LTR Pharma Expands Men's Health Platform Through Exclusive KYZATREX® Pilot Commercialisation Agreement in Australia

1 September 2026

Highlights

- Exclusive pilot agreement executed with Marius Pharmaceuticals, Inc. ("Marius") for KYZATREX®, an FDA-approved oral testosterone therapy commercially available in the U.S.
- Broadens LTR Pharma's Australian men's health portfolio with a complementary therapy that can leverage the prescriber base, telehealth channels and distribution infrastructure already established for SPONTAN®.
- Initial stock now in Australia, with initial patient access to be facilitated through the TGA Special Access Scheme (SAS).
- LTR Pharma and Marius will evaluate physician adoption, patient demand and a potential TGA registration pathway during the pilot.
- LTR Pharma holds a right to negotiate an exclusive Australian licensing agreement following the evaluation period.

LTR Pharma Limited (ASX:LTP) ("LTR Pharma" or "the Company") has entered into an exclusive pilot commercialisation agreement with Marius Pharmaceuticals, Inc. ("Marius"), a US pharmaceutical company focused on men's health, to introduce Marius' lead product, KYZATREX® (testosterone undecanoate oral capsules), in Australia. KYZATREX is FDA-approved and commercially available in the United States. Initial stock has now arrived in Australia, with initial patient access to be facilitated through the TGA Special Access Scheme (SAS).

Strategic Rationale

Testosterone deficiency affects energy, mood, muscle mass, bone density and sexual function. It remains underdiagnosed and undertreated in Australia, where most replacement therapy is delivered by injection, gel, patch or implant.

KYZATREX uses a proprietary formulation designed to facilitate lymphatic absorption, reducing the first-pass hepatic metabolism associated with earlier oral testosterone therapies, and is supported by clinical data demonstrating its ability to restore testosterone levels in men with testosterone deficiency.

Testosterone deficiency and erectile dysfunction can present within the same men's health consultation and involve overlapping prescribers and patient-access channels. KYZATREX therefore represents a complementary opportunity for LTR Pharma to broaden its Australian men's health portfolio while leveraging the clinical networks, telehealth channels and distribution infrastructure already established through SPONTAN®.

This strategy is being pursued alongside continued execution of LTR Pharma's core ED programs, including preparations for the U.S. commercial launch of ROXUS® and planning for the pivotal SPONTAN Phase III study.

Shared Clinical Advisers

The two companies are already connected through clinical advisers. Dr Andrew Y. Sun, M.D. and Dr Amy Pearlman, M.D. each serve on LTR Pharma's Scientific Advisory Board (see ASX announcements dated 11 and 18 August 2025) and on Marius' urology advisory board.

Commercial Structure and Regulatory Status

The agreement establishes an initial exclusive pilot commercialisation phase in Australia, supported by an inventory commitment sized to establish prescriber demand and operational processes. The agreement is not expected to materially affect the Company's financial position.

During the six-month evaluation period, LTR Pharma will retain exclusivity in Australia while the parties evaluate physician adoption, patient demand and the feasibility of pursuing a potential TGA registration pathway.

Following the evaluation period, LTR Pharma has a right to negotiate an exclusive licence for KYZATREX in Australia.

KYZATREX is not registered by the TGA. Initial patient access will be facilitated through the Special Access Scheme, which enables medical practitioners to prescribe unapproved therapeutic goods for individual patients in accordance with applicable TGA requirements.

Next Steps

LTR Pharma will commence initial market development activities, including:

- facilitating initial patient access through compliant SAS pathways;
- engaging and educating an initial group of Australian men's-health KOLs and prescribers;
- evaluating physician adoption and patient demand; and
- working with Marius to assess the potential pathway toward TGA registration in Australia.

LTR Pharma Executive Chairman, Lee Rodne, said:

"We are pleased to partner with Marius to introduce KYZATREX in Australia. As an FDA-approved oral testosterone therapy, KYZATREX represents a complementary opportunity to broaden our men's health portfolio by leveraging the clinical networks, telehealth channels and commercial infrastructure we have already established through SPONTAN.

At the same time, we remain focused on execution of our core programs, with ROXUS moving toward U.S. commercial launch through SHED and Strive, the final SPONTAN Phase II report expected shortly and planning underway for the pivotal Phase III study in 2027."

Amit Shah, COO of Marius Pharmaceuticals, said:

"We are excited to partner with LTR Pharma to introduce KYZATREX in Australia. LTR's established clinical networks and growing telehealth channels make them a strong partner to support patient access and physician adoption in this important market. We look forward to working together to expand access to KYZATREX and address unmet needs in testosterone deficiency."

- ENDS –

This announcement has been approved by the Board of Directors.

Forward-Looking Statement

This announcement contains forward-looking statements, including in relation to patient access, clinical demand, regulatory pathways, U.S. commercial launch and the timing, conduct and reporting of clinical studies. These statements involve risks and assumptions beyond the Company's control, and actual results may differ materially. The Company does not undertake to update any forward-looking statement except as required by law.

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 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.

For more information on Marius Pharmaceuticals, visit: www.mariuspharma.com.

LTR Pharma Investor Centre

Stay informed with LTR Pharma's latest announcements and market updates by visiting our Investor Centre or scan the QR code.

For further information please contact:

Media enquiries
Haley Chartres
haley@hck.digital

Investor enquiries
Peter McLennan
investors@ltrpharma.com