



SPONTAN

Fast-acting nasal
spray treatment for
erectile dysfunction



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Introduction

Executive Summary

Bringing to market the first nasal spray for ED



LTR Pharma is commercialising SPONTAN®

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



Successful Phase I Human Proof of Concept

Indicating 6x faster than oral administration of PDE5 inhibitors (i.e. Viagra)



Funded to progress the business

Raised \$7 million as part of its ASX IPO December 2023



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

Commenced SPONTAN's bioequivalence clinical study to expedite US and Australian regulatory filings within 1-2 years, enable early Australian market access, and clinical package preparation for licencing and regulatory discussions.

Investment Highlights

LTR Pharma positioned in a clear gap in the market



Expedited path to market

Repurposed drugs with novel delivery methods can reach the market in the US and Australia quickly



Promising proof of concept

Demonstrated 6x faster than oral administration of competitor PDE5 inhibitors



Blockbuster market with issues

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



Blue chip partners

Commercial manufacturing partnership with ASX listed Mayne Pharma



Multiple upcoming value inflection points

Key pivotal clinical trial in progress now;
Preparations for early access in Australia
Potential partnerships/licensing



LTR Pharma

Industry overview

ED and its Causes

A major factor in
relationship breakdown

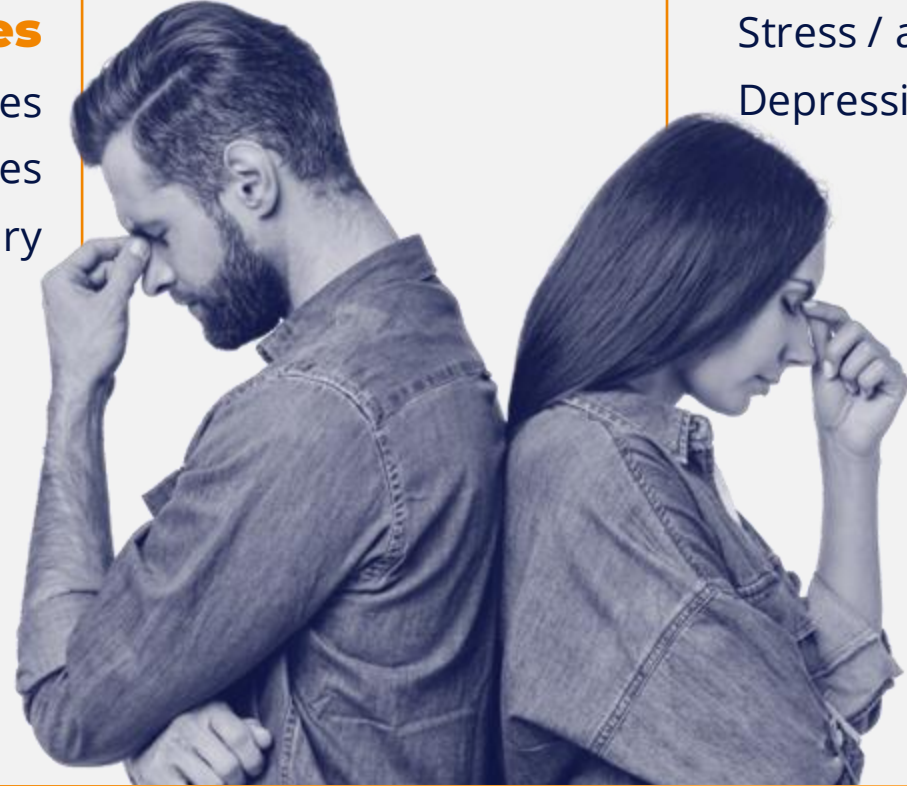
Erectile dysfunction (ED) is a medical condition wherein an individual is unable to get or keep an erection for satisfactory sexual intercourse

Physical causes

Cardiovascular issues
Hormonal issues
Injury

Psychological causes

Relationship problems
Stress / anxiety
Depression



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

Gold standard are PDE5 inhibitors which have several drawbacks

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 PDE5 inhibitors



Does not work
for 30-35% of patients



Long response time of
1 hour + affects spontaneity

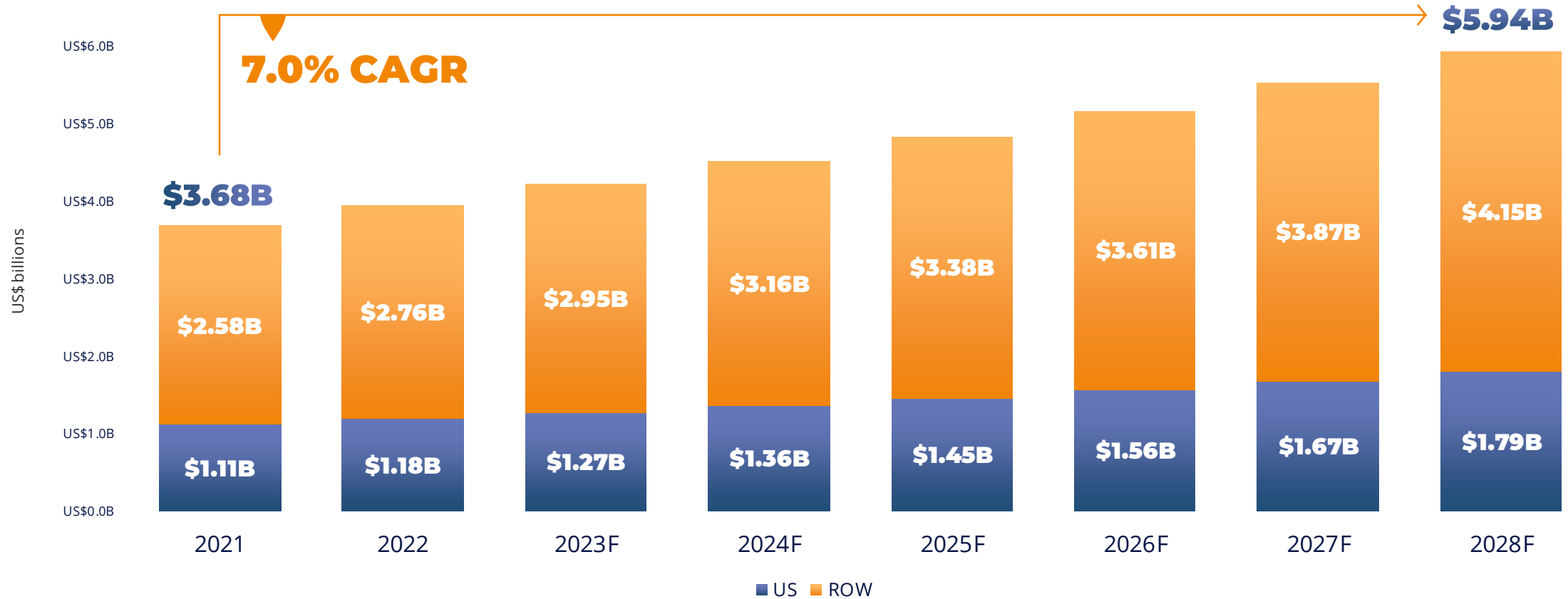


Adverse reactions
in 35% of patients

= High discontinuation rate

Estimated Market size

Forecast to be US\$6.0B market by 2028



The search for a new branded option

Significant opportunity for branded assets



Opportunity to capture market share at higher margins



Generics have grown to 700M* units annually

- ▶ 'Rapid erosion of branded volume following patent expiries
- ▶ No product differentiation in a fragmented market
- ▶ Low margins for currently marketed generics



Branded drugs

- ▶ Commands significantly higher price points / margins
- ▶ Demonstrates pricing power and demand for premium brands



SPONTAN as branded asset

- ▶ Market participants seeking new branded options to differentiate in the marketplace
- ▶ Opportunity to capture market share through improved therapy profile with higher margins than generics

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





LTR Pharma

Company Overview

Company History

Progressed company substantially derisking the proposition



SPONTAN[®] Overview

A novel delivery of a proven ED drug

Drug repurposing

Focused on changing the method of administration of Vardenafil, an existing and approved drug already in global markets since 2003



Intra-nasal delivery

Intra-nasal Vardenafil formulation, SPONTAN[®], is fast acting and low dose compared with the incumbent oral ED treatment products on market



Expedited path to market

Builds on Vardenafil's safety and efficacy data package with upcoming bioequivalence study in advance of FDA and TGA meetings



Competitive Advantages

**A faster acting
lower dose drug
formulation
with a better
safety profile**

	SPONTAN	Sildenafil	Tadalafil	Avanafil	Vardenafil
Mode of delivery	Nasal	Oral	Oral	Oral	Oral
Low dosage	✓	✗	✗	✗	✗
Rapid absorption	✓	✗	✗	✗	✗
Quick onset of action	✓	✗	✗	✗	✗
Higher bioavailability	✓	✗	✗	✗	✗
Fewer side effects	✓	✗	✗	✗	✗

Proof of concept Trial data

Confirmation of rapid onset effect



12 patients in a randomised, single dose cross-over study of males aged between 24-45



The delivery of the SPONTAN nasal spray solution **used a 100 ul per dose nasal spray** device manufactured by Aptar Pharma



The trial compared **Vardenafil HC1 as SPONTAN®** nasal spray (4 mg) and as an oral tablet (10 mg)



Confirmation rapid onset of effect for SPONTAN of **~10 mins compared to 60 mins** of existing oral ED drugs

The trial was published
in May 2023 with
The Journal of Sexual
Medicine confirmed



Peak concentration of drug in patient within 10 mins suggesting patient will respond shortly after administration



No severe adverse events



An acceptable safety profile

Pivotal Bioequivalence clinical study

**Results expedite NDA filing
& ARTG registration in the US & Australia**

Trial objective – study has commenced

To assess the relative bioavailability of Vardenafil following administration of SPONTAN[®] as a nasal spray compared to Vardenafil tablets

Subjects

Recruitment commenced in February of 18 healthy adult male subjects

Trial design

A single-dose, randomised, open-label, 2-treatment, 2-period crossover study of SPONTAN[®] nasal spray (5 mg Vardenafil: a single 2.5 mg spray in each nostril) compared to Vardenafil tablets (10 mg Vardenafil)

Outcome

Successful completion of the bioequivalence trial provides data for early access scheme in Australia and potential partnering and licensing deals



Expedited path to market

LTR requires FDA and TGA approval to operate in the US & Australia



FDA

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**

Targeting NDA filing at beginning of CY 2025



TGA

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**

Targeting filing at middle of CY 2025

SPONTAN

SPONTAN® may be made available to patients via the TGA's SAS or APS on an as needs basis and subject to the **relevant regulatory framework**

Upcoming Key Milestones

Multiple value inflection points in Calendar Year 2024



Pivotal clinical trial

- ▶ Recruitment
- ▶ Dosing
- ▶ Results



Early access use Australia



Pre submission meetings with FDA & TGA



2nd Nasal Spray product



Licensing / Partnering discussions

Financial Summary

Strong Funding to Commercial Outcomes

(ASX:LTP) Public Market Overview (15 March 2024)

Share Price	A\$0.32
52-week range	A\$0.25 – A\$0.41
Market Cap	A\$46.00M
Cash equivalents (31 December 2023)	A\$6.01M
Top 20 shareholder percentage	57.94%



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