



Investor Webinar

Final Phase II Results
Real-World Evidence
ROXUS® U.S. Update

October 2026

Lee Rodne, Executive Chairman
Professor Geoffrey Strange, Chief Medical Officer
Melissa Hadley Barrett, Nurse Practitioner and
Sexologist, Director, Restorative Health Clinic



Your presenters



**Lee
Rodne**

LTR Pharma Executive Chairman

- ▶ Healthcare entrepreneur and executive with 25+ years' experience building, commercialising and scaling healthcare and technology businesses across public and private markets.
- ▶ Former CEO and Managing Director of Allied Medical, a Fortescue Metals Group spin-out (later Admedus Ltd, now Anteris Technologies), which he led from an approximately \$800k valuation to a peak valuation of approximately \$250m.
- ▶ Track record commercialising medical products across Australia, North America, Europe and Asia, including experience in nasal drug-delivery products.



**Professor
Geoffrey Strange**

LTR Pharma CMO PhD, FESC,
FCSANZ

- ▶ Chief Medical Officer, LTR Pharma Ltd
- ▶ Professor, School of Medicine, University of Notre Dame Australia
- ▶ Faculty of Medicine and Health, The University of Sydney



**Melissa
Hadley Barrett**

MNurs, PGrad Dip Sexology, PGrad
Dip Mid, GradCertDiab, BSc

- ▶ Nurse Practitioner and Sexologist, 25+ years
- ▶ Director, Restorative Health Clinic, Perth, WA
- ▶ Leading prescriber of SPONTAN (ROXUS in the U.S.); lead author of the 147-patient real-world SPONTAN study

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Executive Summary

Clinical validation → Real-world validation → U.S. prescriptions commenced

1

Clinical proof established

- SPONTAN / ROXUS is a rapid-acting intranasal PDE5 therapy. Final Phase II data confirmed six-fold faster median absorption than oral vardenafil ($p < 0.0001$), with a favourable safety and tolerability profile.¹

- Lead program: SPONTAN / ROXUS

6× faster
median absorption

2

Real-world demand validated

- A 147-patient Australian TGA SAS cohort: 93% of men seeking greater convenience and spontaneity reported improved erectile hardness and/or penetration (42 of 45); 68% across the full cohort.²

- Evidence: clinical + patient reported

Real-world response
in men seeking
convenience (42 of 45)

3

U.S. prescriptions commenced

- ROXUS patient-specific prescription fulfilment commenced under Shed and Strive (Oct 2026). The FDA pharmacokinetic dataset is complete; pivotal Phase III is targeted for 1H CY2027. \$19.6M cash and zero debt support near-term execution.³
- Commercial partners: Shed, Strive, Aptar, Mayne, EBOS/Symbion

Minimum ROXUS prescription
units supported by Shed

ED in the US: common, age-related, cardiometabolic

2021 National Survey of Sexual Wellbeing: nationally representative sample of 1,822 US men aged 18–87, IIEF-5.

24.2%

of US men aged 18+ meet IIEF-5 criteria for ED, about 1 in 4

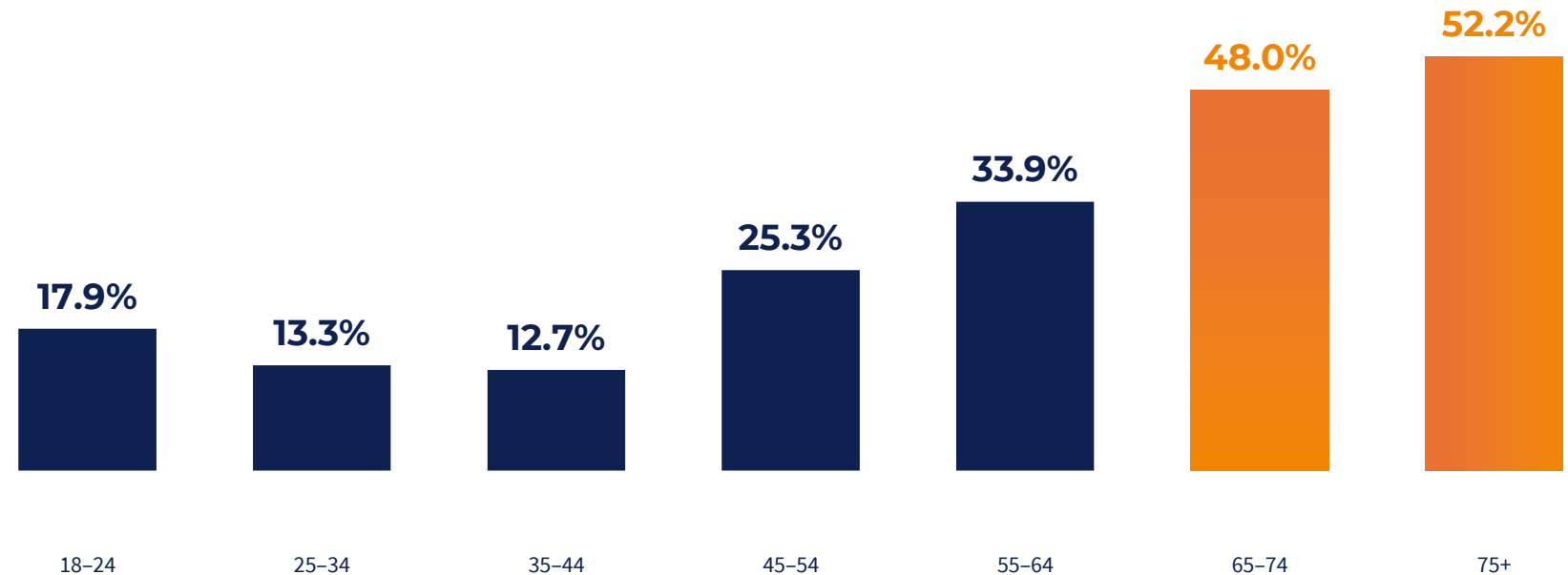
≈ 1 in 2

men aged 65+ meet criteria for ED (48.0% at 65–74, 52.2% at 75+)

Only 7.7%

diagnosed by a provider; only 16.7% had discussed erections with one

Men meeting IIEF-5 criteria for ED, by age (%)



Age group (years). Among men with a prior heart attack or heart failure, about 65% met criteria for ED; with diabetes 41% and hypertension 40%.

PDE5 inhibitors work. Oral delivery is the constraint

Same mechanism the difference is absorption = speed



First-pass metabolism

Oral PDE5is are absorbed through the gut and pass through the liver, where 90 to 95% of the drug is removed before it reaches the circulation.

Higher doses are needed to reach therapeutic levels



30 to 120 minutes to peak

Median Tmax: avanafil 30 min, sildenafil 60 min, vardenafil 60 min, tadalafil 120 min.

Intimacy has to be planned around the tablet



Food, alcohol and the gut

A high-fat meal delays and reduces absorption of sildenafil and vardenafil. Dyspepsia and reflux are common reasons men avoid daily dosing.

Timing rules add friction to an already sensitive moment.

Agent	US brand	Usual on-demand dose	Route	Median Tmax	Half-life
Sildenafil	Viagra®	25, 50, 100 mg	Oral	60 min	~4 h
Vardenafil	Levitra®	10, 20 mg	Oral	60 min	~4 h
Tadalafil	Cialis®	10, 20 mg (5 mg daily)	Oral	120 min	17.5 h
Avanafil	Stendra®	50, 100, 200 mg	Oral	30 min	~5 h
Vardenafil	ROXUS®	5 mg (2.5 mg per nostril)	Intranasal	10 min	~4 h

Final Phase II Report Confirms Six-Fold Faster Absorption and Completes FDA PK Dataset

Final Clinical Study Report | n=27 (14 aged ≥65) | randomised three-way crossover | independent CRO

Key Findings

- ▶ Six-fold faster absorption than oral vardenafil (p<0.0001)
- ▶ Approximately dose-proportional exposure; substantially lower metabolite (M1) exposure than the oral tablet
- ▶ No drug accumulation over five days of once-daily dosing
- ▶ Comparable pharmacokinetics in men aged 65 and over (14 of 27)
- ▶ No SAEs, no Grade 3+ events, no discontinuations; most frequent treatment-related events nasal congestion and headache, mild and self-resolving

Comparative PK results		Six-fold faster absorption, p<0.0001		
Parameter	SPONTAN 5 mg	SPONTAN 2.5 mg	Vardenafil 20 mg oral	
Tmax, median (range)	10 min (10–15)	11 min (5–60)	60 min (30–186)	
Cmax (mean ± SD, ng/mL)	8.9 ± 6.8	5.8 ± 4.9	19.8 ± 8.8	
Half-life (t½, mean)	4.4 hours	3.8 hours	4.4 hours	
Dose-normalised AUC0-inf (ng·h/mL/mg)	3.6	4.8	3.2	
Accumulation ratio (5 days once daily)	1.0 ± 0.9	n.a.	n.a.	
SAEs / Grade 3+ TEAEs / discontinuations	0	0	0	

Design agreed with FDA at Pre-IND. Final report completes the PK dataset for the planned 505(b)(2) submission.

Half of men stop oral therapy

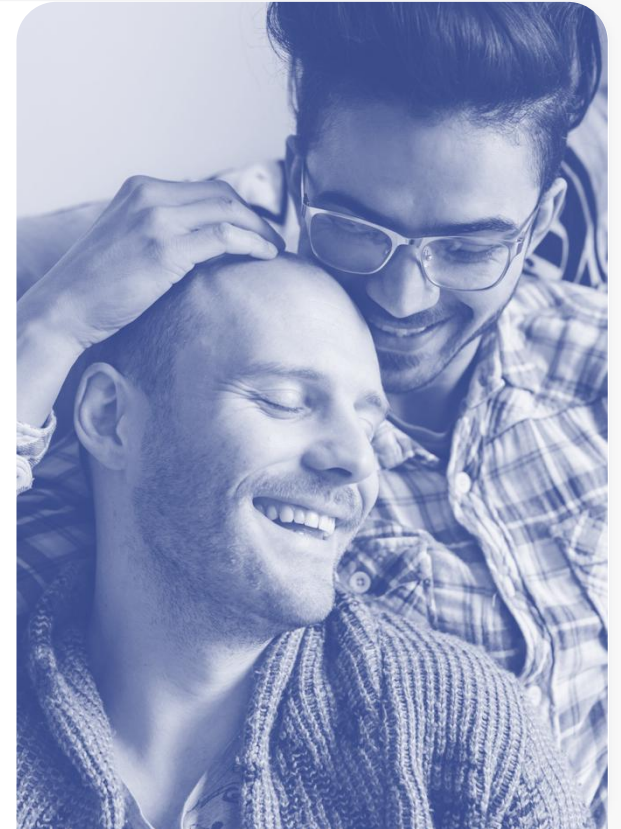
48.9%

of 327 men with ED
discontinued oral PDE5
inhibitor treatment
(Carvalheira et al. 2012)

Men often stop for a combination of reasons. The practical ones, waiting an hour, empty stomach, planning around the tablet, are the ones a faster, food-independent route can change.

Reasons given for stopping

(Carvalheira et al. 2012, n = 160 dropouts)



Real-World Cohort: 147 Treatment-Experienced Men

TGA Special Access Scheme | retrospective, single specialist clinic, Jan to Dec 2025 | patient-reported outcomes

147 treatment-experienced men,
mean age 65.6 years

62% history of prostate cancer;
59% post-prostatectomy

100% previously treated with oral
PDE5 inhibitors

Why men sought SPONTAN®, and the clinical context

102 men

Seeking improved efficacy after
inadequate response to oral therapy

45 men

Seeking greater convenience
and spontaneity

About 50%

Oral PDE5i dropout rates; lack
of spontaneity consistently cited³

Post-prostatectomy context: oral PDE5i response 12–17%
in the first six months²; ED in up to 85% of men¹

Outcome measure: improved erectile
hardness and/or achieving penetration

Treatment-experienced men seeking either better efficacy or greater spontaneity than oral tablets
provided, assessed on patient-reported outcomes in routine clinical practice.

Real-World Outcomes: Patient-Reported Response

Improved erectile hardness and/or achieving penetration | 147 treatment-experienced men

93% men seeking greater convenience and spontaneity (42 of 45)

68% overall cohort (100 of 147)

53% achieved penetration following treatment (78 of 147)

Composite endpoint by subgroup

By reason for seeking treatment and prostatectomy status

57% 58 of 102

Inadequate response to oral PDE5 therapy

64% 56 of 87

Post-prostatectomy subgroup

73% 44 of 60

Non-prostatectomy subgroup

Post-prostatectomy context: oral PDE5i response 12–17% in the first six months²; ED in up to 85% of men¹

Highest response among men seeking greater convenience and spontaneity, with encouraging results in men inadequately served by oral therapy and men following prostatectomy.

ROXUS® U.S. Prescriptions Commenced

First valid patient-specific ROXUS® prescriptions fulfilled by Strive through Mavrox



Demand Engine

Shed Holdings LLC | Executed 17 Jul 2026

US direct-to-consumer telehealth platform: Mavrox

- ▶ First U.S. commercial route-to-market; first valid patient-specific prescriptions received through Mavrox and fulfilled
- ▶ Minimum 150,000 ROXUS® prescription units in the first 12 months from Commercial Launch, subject to performance
- ▶ Two-year U.S. DTC telehealth exclusivity from launch, subject to performance



Supply Engine

Strive Specialties Inc. | Executed 20 Jul 2026

Exclusive US 503A pharmacy and fulfilment partner

- ▶ Five-state 503A platform with nationwide compounding and fulfilment licensure
- ▶ Technology transfer and readiness complete; approximately 100,000 Aptar pump and bottle components received
- ▶ Two-year exclusivity, subject to performance; LTR retains product ownership, IP and formulation supply



ROXUS® U.S. patient-specific prescription fulfilment has commenced.

- ▶ Moves ROXUS® from U.S. Market preparation to prescription fulfilment
- ▶ Capital-light model using established telehealth and pharmacy infrastructure
- ▶ First patient-specific prescriptions now being fulfilled
- ▶ Premium ED positioning without LTR building U.S. prescribing, pharmacy or fulfilment infrastructure

ASX announcement 6 October 2026

Key Milestones

Completed milestones → current execution → next major value inflection points



Cash \$19.6M | Avg. quarterly net operating outflow \$2.8M¹ | Zero debt |
Funded to deliver near-term U.S. commercial, clinical and regulatory value inflection points

Source: Appendix 4C for the quarter ended 30 June 2026. 1) Average net operating cash outflow per quarter over the twelve months to 30 June 2026. June 2026 quarter net operating outflow: \$4.4M. Cash figures in Australian Dollars.



Questions

 investors@ltrpharma.com

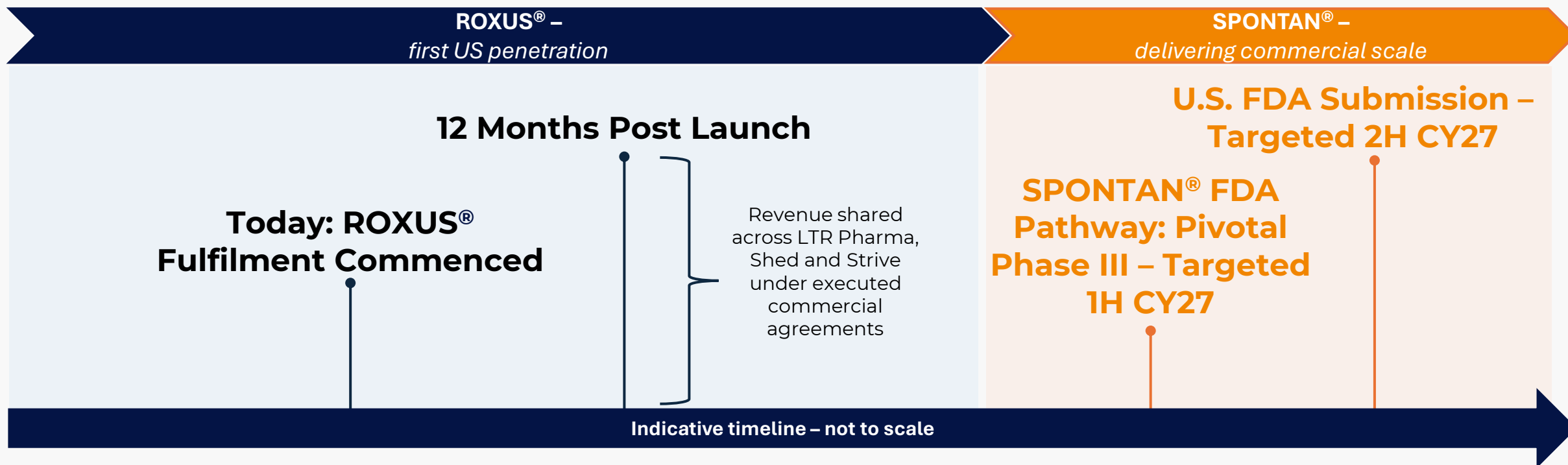
 www.ltrpharma.com



Backup slides

For Q&A reference

US Commercialisation: Launch Strategy



ROXUS® Launch Readiness – Complete:

- Technology transfer, testing and operational readiness complete
- ~100,000 Aptar device components received
- First prescriptions fulfilled through Mavrox

ROXUS® Volume and Pricing:

- Shed commitment to support not less than **150,000 ROXUS® units** during the first 12 months
- LTP anticipates **pricing will be in line with other premium** ED competitors

ROXUS® Capital-light US Penetration:

- Capital-light market entry for LTR Pharma
- Shed actively promoting ROXUS® as a differentiated ED product on their platform

SPONTAN® FDA Approval for Commercial Scale:

- Unlocks pharma licensing partnerships
- Expands U.S. commercial channels
- Expands the addressable U.S. opportunity
- Supports scalable long-term U.S. revenue growth

Portfolio Overview and Development Focus

Validated Platform and Expanding Men's Health Portfolio



Lead Clinical Program

SPONTAN **ROXUS**

*Intranasal Sprays for Erectile
Dysfunction*

- ▶ TGA Early Access – ACTIVE
- ▶ FDA 505(b)(2) regulatory pathway
 - ▶ Phase II PK study complete; final report completes FDA PK dataset
- ▶ 503A Commercial partners secured (US)

Early Development

OROFLOW – Platform Expansion

*Intranasal Spray for
Oesophageal Motility Disorders (OMD)*

- ▶ HREC-approved study; initiation pending hospital contract sign-off
- ▶ First platform application beyond ED, in gastrointestinal disease
- ▶ Capital prioritised to lead program

Portfolio Expansion

KYZATREX®

*Oral Therapy for Testosterone
Deficiency*

- ▶ Exclusive pilot commercialisation agreement with Marius Pharmaceuticals (US)
- ▶ FDA-approved oral testosterone therapy; initial Australian patient access via the TGA Special Access Scheme
- ▶ Six-month evaluation period, with a right to negotiate an exclusive Australian licence

Strategic Investment

LevOmega

Nature-Identical omega-3 Products

- ▶ Equity Investment – 43%
- ▶ Focused on development of nature-identical omega-3 products
- ▶ Separate development pathway and capital structure
- ▶ Complementary to LTR's core intranasal programs

US Strategy: What FDA approval unlocks

503A enables rapid commercialisation today, while the FDA approval has the potential to materially expand the addressable market and long-term commercial opportunity

ROXUS® - 503A

Rapid commercial launch and market validation

- ✓ Rapid route to initial US revenues through cash-pay DTC and telehealth channels
- ✓ Efficient made-to-order manufacturing model with limited inventory requirements
- ✓ Generates commercial experience, physician adoption and real-world data to support broader strategy
- ✓ Establishes early physician adoption, prescribing behaviour and commercial proof points ahead of FDA approval

SPONTAN® - 505(b)(2) approval

Expanded commercial opportunity

- 1 Regulatory protection and intellectual property**
505(b)(2) pathway may provide regulatory exclusivity and strengthen intellectual property protection through potential Orange Book listing
- 2 Broader commercial reach**
FDA-approved labelling supports promotional claims, payer engagement and potential reimbursement, expanding commercial opportunities
- 3 Scalable pharmaceutical supply**
Commercial-scale manufacturing supports broader distribution channels and long-term supply flexibility
- 4 Strategic partnering opportunities**
An FDA-approved product may enhance licensing, partnering and ex-US expansion opportunities via dossier

LTR's phased US strategy is designed to generate near-term commercial momentum while creating the foundation for a significantly larger long-term value opportunity

Large ED Market with a Clear Treatment Gap

Oral PDE5 inhibitors remain first-line, but response and persistence limitations leave a sizeable unmet need

~US\$5B

estimated annual global
ED drug market¹

~322M

men globally estimated
to have ED in 2025¹

Treatment pathway and gap

1 Oral PDE5 inhibitors

First-line therapy; delayed onset
and high discontinuation

2 30–35% inadequate response

Higher failure rates in difficult-
to-treat populations²

3 Invasive second-line options

Intracavernosal injection utilisation
has fallen >55-fold from peak³

SPONTAN roXUS

**Rapid-onset,
non-invasive PDE5 option**

- Positioned across the broad ED market
- Supports patients seeking greater spontaneity
- Provides a non-invasive option for patients inadequately served by oral therapy
- Positioned before invasive treatments