



# Lead nasal spray portfolio

Bell Potter Healthcare Conference  
November 2025



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# Executive Summary

## LTR Pharma

Late-Stage Pharmaceutical Platform with Validated Early Market Access



### Rapidly commercialising SPONTAN® and ROXUS®

First-in-class rapid, on-demand nasal spray treatments for Erectile Dysfunction (ED)



### SPONTAN

Now available under TGA's Special Access Scheme (SAS), generating real-world evidence to support full commercial rollout and upcoming FDA Phase II clinical study (Q1 2026)



### ROXUS

Targeted for H1 2026 launch in the U.S., addressing the personalised medicine market for ED



### Clinically validated platform

Demonstrating rapid onset and consistency – supporting expansion into multiple indications



### Growing pipeline

Additional SPONTAN® variants under development for ED and new indications, price points, including OROFLOW® for oesophageal motility disorders

# Investment Highlights

LTR Pharma positioned in a clear gap in the market



## Multiple path to market

- ▶ SPONTAN® active in Australia via SAS
- ▶ ROXUS® targeting US personalised medicine H1 CY2026
- ▶ Regulatory approvals expanding market access



## Compelling pivotal pharmacokinetic study data

- ▶ 5x faster absorption than oral tablets



## Blockbuster market with issues

- ▶ Existing PDE5 inhibitors have a high discontinuation rate due to poor efficacy and side effects



## Blue chip partners

- ▶ Aptar Pharma: Strategic Co-development partner - Nasdaq listed;
- ▶ Mayne Pharma: Commercial manufacturing partner (CMO) - ASX listed
- ▶ Symbion – Australian distributor, owned by ASX listed EBOS Group



## Multiple upcoming milestones

- ▶ SPONTAN Phase II PK Study
- ▶ ROXUS launch H1 CY 2026
- ▶ ROXUS® development completed
- ▶ Growing Online Prescribing
- ▶ SPONTAN Animal Tox Study
- ▶ Published data
- ▶ Partnership discussions
- ▶ OROFLOW® development for OMD

# Understanding the Market Need

A significant healthcare challenge affecting relationships and quality of life

 **50%** Stop purchasing PDE5 tablets<sup>1</sup>

 **60%** Of men over 45 experience ED<sup>2</sup>

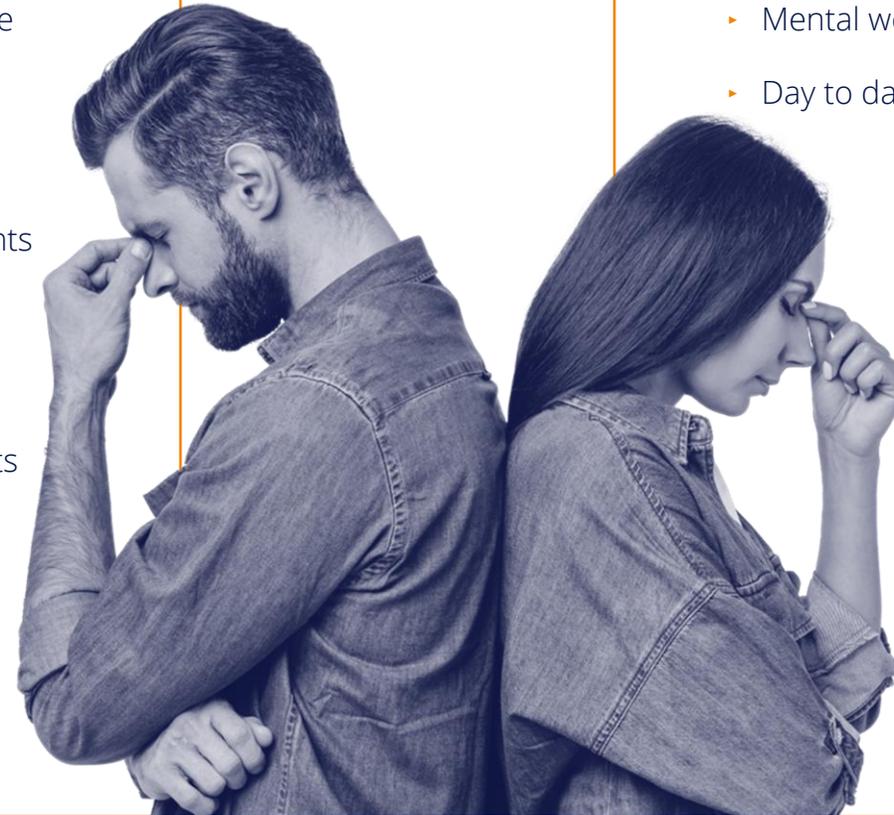
 Growing prevalence with age impacts quality of life

## 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%**

# Prevalence In Key Markets

As risk factors become more prevalent, so does ED

Global ~322m men by 2025



# Current Treatments

## Oral PDE5 inhibitors & SPONTAN<sup>®</sup> 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
<b>Sildenafil</b>	Viagra	1 hour+	1998	Yes
<b>Tadalafil</b>	Cialis	1 hour+	2003	Yes
<b>Varendafil</b>	Levitra, Staxyn	1 hour+	2003	Yes
<b>Avanafil</b>	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.

# Nasal Administration

Delivery mechanism can solve many of issues facing PDE5 inhibitors

## Advantages vs oral administration



**More rapid**  
onset of action



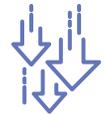
**Less active**  
pharmaceutical  
ingredients required



**Higher rate**  
of absorption



**Less drug degradation**  
due to bypassing the  
digestive system



**Lower adverse**  
reactions



# SPONTAN<sup>®</sup>

## Pivotal Pharmacokinetic Study

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

- ▶ SPONTAN<sup>®</sup> nasal spray achieved rapid absorption and faster onset of action compared to oral PDE5 inhibitors.
- ▶ SPONTAN<sup>®</sup> delivered similar bioavailability (Cmax) at half the dose of oral PDE5 inhibitors.
- ▶ Significantly faster (Tmax) with SPONTAN<sup>®</sup> in as little as 9 min (avg. 12 min) vs oral (56 min) - longest 2.5 hours.
- ▶ Confirmed safety and tolerability profile of SPONTAN<sup>®</sup> vs oral dosing PDE5 Inhibitors.
- ▶ SPONTAN<sup>®</sup> demonstrated more consistent dosing than oral PDE5 Inhibitors.
- ▶ Data to be used in regulatory filings in US, Australia and other key markets.

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

# In-Market NOW

## Commercial Platform Active: Growing Prescriber Network

### 1. JV with Restorative Health Clinic (RHC)

- ▶ RHC – experts in treating ED and early adopters of SPONTAN
- ▶ Online bookings, consults, men's health education, telehealth solutions and prescribing SPONTAN on
- ▶ <https://rshealth.com.au> and <https://makehardeasy.com.au>

### 2. Men's Health Downunder (MHDU)

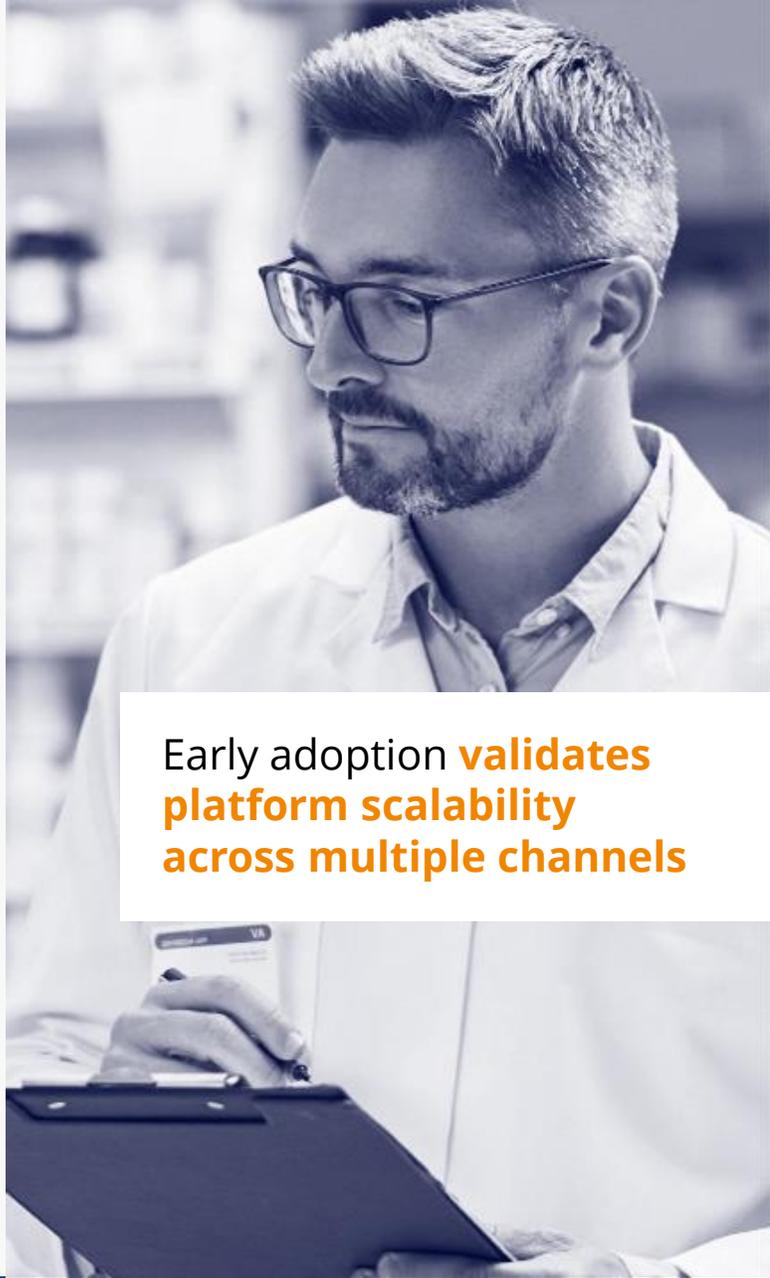
- ▶ Australia's largest men's health pharmacy clinic network
- ▶ Significant referral network of GPs, urologists, and sexual health clinics
- ▶ Online telehealth appointment / SPONTAN Nasal Spray prescribing on
- ▶ <https://menshealthdownunder.com.au>

### 3. Kangaroo Point

- ▶ Specialist GP Men's Health Services
- ▶ Online telehealth appointments on
- ▶ <https://kangaropointmedicalcentre.com.au>

### 4. Pharmacy Networks

- ▶ Symbion pharmacy network of over 3900 pharmacies
- ▶ Terrey White Chemmart nationwide



Early adoption **validates platform scalability across multiple channels**

# US Commercialisation

## Multiple Active Routes to Market

### ROXUS > Early Market Entry via Personalised Medicine

- ▶ ROXUS to be available via 503(a) personalised medicine pathway
- ▶ Market entry with 1<sup>st</sup> sales targeted for H1 CY2026
- ▶ Focus on urology/men's health prescribers and telehealth
- ▶ Builds US brand, relationships, and real-world use case data
- ▶ Accesses \$6B+ US personalised healthcare market (2025), independent of SPONTAN FDA timeline



### SPONTAN® > Broad Market Expansion

- ▶ FDA 505(b)(2) pathway
- ▶ FDA Approval enables broad market expansion
- ▶ Benefits from ROXUS commercialisation in the market
- ▶ Phase II PK study, enrolling Q1 2026 and then progressing to Phase III Safety and Efficacy study



# 2025-2026

## Key Milestones

Calendar Year

Q1 2026

Phase II Clinical Study enrolment

ROXUS Development Completed

Human factor study completion

H1 2026

 1<sup>st</sup> US Sales

Phase II completion and data read out

2026

Published data

OROFLOW development

Partnerships discussions

Animal Toxicology Program

# Growing Pipeline of Novel Nasal Spray Treatments

## Validated Platform Supporting Multiple Indications

Indication/ Program	Pre-clinical	Proof of Concept	Phase 1 (PK study)	Phase 2 (PK study)	Phase 3
<b>Erectile Dysfunction (ED)</b>					
<b>SPONTAN</b> / TGA early access	Available now				
<b>ROXUS</b> / FDA 503(a) Personalised Medicine	Current	Launch in US via personalised healthcare market			
<b>SPONTAN</b> / FDA 505(b)(2)	Completed	Completed	Completed	Current	Planned
<b>Expanding Pipeline &amp; Strategic Investments</b>					
OROFLOW	Completed	Current			
omega-3	Current	Planned			

Platform scalability demonstrated through successful clinical validation

# Corporate Structure

ASX Code

LTP

Shares on issue	181.61M
Market Capitalisation	A\$79.91M
Cash and cash equivalents (30 June 2025)	A\$31.84M
Top 20 shareholder percentage	43.22%

As of 7 November 2025



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