ROXUS® U.S. Commercial Rollout Reaches 500 Bottles Fulfilled Across 43 States in Initial Commercial Phase

23 November 2026

Highlights

- **500+ ROXUS® bottles fulfilled** since U.S. commercial launch on 5 October 2026.
- **ROXUS bottles fulfilled across 43 U.S. states,** demonstrating the broad geographic reach and licensure of the partner network.
- **First U.S. ROXUS revenue received,** with prescribing, fulfilment, invoicing and payment infrastructure now operational.
- **Healthcare professional and direct-to-clinic channel now opening,** with electronic prescribing connectivity through Surescripts and initial prescribing by U.S. specialists, including Scientific Advisory Board members Dr Amy Pearlman and Dr Andrew Sun.
- **Early patient feedback includes reports of rapid onset and positive treatment experiences,** with Australian specialist prescribing experience being applied to first-use education and administration guidance in the U.S.
- **ROXUS is in its initial commercial phase,** with marketing activity and prescribing channels being developed progressively as LTR and its partners assess patient experience, retention and repeat activity.

LTR Pharma Limited (ASX: LTP) ("LTR Pharma" or "the Company") is pleased to announce that more than 500 ROXUS® bottles have been fulfilled across 43 U.S. states since commercial launch on 5 October 2026. ROXUS is LTR Pharma's intranasal vardenafil formulation, made available through its U.S. commercial partners under the patient-specific 503A pathway.

LTR Pharma Executive Chairman, Lee Rodne, said:

"Reaching more than 500 bottles is an encouraging early milestone and, importantly, the initial U.S. rollout is giving us valuable insight into demand, treatment response and the patient experience. Early feedback includes patients reporting rapid onset and positive treatment experiences. The initial rollout has also reinforced the importance of first-use education and administration guidance, consistent with our experience in Australia.

We are working closely with Shed and Strive to apply these learnings to patient education, onboarding and provider support in the U.S. before progressively scaling commercial activity.

Our focus at this stage is establishing the patient experience, retention and prescribing pathways required to support sustainable broader adoption."

Early U.S. commercial activity

ROXUS prescriptions are fulfilled through LTR Pharma's U.S. commercial relationships with Shed, including Mavrox, Shed's men's health telehealth platform, and Strive Pharmacy. Pharmacies operating under Section 503A are licensed state by state, so fulfilment across 43 states as at 20 November 2026 reflects both the reach of the telehealth channel and the licensure of Strive Pharmacy.

LTR has invoiced Strive Pharmacy and received payment for October, its first ROXUS revenue in the United States. With prescribing, fulfilment, invoicing and payment now operating, the commercial infrastructure for the rollout is in place.

Initial commercial phase

ROXUS is in the initial phase of its U.S. commercial rollout, which is being sequenced in stages. Shed is leading digital patient acquisition through an initial testing and optimisation phase, including testing marketing creative and assessing patient experience, retention and repeat activity to inform broader scaling of marketing activity. The healthcare professional channel is also in its early stages.

As ROXUS is an on-demand treatment, patient usage and reorder timing will vary, and repeat purchasing and retention trends will become clearer as the initial cohorts mature.

Patient experience and education

Early patient feedback from the U.S. rollout includes reports of rapid onset and positive treatment experiences. Some patients have reported transient nasal irritation or sneezing following administration, local effects that are recognised with intranasal medicines and are generally short-lived. LTR and its U.S. partners are applying Australian prescribing experience to first-use education and administration guidance to help patients know what to expect.

Melissa Hadley Barrett is the leading prescriber of SPONTAN under the TGA Special Access Scheme in Australia.

Nurse Practitioner and Sexologist, Melissa Hadley Barrett, said:

"In our Australian clinical experience, preparing patients for what to expect with an intranasal treatment and providing appropriate administration guidance can make an important difference to the overall treatment experience.

Some men experience temporary nasal irritation or sneezing, particularly during initial use. For many patients these effects diminish or resolve with regular use, and appropriate counselling helps patients understand what to expect while assessing the benefits of the rapid-acting intranasal treatment.

Simple administration techniques, including briefly pinching the nostrils after administration, can also help some patients."

Expanding healthcare professional access

Alongside Shed's telehealth channel, LTR is developing a separate healthcare professional and direct-to-clinic channel, in which clinics prescribe ROXUS for eligible patients and Strive Pharmacy fulfils the patient-specific prescriptions.

Work to enable ROXUS within established electronic prescribing workflows has progressed, including connectivity through Surescripts, the most widely used U.S. electronic prescribing network, used by 1.39 million prescribers and 98.3% of U.S. pharmacies.[1] This integration provides a more streamlined prescribing and fulfilment pathway for clinics participating in the ROXUS rollout.

LTR is initially focusing direct-to-clinic development on specialist men's health, urology and sexual medicine practices with established erectile dysfunction patient populations. Initial prescribing has commenced through a small number of clinics, including by two members of LTR Pharma's Scientific Advisory Board: Dr Amy Pearlman, co-founder of Prime Institute in Miami, and Dr Andrew Sun, Director of Men's Health at Urology Partners of North Texas.

LTR is also continuing clinician education following the October 2026 Sexual Medicine Society of North America meeting, where the Company engaged with U.S. specialists regarding intranasal PDE5 therapy, administration and Australian real-world experience.

Intranasal platform and FDA pathway

ROXUS is based on LTR Pharma's intranasal vardenafil technology. In the Company's Phase II study, SPONTAN 5 mg reached peak blood concentration in a median of 10 minutes, compared with 60 minutes for the 20 mg oral vardenafil tablet.

ROXUS commercial activity under the patient-specific 503A pathway is separate from LTR Pharma's FDA 505(b)(2) development program for SPONTAN, for which preparations for the planned pivotal Phase III program continue.

LTR will update shareholders as further commercial milestones are achieved.

About ROXUS

ROXUS is a compounded intranasal vardenafil formulation prepared for identified individual patient needs pursuant to valid prescriptions through appropriately licensed U.S. pharmacy arrangements.

ROXUS has not been reviewed or approved by the U.S. Food and Drug Administration for safety or efficacy.

- ENDS -

This announcement has been approved by the Board of Directors.

[1] Surescripts, "The health intelligence platform behind virtually every prescription", surescripts.com, 2026. At the end of 2025, 1.39 million prescribers and 98.3% of pharmacies were actively using Surescripts E-Prescribing.

About LTR Pharma

LTR Pharma is a commercial-stage pharmaceutical company delivering innovative therapies to address significant unmet medical needs through its proprietary rapid-acting intranasal platform. The Company has commenced commercial access to its rapid-acting treatment technology in Australia through the Special Access Scheme (SAS) and Authorised Prescriber Scheme (APS), and in the United States through the patient-specific 503A pathway, while continuing to advance regulatory pathways in the U.S. 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®**, an intranasal therapy under development for the treatment of Oesophageal Motility Disorders (OMD), and investigator-initiated clinical evaluation of intranasal PDE5 therapy in pulmonary arterial hypertension (PAH).

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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