cash share-based payment expense** as well as equity-accounting and impairment impacts associated with the Company's investments in associates.

Operational Highlights

SPONTAN Phase II Advances FDA Development Pathway

LTR Pharma completed recruitment in its Phase II pharmacokinetic and multiple-dose study during FY26, enrolling 27 healthy adult males, including 14 participants aged 65 years or older.

Interim results demonstrated a median time to peak plasma concentration of approximately 10 minutes for 5 mg intranasal SPONTAN, compared with approximately 60 minutes for a 20 mg oral vardenafil tablet. Pharmacokinetic profiles in the older cohort were comparable with the broader adult cohort, with no evidence of drug accumulation following repeat dosing and no serious or severe treatment-emergent adverse events reported.

The results address important elements of the FDA's Pre-IND feedback and support continued advancement of SPONTAN through the 505(b)(2) development pathway.

Growing Australian Real-World Use

SPONTAN continued to expand its real-world footprint in Australia during FY26, with **more than 1,000 prescriptions issued** through the Therapeutic Goods Administration's Special Access Scheme and Authorised Prescriber pathways.

The growing prescribing base, together with repeat prescribing and emerging real-world evidence, continues to build practical experience among clinicians and patients while supporting LTR Pharma's future regulatory, commercial and market-access activities.

Australian distribution continued through Symbion's national network of more than 3,900 pharmacies, including more than 600 TerryWhite Chemmart pharmacies.

ROXUS US Commercial Pathway Established

During FY26, LTR Pharma converted its ROXUS US commercial strategy into a contracted commercial framework.

In June 2026, the Company entered into binding term sheets with:

- **Shed Holdings,** providing for exclusive direct-to-consumer telehealth distribution of ROXUS through its Shed and Mavrox platforms, including a commitment to support delivery of not less than 150,000 ROXUS prescription units during the first 12 months following Commercial Launch; and
- **Strive Pharmacy,** providing for exclusive US Section 503A pharmacy fulfilment for ROXUS.

Under the model, LTR Pharma retains ownership of the ROXUS brand, associated intellectual property and product supply, while specialist partners provide patient acquisition, prescribing, compounding and fulfilment infrastructure.

The structure is designed to provide LTR Pharma with a capital-efficient pathway into the United States while SPONTAN continues through the FDA regulatory pathway.

OROFLOW Extends Intranasal Platform Beyond ED

In June 2026, the South Eastern Sydney Local Health District Human Research Ethics Committee approved the first investigator-initiated pilot study of OROFLOW®.

OROFLOW is being developed as an intranasal treatment for oesophageal motility disorders and represents the first clinical evaluation of LTR Pharma's intranasal platform outside erectile dysfunction.

The study is designed and led independently by Dr Peter Wu, Director of St George Motility Services at St George Hospital, and is funded through a research grant from LTR Pharma.

The programme provides an opportunity to evaluate whether the Company's formulation and intranasal drug-delivery expertise can be applied to other established medicines where rapid, predictable or tablet-free administration may provide meaningful clinical benefit.

Matters Subsequent to the End of the Financial Year

Following the end of FY26, LTR Pharma completed the two commercial pillars required for its planned US launch of ROXUS.

On **17 July 2026,** the Company executed a definitive Telehealth Distribution Agreement with Shed Holdings LLC, converting the binding term sheet announced on 9 June 2026 into a long-form commercial agreement.

On **20 July 2026,** LTR Pharma executed a definitive Compounding and Supply Agreement with Strive Specialties Inc. (Strive Pharmacy), covering the manufacture, compounding, fulfilment and supply of ROXUS in the United States.

In August 2026, the Company also reported real-world outcomes from 147 Australian SPONTAN patients, providing further evidence of treatment outcomes across a broad ED population, including men with prior inadequate response to oral PDE5 inhibitors and post-prostatectomy patients.

LTR Pharma is now focused on completing technology transfer, manufacturing readiness and the remaining operational and regulatory activities required for Commercial Launch, targeted for the second half of calendar year 2026 subject to completion of those activities and applicable regulatory requirements.

FY27 Outlook

LTR Pharma enters FY27 with a strong balance sheet and a milestone-driven strategy focused on commercial execution and late-stage clinical development.

The Company's priorities are to:

- execute the planned US commercial launch pathway for ROXUS;
- complete the full statistical analysis of the SPONTAN Phase II programme;
- progress non-clinical toxicology, human-factors and Phase III planning for SPONTAN;
- continue expanding SPONTAN awareness and adoption in Australia; and
- generate initial clinical evidence for OROFLOW.

LTR Pharma will also continue to evaluate additional indications and strategic partnerships capable of leveraging its proprietary intranasal drug-delivery platform.

LTR Pharma Executive Chairman Lee Rodne said:

"FY26 was a significant year in LTR Pharma's transition from clinical development towards commercial execution.

We strengthened the clinical evidence supporting SPONTAN, expanded its real-world footprint in Australia and established the commercial pathway for ROXUS in the United States.

Importantly, we enter FY27 with a strong balance sheet, no debt and clear value-driving milestones ahead of us. Our focus is now firmly on execution — progressing the planned US launch of ROXUS, advancing SPONTAN towards Phase III and through the FDA regulatory pathway, and continuing to demonstrate the broader potential of our intranasal platform.

I would like to thank our shareholders, clinicians, employees and commercial partners for their continued support as we move into this next stage of LTR Pharma's development."

- ENDS –

This announcement has been approved by the Board of Directors.

About LTR Pharma

LTR Pharma is a commercial-stage pharmaceutical company developing and commercialising innovative therapies to address significant unmet medical needs. The Company's lead programs utilise its proprietary intranasal technology 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 being developed to address the limitations of conventional oral erectile dysfunction treatments through rapid and predictable drug absorption. 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.

LTR Pharma Investor Centre

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