SPONTAN® 147-patient real-world study: 93% response in convenience-seeking men

11 August 2026

Highlights

- **93% response (42 of 45 men)** among treatment-experienced men seeking greater convenience and spontaneity, reporting improved erectile hardness and/or achieving penetration with SPONTAN.
- **64% of post-prostatectomy patients (56 of 87 men)** reported improved erectile hardness and/or achieving penetration with SPONTAN.
    - **An encouraging result in a particularly challenging patient population,** where oral PDE5 inhibitors such as Viagra and Cialis can have limited effectiveness following prostate surgery, particularly in the early recovery period, and patients may otherwise progress to more invasive treatments such as penile injections.
- **57% response (58 of 102 men)** among the more difficult-to-treat subgroup who had previously reported inadequate efficacy with oral PDE5 inhibitor therapy.
    - **Importantly, more than half of these men reported improved erectile hardness and/or achieving penetration with SPONTAN despite having previously reported inadequate results with conventional oral ED treatments.**
- **Across the overall 147-patient cohort, 68% (100 of 147)** reported improved erectile hardness and/or achieving penetration with SPONTAN.
- **Data will be presented at APCC in Melbourne on 13–15 August 2026**, with the manuscript submitted to Sexual Medicine for peer review.

LTR Pharma Limited (ASX: LTP) ("LTR Pharma" or "the **Company**") today reports outcomes from a retrospective real-world cohort of 147 treatment-experienced men prescribed SPONTAN®, the Company's rapid-onset intranasal vardenafil spray, in routine Australian clinical practice. Importantly, the real-world findings indicate that SPONTAN may provide an alternative treatment option for men who report inadequate results with conventional oral ED therapies such as sildenafil (Viagra) and tadalafil (Cialis).

The cohort is the largest real-world dataset reported for SPONTAN to date and includes a substantial prostate cancer and post-prostatectomy population – a large, clearly identifiable patient group in which ED is common, persistent and can be poorly served by existing oral therapies.

Key Outcomes

Measure	Population	Result
Composite endpoint: improved erectile hardness and/or achieving penetration	Men seeking greater convenience and spontaneity	93% (42 of 45)
Composite endpoint	Men seeking improved efficacy following inadequate response to oral therapy	57% (58 of 102)
Composite endpoint	Overall cohort	68% (100 of 147)
Achieved penetration following treatment	Overall cohort	53% (78 of 147)
Composite endpoint	Post-prostatectomy subgroup	64% (56 of 87)
Composite endpoint	Non-prostatectomy subgroup	73% (44 of 60)

Study Overview

The cohort comprised 147 treatment-experienced men with a mean age of 65.6 years, all of whom had previously been treated with oral PDE5 inhibitors. 62% had a history of prostate cancer, and 59% had undergone prostatectomy. Men were grouped according to their primary reason for seeking SPONTAN: greater convenience and spontaneity (n=45), or improved efficacy following an inadequate response to oral therapy (n=102).

Outcomes were assessed using a patient-reported composite measure of improved erectile hardness and/or achieving penetration following treatment.

Post-Prostatectomy Findings

Post-prostatectomy erectile dysfunction represents a particularly challenging and clearly identifiable patient population. Oral PDE5 inhibitors such as sildenafil (Viagra) and tadalafil (Cialis) remain first-line therapy; however, response can be limited following radical prostatectomy, particularly during the early recovery period when cavernous nerve injury reduces the nitric oxide pathway required for these medicines to work.

Published literature has reported oral PDE5 inhibitor response rates of approximately 12-17% during the first six months following radical prostatectomy. Patients who remain inadequately treated may progress to more invasive therapies, including intracavernosal treatments such as CAVERJECT® (alprostadil), which requires direct penile injection. Initial CAVERJECT dosing is administered and titrated under healthcare-provider supervision, with patients trained in self-injection for subsequent at-home use.

Against this challenging treatment background, nearly two-thirds (64%; 56 of 87) of post-prostatectomy patients in the SPONTAN real-world cohort reported improved erectile hardness and/or achieving penetration following treatment. While the results are not directly comparable with historical studies of oral PDE5 inhibitors, the findings highlight the potential role of rapid, non-invasive intranasal treatment with SPONTAN and ROXUS for men experiencing ED following prostate cancer surgery. LTR Pharma believes this represents an important potential area for further clinical investigation and commercial development.

Market and Clinical Context

Prostate cancer is the most commonly diagnosed cancer in Australian men, with an estimated 28,868 new cases in 2025[1] and approximately 8,500 radical prostatectomies performed annually.[2]

In the United States, an estimated 333,830 new cases are projected for 2026[3], with more than 3.5 million men living with a prostate cancer diagnosis,[4] and global incidence is projected to reach approximately 2.9 million new cases annually by 2040.[5]

ED is among the most common and persistent consequences of prostate cancer treatment, with published rates as high as 85% following radical prostatectomy,[6] while dropout rates exceeding 50% have been reported for oral PDE5 inhibitors, with lack of spontaneity a consistently cited reason.[7] This represents a large, durable and under-served patient population.

Relevance to SPONTAN® and ROXUS®

The 93% response among men seeking greater convenience and spontaneity suggests that the potential addressable population for a rapid-onset intranasal therapy may extend beyond men who experience an inadequate response to oral PDE5 inhibitors. It may also include the broader group of men who obtain an effect from oral therapy but are constrained by its timing and planning requirements.

The post-prostatectomy result is particularly relevant to the U.S. market, where LTR Pharma is advancing SPONTAN via the FDA 505(b)(2) regulatory pathway and preparing ROXUS®, its rapid-acting intranasal ED treatment, for U.S. commercial availability through patient-specific prescriptions compounded under Section 503A. With definitive agreements now executed with Shed Holdings LLC (ASX announcement, 17 July 2026) and Strive Specialties Inc. (ASX announcement, 20 July 2026), this real-world evidence in a defined and clinically identifiable population may support targeted engagement with urologists and men's health prescribers as the Company progresses its U.S. commercialisation strategy.

Data Status and Limitations

The findings are derived from a retrospective, single-centre real-world cohort based on patient-reported outcomes and should be interpreted in the context of the study design. The manuscript has been submitted to Sexual Medicine and is currently undergoing peer review.

SPONTAN is not registered on the Australian Register of Therapeutic Goods and is made available in Australia under the Therapeutic Goods Administration's Special Access Scheme and Authorised Prescriber pathways.

Commentary

Melissa Hadley Barrett*, Nurse Practitioner and Sexologist, said:

"What stands out in this cohort is who responded. These were treatment-experienced men, the majority with a prostate cancer history, a population where oral therapy frequently disappoints. The response in men who wanted spontaneity rather than a stronger drug tells me timing and ease of use are clinical variables in their own right. I look forward to presenting these findings at APCC."

LTR Pharma Executive Chairman, Lee Rodne, said:

"We regard this as an important real-world dataset for LTR Pharma. The 93% response among men seeking greater convenience reinforces our belief that the opportunity for SPONTAN and ROXUS extends beyond patients who simply fail oral tablets – it includes men seeking greater spontaneity and control over their treatment.

The finding that nearly two-thirds of post-prostatectomy patients reported improved erectile hardness and/or achieving penetration is particularly encouraging given the recognised difficulty in treating ED following prostate cancer surgery. Oral therapies may provide limited benefit for some men and patients may ultimately progress to invasive treatments such as penile injections. We believe rapid, non-invasive intranasal treatment has the potential to address an important unmet need in this clearly identifiable patient population.

With our U.S. commercial partnerships now in place, these findings provide an important clinical narrative as we engage urologists, men's health prescribers and commercial partners ahead of ROXUS U.S. availability."

Next Steps

LTR Pharma's next steps include presentation of the cohort data at APCC on 13–15 August 2026, progression of the submitted manuscript through peer review, evaluation of a prospective study in the post-prostatectomy population, continued Australian real-world evidence collection, and implementation activities with Shed and Strive ahead of ROXUS U.S. commercial availability.

[1] Cancer Australia, Prostate cancer in Australia statistics, based on Australian Institute of Health and Welfare data, 2025 estimate.
[2] Australian Commission on Safety and Quality in Health Care, Australian Atlas of Healthcare Variation, 2012-13 hospital admissions data.
[3] American Cancer Society, Cancer Facts & Figures 2026, Atlanta: American Cancer Society, 2026.
[4] Wagle NS, Nogueira L, Devasia TP, et al., "Cancer treatment and survivorship statistics, 2025", CA: A Cancer Journal for Clinicians, 2025.
[5] James ND et al., The Lancet Commission on prostate cancer: planning for the surge in cases, The Lancet, 2024.
[6] Emanu JC, Avildsen IK, Nelson CJ, "Erectile Dysfunction after Radical Prostatectomy: Prevalence, Medical Treatments, and Psychosocial Interventions", Current Opinion in Supportive and Palliative Care, 2016;10(1):102-107.
[7] Carvalheira et al., "Dropout in the Treatment of Erectile Dysfunction with PDE5", Journal of Sexual Medicine, May 2012.

* Melissa Hadley Barrett is Director of Restorative Health Clinic, in which LTR Pharma holds a joint venture interest.

- ENDS -

This announcement has been approved by the Board of Directors.

Forward-Looking Statement

This announcement contains forward-looking statements concerning LTR Pharma's regulatory and commercial strategy, potential future clinical studies and planned U.S. commercial availability of ROXUS. These statements are based on the Company's current expectations and assumptions and are subject to risks and uncertainties that may cause actual outcomes to differ materially. The Company undertakes no obligation to update these statements except as required by applicable law and the ASX Listing Rules.

About LTR Pharma

LTR Pharma is a commercial-stage pharmaceutical company delivering innovative therapies to address 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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