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# Building a Portfolio of Differentiated Specialty Therapies

Investor Update | May 2026

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# Executive Summary

## LTR Pharma: Late-Stage Pharmaceutical Platform with Validated Early Market Access

### Differentiated Lead Program – SPONTAN / ROXUS

Rapid-acting intranasal PDE5 therapy demonstrating 5x faster absorption versus oral tablets at half the dose, with a validated safety and tolerability profile.

### Dual U.S. Pathway Strategy

Advancing SPONTAN via the 505(b)(2) regulatory pathway following successful Pre-IND engagement. In parallel, progressing commercial discussions to support U.S. launch of ROXUS through the personalised medicine (503A) channel.

### Early Commercial Validation (Australia)

1,000+ prescriptions under the TGA Special Access Scheme (SAS), supporting prescriber adoption and expanding real-world safety and efficacy data.

### Strategic Partnerships

Co-development agreement with Aptar Pharma (Nasdaq). Commercial manufacturing with Mayne Pharma (ASX). National distribution via EBOS/Symbion (ASX).

### Funded Through Key Milestones

$24.1M cash, zero debt, funding Phase II data readout and continued regulatory and commercial advancement.[1]



1. Source: Appendix 4C for quarter ended 31 March 2026. Cash figures in Australian Dollars.



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# Market Inefficiency: High Discontinuation and Delayed Onset

# Global Erectile Dysfunction Treatment Market

- Global ED drug market estimated at **~US$5B annually**[1]
- **Oral PDE5 inhibitors** currently dominate prescribing
- **High discontinuation rates (>50%) reported with oral PDE5 inhibitors** due to delayed onset, inconsistent response and tolerability[2]
- **Rapid growth in telehealth** prescribing channels
- **Opportunity for differentiated therapies** with faster onset and alternative delivery
- **Potential adoption in difficult-to-treat ED segments** (e.g., post-prostatectomy, performance anxiety, BPH)



1) Source: Frost and Sullivan Report, The Erectile Dysfunction Medicines Market, September 2023. 2) Carvalheira et al., "Dropout in the Treatment of Erectile Dysfunction with PDE5: A Study on Predictors and a Qualitative Analysis of Reasons for Discontinuation," Journal of Sexual Medicine, May 2012.

# Understanding the Market Need

## A significant healthcare challenge affecting relationships and quality of life

**50%** Stop purchasing PDE5 tablets[1]

**60%** Of men over 45 experience ED[2]

Growing prevalence with age impacts quality of life

### Physical causes

- Heart health
- Hormone balance
- Prostate Cancer
- Diabetes
- Medical treatments
  - Hair loss
  - Weight loss
  - Antidepressants

### Psychological Impact

- Relationship problems
- Mental wellbeing
- Day to day stress

Prevalence of ED with individuals with cardiovascular risk factors, hypertension and diabetes, **is reported as high as 50%**

1) Carvalheira et al., "Dropout in the Treatment of Erectile Dysfunction with PDE5: A Study on Predictors and a Qualitative Analysis of Reasons for Discontinuation," Journal of Sexual Medicine, May 2012. 2) Source: Frost and Sullivan Report, The Erectile Dysfunction Medicines Market, September 2023

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# Current Treatments

## Oral PDE5 inhibitors and SPONTAN® Nasal Spray

### Oral Phosphodiesterase-5 (PDE5) inhibitors are first-line treatments

| Product | Main Brand(s) | Time before sexual activity for dose | Approval Date (US) | Generic availability |
|---|---|---|---|---|
| **Sildenafil** | Viagra | 1 hour+ | 1998 | Yes |
| **Tadalafil** | Cialis | 1 hour+ | 2003 | Yes |
| **Vardenafil** | Levitra, Staxyn | 1 hour+ | 2003 | Yes |
| **Avanafil** | Stendra | 30 minutes+ | 2012 | No |

### Issues with oral PDE5 inhibitors

- Does not work for 30-35% of patients
- Long response time of 1 hour + affects spontaneity
- Adverse reactions in up to 35% of patients

**= High discontinuation rate**


**SPONTAN** **First and only PDE5 nasal spray,** available now in Australia under TGA early access.

# Where SPONTAN Fits in the ED Treatment Landscape

**Current first-line therapy:** Oral PDE5 inhibitors (Viagra, Cialis, Levitra)

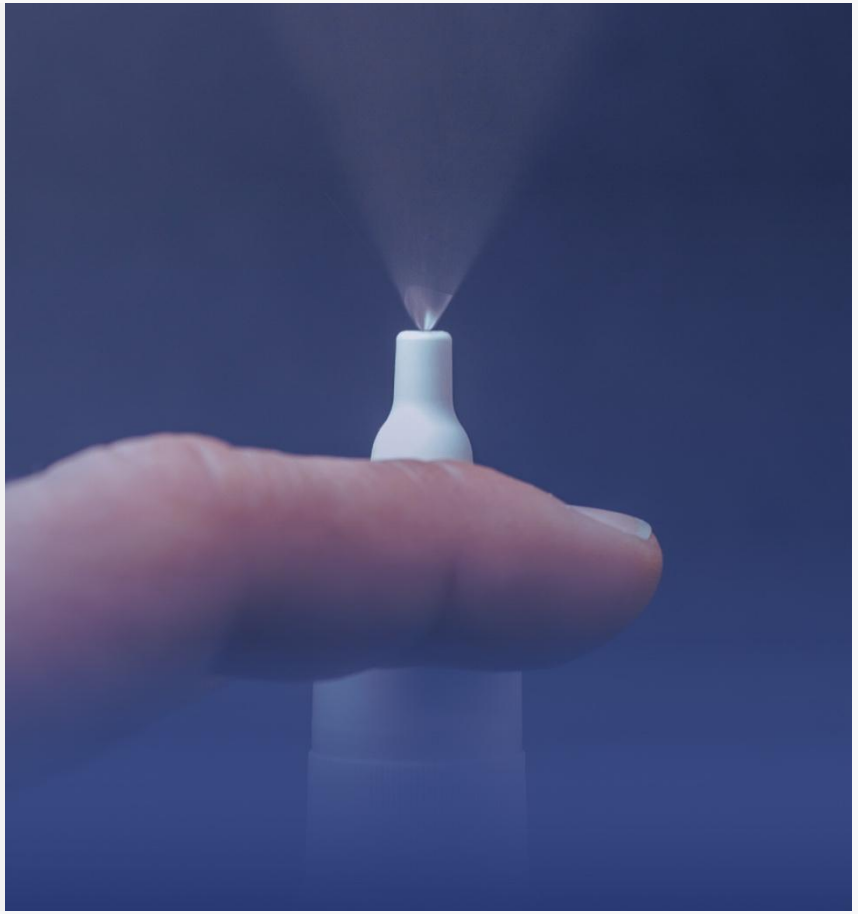
**Limitations of oral therapies** include delayed onset, food interactions, and high discontinuation rates

**SPONTAN ®** intranasal delivery bypasses first-pass metabolism and enables faster systemic absorption

**Rapid onset potential** supports more spontaneous use compared with traditional oral treatments

May offer **advantages for patients** who do not respond optimally to oral PDE5 inhibitors

**Applicable across the broad ED population**, particularly for patients seeking faster onset and improved spontaneity, with potential advantages in difficult-to-treat segments such as post-prostatectomy and performance-related ED.



# Prevalence in Key Markets

## As risk factors become more prevalent, so does ED

**Global ~322m men by 2025**


Source: Frost and Sullivan Report, The Erectile Dysfunction Medicines Market, September 2023

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# Solution

# SPONTAN

# SPONTAN®

# Phase I Pharmacokinetic Study

## Rapid onset effect, consistent delivery and improved safety profile

- SPONTAN® nasal spray achieved **rapid absorption and faster onse**t of action compared to oral PDE5 inhibitors.
- SPONTAN® delivered **similar bioavailability** (Cmax) at half the dose of oral PDE5 inhibitors.
- **Significantly faster** (Tmax) with SPONTAN® in as little as 9 min (avg. 12 min) vs oral (56 min) - longest 2.5 hours.
- **Confirmed safety and tolerability** profile of SPONTAN® vs oral dosing PDE5 Inhibitors.
- SPONTAN® demonstrated *more consistent dosing* than oral PDE5 Inhibitors.
- **Phase I findings reproduced and extended in the Phase II interim dataset**.

| Parameter | SPONTAN (5mg) | Vardenafil (10mg) oral |
|---|---|---|
| Cmax (ng/ml) | 13.0 | 16.7 |
| Tmax (min) | 12 (range 9-15) | 56 (Longest 150) |
| Adverse Events | 0 | 1 |

# SPONTAN® the Science of Superior Delivery

## Faster and more potent

### Speed Superiority

- Tmax: 5x faster than oral tablets
- Peak concentration in as little as 9 mins
- Average onset: 12 mins vs 56 mins

### Potency Advantage

- Half the dose
- Dose-normalised Cmax is 155.6% higher than orals
- Consistent effectiveness
- Direct bloodstream delivery bypasses liver metabolism

### Proven Safety

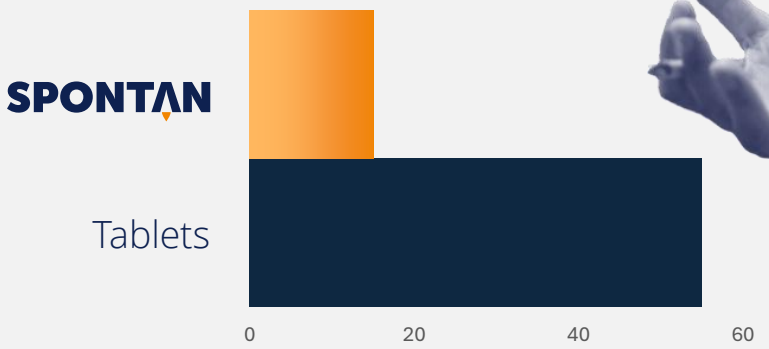
- Validated safety profile
- No severe events
- Clinically proven

**Healthcare Professional Insight**

Patients can respond in as little as 5 minutes, well before peak concentration is reached*

*Based on healthcare professional feedback

**Time to peak concentration (Tmax)**
(minutes)




# Phase II Interim Data Reinforce Rapid-Onset Profile and Expand Dataset

## Key Highlights

### Rapid Absorption Profile

- Median Tmax ~10 minutes for SPONTAN® (5 mg)
- Compared with ~60 minutes for 20 mg oral vardenafil

### Consistent Pharmacokinetic Profile

- Comparable PK observed across adult and ≥65-year cohorts in the interim dataset

### Repeat Dosing Behaviour

- No evidence of drug accumulation observed following 5 days of dosing (5 mg)
- Supports predictable exposure with repeat dosing

### Favourable Safety Profile

- No serious adverse events
- No Grade 3 or 4 treatment-emergent adverse events
- No treatment-related discontinuations

**Study designed in accordance with FDA Pre-IND guidance**
Dataset includes key PK parameters (absorption, repeat dosing, age effects)



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Interim data based on preliminary analysis of 27 subjects. Full statistical analysis ongoing. Refer to the ASX announcement for details.

# Phase II Interim Pharmacokinetic Profile

## SPONTAN® vs Oral Comparator

- **Faster onset** profile observed with intranasal SPONTAN® compared with oral vardenafil.
- **Comparable PK observed across adult and ≥65-year cohorts** in the interim dataset.
- **No accumulation observed** following 5 days of repeat dosing.
- **Favourable safety** with no serious or severe treatment-emergent adverse events.

| Parameter | SPONTAN 5 mg (Intranasal) | Vardenafil 20 mg (Oral) |
|---|---|---|
| Median Tmax | ~10 minutes (10–15 min) | ~60 minutes (30–180 min) |
| Onset profile | Rapid and consistent | Slower, variable |
| Repeat dosing | No accumulation observed | Not assessed |
| Safety (interim) | No serious or severe TEAEs | No serious or severe TEAEs |

**Commercial Relevance: Faster onset aligns with on-demand patient use, Consistent PK supports a predictable profile with repeat use, Applicable across a broad patient population including ≥ 65**

Data are interim and based on preliminary analysis. Full statistical analysis ongoing. Refer to the ASX announcement for full details.
Lower Cmax relative to oral comparator reflects lower dose, while maintaining rapid systemic exposure.

# Australian Early Access Program: Real-World Clinical and Prescriber Validation

## TGA Special Access Scheme - 1,000+ prescriptions supporting real-world clinical and prescriber validation

### Prescriber Adoption

- 1,000+ prescriptions and growing
- Expanding prescriber base
- Repeat prescribing behaviour observed

### Real-World Clinical Data

- Published case series (APCC 2025)
- Positive patient preference versus oral PDE5 in post-prostatectomy cohort[1]
- Positive outcomes in performance-related ED[2]
- Growing real-world safety and efficacy dataset

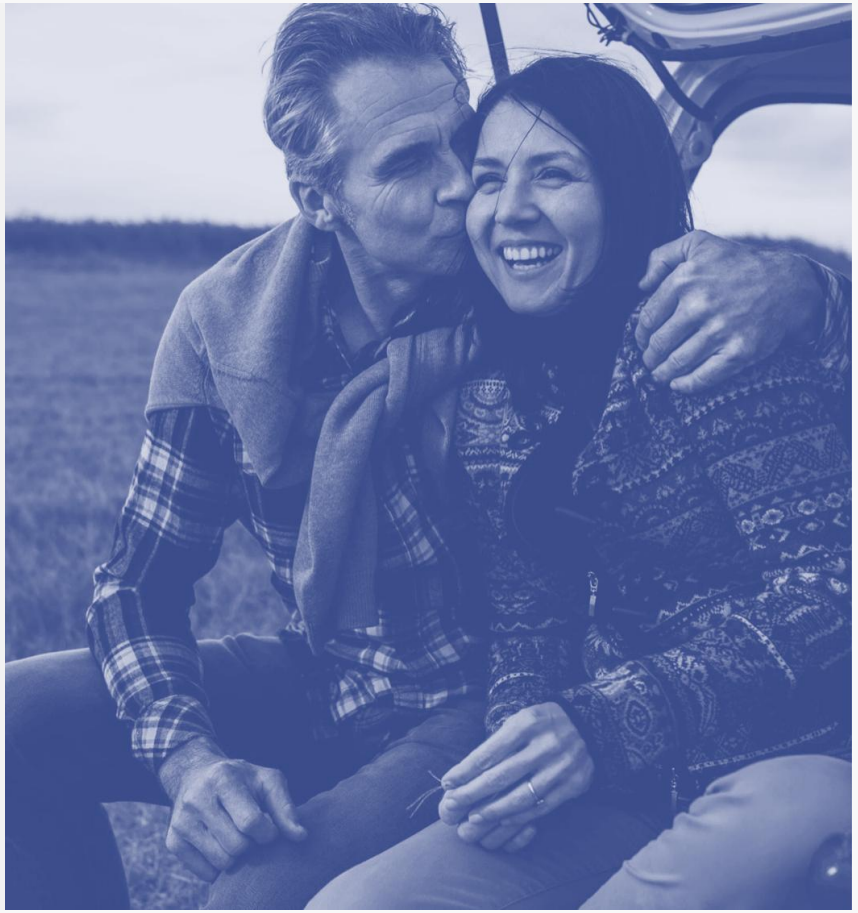
### Commercial Infrastructure Established

- 600+ pharmacies via Symbion / TerryWhite Chemmart
- Telehealth integration underway
- Distribution and fulfilment processes operational

[1] APCC 2025 Case Series (ASX: 25 Aug 2025) [2] Performance-Related ED Observations (ASX: 2 Feb 2026)

# Why LTR Pharma Can Win in the ED Treatment Market

- **Clinically differentiated product:** SPONTAN demonstrates ~5x faster absorption versus oral PDE5 tablets
- **Intranasal delivery** bypasses first-pass metabolism, enabling rapid systemic exposure
- **Real-world validation:** 1,000+ prescriptions under the Australian TGA Special Access Scheme
- **Efficient regulatory strategy** via the FDA 505(b)(2) pathway
- **Strategic partnerships supporting development and commercialisation** (Aptar, Mayne, EBOS/Symbion)
- **Potential early U.S. market entry** via personalised medicine (503A) pathway while advancing toward **FDA approval**



# US Market Strategy

## Dual Pathway Approach

### Primary Value Pathway – FDA 505(b)(2)

- Pre-IND meeting completed with FDA
- Agreed development framework
- Phase II PK study underway
- Single pivotal Phase III Safety and Efficacy study required
- CMC and human factors programme progressing with Aptar
- Designed to support NDA submission under the 505(b)(2) pathway

### Complementary Commercial Pathway – ROXUS (503A)

- Progressing commercial discussions with U.S. personalised medicine pharmacies and telehealth
- Intended to support early market presence
- Generates commercial experience and real-world insights
- Complementary to the FDA regulatory programme

### FDA Regulatory Program Check Points

- ✓ Pre-IND Meeting
- ✓ CMC, Non-clinical, Clinical
- ◔ Non-Clinical Program (toxicology)
- ◔ Phase II interim data reported
- ○ Phase III Safety & Efficacy
- ○ NDA submission
- ○ FDA Review

# Portfolio Overview and Development Focus

## Validated Platform Supporting Multiple Indications


### Lead Clinical Program

SPONTAN ROXUS

*Intranasal Sprays for Erectile Dysfunction*

- TGA Early Access – ACTIVE
- FDA 505(b)(2) regulatory pathway
  - Phase II PK Study – interim data released
  - 503A Commercial Discussions Progressing

### Early Development

**OROFLOW – Platform Expansion**

*Intranasal Spray for Oesophageal Motility Disorders (OMD)*

- Pre-clinical / proof-of-concept Stage
- Evaluating additional intranasal indications
- Capital prioritised to lead program

### 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

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# Strategic Execution

## Milestones, Partnerships and Regulatory Progress

# Global Co-Development Agreement Aptar Pharma

## Strategic partnership driving regulatory success and market readiness

### Combination product expertise

- Co-development agreement with Aptar Pharma (Nasdaq)
- VP7 multidose nasal spray platform
- Integrated drug-device development programme

### Regulatory and development

- Extractables study completed
- Leachables study underway
- Human factors studies progressing
- Supporting FDA combination product requirements

### Strategic significance

- Global supply and FDA expertise
- Alignment with 505(b)(2) development pathway
- Established pharmaceutical partner

# Financial Position

## Disciplined capital management supporting clinical and commercial execution

**Cash in Bank**
$24.1 million

**Quarterly Operation Cash Outflow**
$1.8 million

**Debt Position**
Zero debt

### Funded Value Inflection Points

**Completion of Phase II PK Study**
- Interim data reported; final results Q3 CY2026

**Human factors programme**
- Underway

**Non-clinical toxicology programme**
- Progressing

**US Market Entry Preparations** — Ongoing

**Funded to deliver near-term clinical milestones**

Source: Appendix 4C for quarter ended 31 March 2026. Cash figures in Australian Dollars.

# Key Milestones

## Executing across clinical, regulatory and commercial programmes

### Achieved

- Phase II PK interim data reported
- Pre-IND meeting completed with FDA endorsement
- Extractables study completed — all compounds below ICH thresholds
- 1,000+ prescriptions under TGA early access
- Clinical data published in European Journal of Pharmaceutical Sciences

### Near-Term (H1 2026)

- Human factors study completion
- Leachables study completion
- Progression of commercial discussions in support of entering the U.S. personalised medicine (503A) pathway

### Development Progression (H2 2026+)

- Full Phase II data set
- Animal toxicology completion
- Phase III planning
- OROFLOW® proof-of-concept progression
- Strategic partnership discussions

**$24.1M cash | Zero debt | Supporting key clinical and regulatory milestones**

# Why Invest in LTR Pharma

## Clinical proof. Contracted partners. Funded to deliver

### Clinical Differentiation

- SPONTAN / ROXUS demonstrates 5x faster absorption at half the dose versus oral PDE5 tablets, reinforced by Phase II interim data confirming rapid onset and consistent safety in adult and ≥65 populations.

### Clear and Efficient Regulatory Pathway

- Advancing via the FDA 505(b)(2) framework following successful Pre-IND engagement, requiring a single Pivotal Phase III study.

### Early Validation and U.S. Strategy

- 1,000+ prescriptions under Australia's SAS programme supporting prescriber adoption.
- Dual U.S. approach: FDA pathway complemented by potential personalised medicine (503A) entry.

### Capital and Strategic Position

- $24.1M cash, zero debt, disciplined capital allocation.
- Partnerships with Aptar (Nasdaq), Mayne (ASX), and EBOS/Symbion (ASX).



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