



# SPONTAN

Fast-acting nasal spray  
treatment for erectile  
dysfunction



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# Executive Summary

**Bringing to market the first nasal spray for ED**



## **LTR Pharma is commercialising SPONTAN® and ROXUS®**

A 'First-in-Class' rapid, on-demand nasal spray treatment for Erectile Dysfunction (ED)



## **Successful pivotal pharmacokinetic study**

Demonstrated rapid onset and consistency of delivery



## **Disrupting the blockbuster PDE5 inhibitor market**

Targeting to be the first PDE5 inhibitor nasal spray registered in market estimated to reach US\$6.0B in 2028



## **Clear commercial pathway**

Expedited pathway to market – SPONTAN in market now in Australia under Early Access Scheme – ROXUS targeting US entry in 1H CY26. FDA 505(b)(2) pathway being progressed in parallel



## **Additional nasal spray products planned for development**

Plan for additional SPONTAN® products for ED, different variations, price points and other indications in 2025



# Investment Highlights

LTR Pharma positioned in a clear gap in the market



- SPONTAN® is available now in Australia via TGA's special access scheme
- Roxus® accelerating US entry through personalised medicine
- Regulatory approvals progressing with the FDA and TGA



- 5x faster absorption than oral tablets
- 111.8% dose-normalised bioavailability of traditional treatments
- 155.6% higher peak concentration with only half the dose



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



- **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



- Expanding product portfolio
- Manufacturing Scale up
- Roxus Product Development completion
- Growing Online Prescribing
- Regulatory studies & meetings
- Published data
- Continued partnerships/licensing

# 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
- ▶ 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

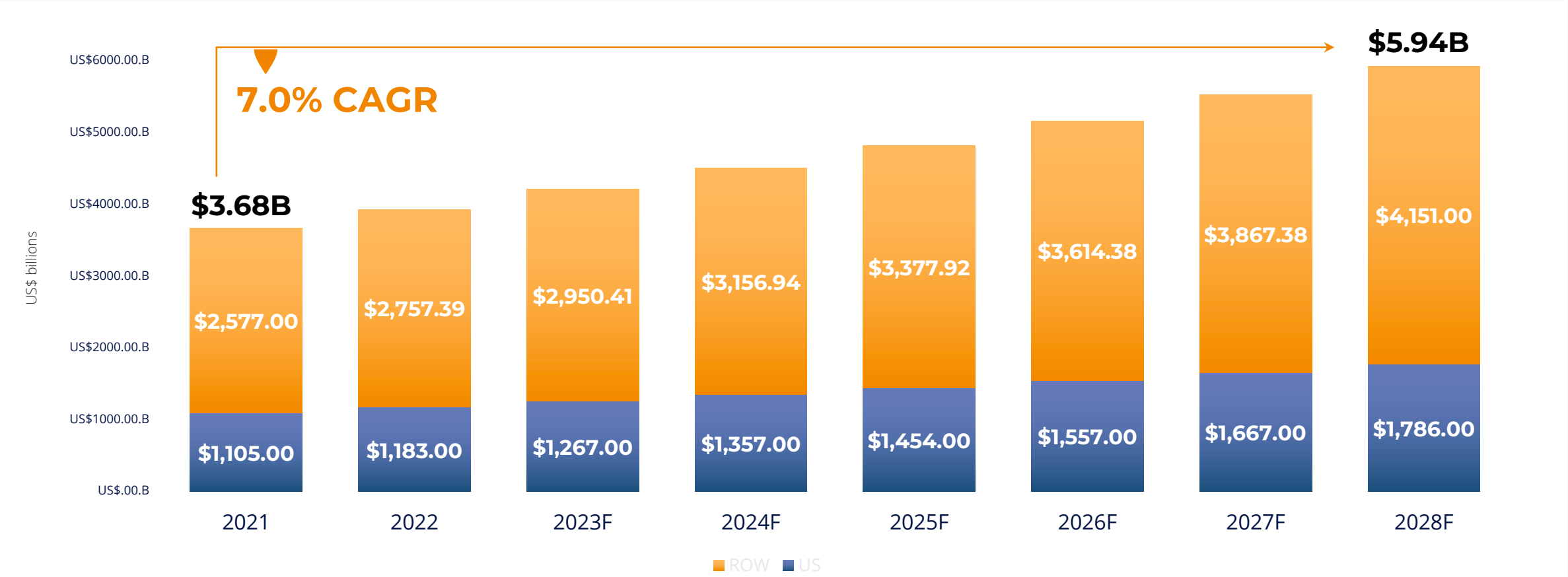
As risk factors become more prevalent, so does ED

Global ~322m men by 2025



# Estimated Market Size

Forecasted to be US\$6.0B market by 2028



**Online sales expansion:** Majority of ED medication is now sold through online channels

# Accelerating US Market Entry

## Dual-Track Strategy

### Path 1: SPONTAN® > Full Approval

**SPONTAN**

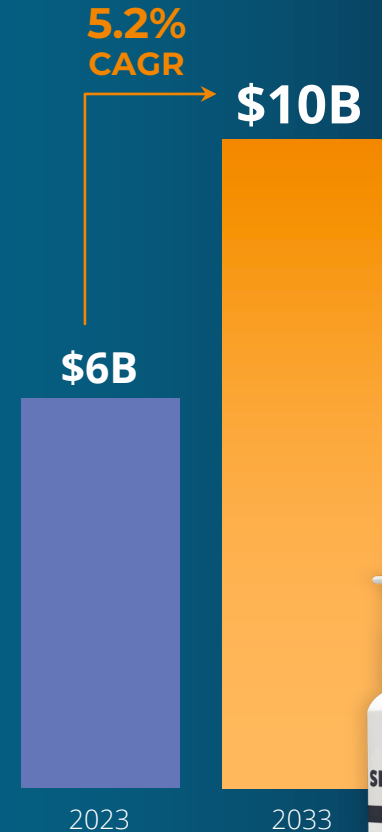
- ▶ FDA 505(b)(2) pathway
- ▶ Real-world patient and prescriber insights
- ▶ Full market authorisation upon approval
- ▶ Target: Mass market

### Path 2: ROXUS > Personalised Medicine

**ROXUS**

- ▶ US 503(a) pathway
- ▶ Early market entry in 2026
- ▶ Target: Personalised healthcare sector
- ▶ Accessing \$6B US compounding market
- ▶ Revenue generation from the US market 2026
- ▶ Building prescriber relationships and brand recognition
- ▶ Enabling US based KOL and Health Care Professionals engagement
- ▶ Establishing strategic commercial footprint in world's largest market

## Personalised Care Compounding Pharmacy Market\*





# Expedited path to market

Seeking FDA and TGA approvals in the US & Australia and then other key markets



Targeting a 505 (b)(2) approval pathway regulatory strategy, on basis it is “repurposing” of an existing approved drug

Previous approval of oral tablet Vardenafil by the FDA would allow inclusion of existing safety and efficacy clinical and nonclinical data

## Milestones for FDA

1. Preparation of regulatory documentation
2. E&L Studies (with Aptar)
3. Human Factors Studies (with Aptar)
4. Animal Toxicology
5. Pharmacokinetic (PK) Clinical Trial
6. Safety and Efficacy Trial
7. New Drug Application (NDA)



ROXUS® is expected in the US market 1H CY26



Targeting Category 1 - Type F Application process is expected to be available to the Company

Given the existing safety profile of Vardenafil, the regulatory pathways for repurposed drugs allows for expedited application

## Milestones for TGA

1. Preparation of regulatory documentation
2. Targeting pre submission meeting (Q2 CY 25)



SPONTAN® is available to patients via the TGA's SAS and APS for unmet needs

# In-Market NOW

## Growing Telehealth and Online Prescribing via TGA's Early Access Programs

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

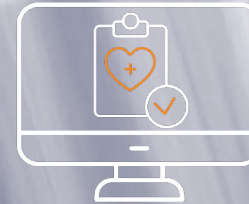
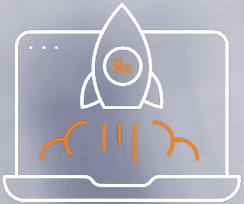
### Kangaroo Point

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



# Capturing the Digital Health Revolution

Building tomorrow's ED treatment platform today



## US\$140B<sup>+</sup>

market size by 2032\*

- ▶ Digital health revolution transforming patient care
- ▶ 22% CAGR outpacing traditional healthcare\*

- ▶ Positioning SPONTAN® and ROXUS® for online access
- ▶ 1st test market in Australia early 2025 – replicate success in US 2026
- ▶ telehealth integration and electronic prescribing
- ▶ Partner with other online prescribers in 2025/26

### Online Prescribing Q1 CY25

- ▶ Platform development – Q4 CY24
- ▶ Test rollout in Q1 CY25
- ▶ Direct patient access through experts in ED

### US Prescribing 1H CY26

- ▶ Roxus® development – Q4 CY25
- ▶ Test rollout in Q1 CY26
- ▶ Direct patient access 1H CY26

- ▶ Specialist sexual health practitioners providing personalised care
- ▶ Comprehensive medical assessment, not just medications
- ▶ Telehealth platform complementing established clinical expertise
- ▶ Privacy-focused patient solution



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