LTR Pharma

SPONTAN

Fast-acting nasal spray treatment for erectile dysfunction

Investor Overview | March 2024

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LTR Pharma

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

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Industry overview

ED and its Causes

A major factor in relationship breakdown

Erectile disfunction (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

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

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

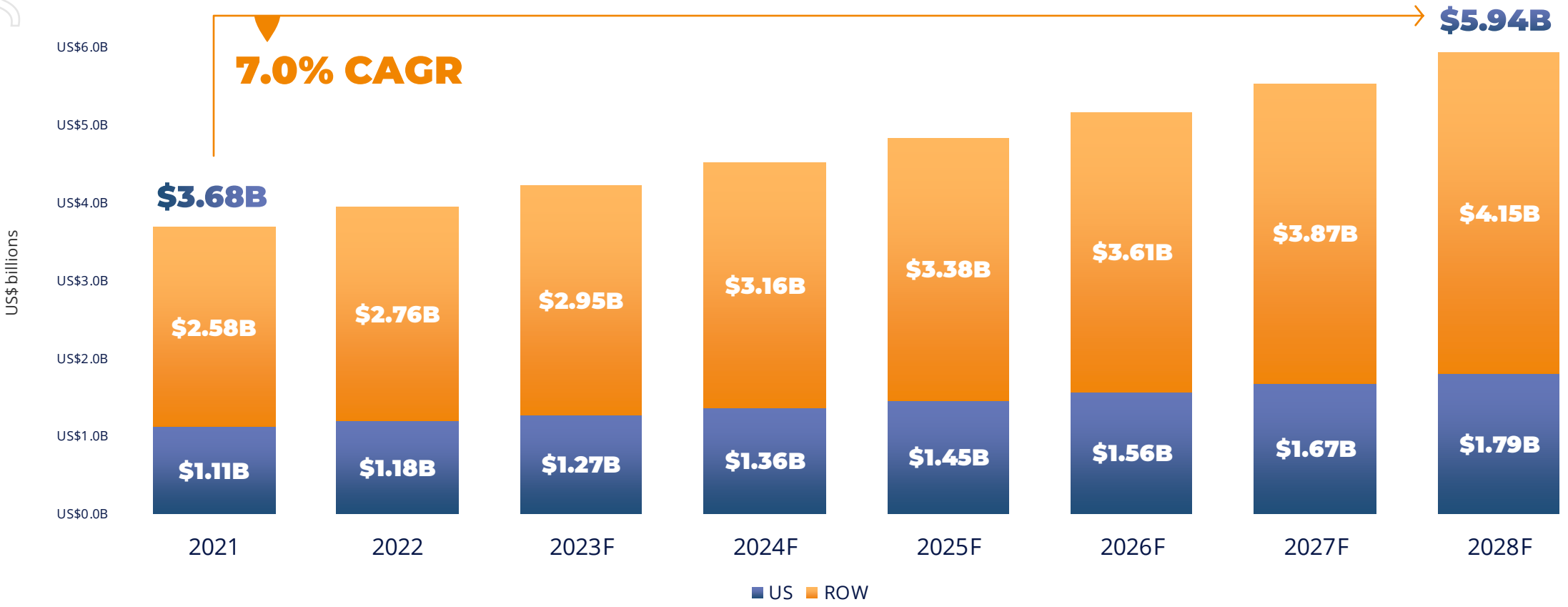
Long response time of 1 hour + affects spontaneity

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

Note: * 700M units claimed and does not include self-funded purchases

Nasal Administration

Delivery mechanism can solve many of issues facing PDE5 inhibitors

Advantages vs oral administration

More rapid onset of action

Higher rate of absorption

Lower adverse reactions

Less active pharmaceutical ingredients required

Less drug degradation due to bypassing the digestive system

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Company Overview

Company History

Progressed company substantially derisking the proposition

2020 - 2021

Acquired **exclusive worldwide rights** to develop, manufacture and market SPONTAN® through a licence agreement with SDS

Establishment of the **Scientific Advisory Board in the field of Men's Health**

Validated the US FDA's 505(b)(2) regulatory pathway through an **expert regulatory review**

2022

Optimised delivery and commercial development of its nasal formulation with drug stability data from nasal spray device developer

Adopted Mayne Health as a **high-quality commercial manufacturing partner** to product SPONTAN to GMP standards

Received **early acceptance from IP Australia** for our product trademark name "SPONTAN"

2023

Initial Public Offer (IPO)
Successfully completed an oversubscribed IPO. The Company listed on the ASX on 11 December 2023 and raised AU $7M.

2024

Developed the protocol for its bioequivalence study, and gained ethics approval

2020 Proof of Concept trial results published in 2023 in The Journal of Sexual Medicine

Completed packaging studies for final commercial product ahead of bioequivalence study and commercial sales

Conducted crucial derisking activities before moving into clinical development

Pivotal Trial Commences
Commenced SPONTAN's bioequivalence clinical study to expedite regulatory filings, enable early Australian market access and preparation for licensing and partnering discussions

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 (US)

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 (AUS)

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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