LTR Pharma

SPONTAN

Fast-acting nasal spray treatment for erectile dysfunction

Corporate Presentation | 28 November 2024

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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 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 – FDA 505(b)(2) pathway in the US; Special Access in the Australian marketplace as an unmet need

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

Expedited path to market

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

Compelling pivotal pharmacokinetic study data

470% 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

Multiple upcoming milestones

Expanding product portfolio
Manufacturing Scale up
Online Prescribing
Regulatory studies / meetings
Potential partnerships/licensing

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Market Problem & Opportunity

Understanding the Market Need

A significant healthcare challenge affecting relationships and quality of life

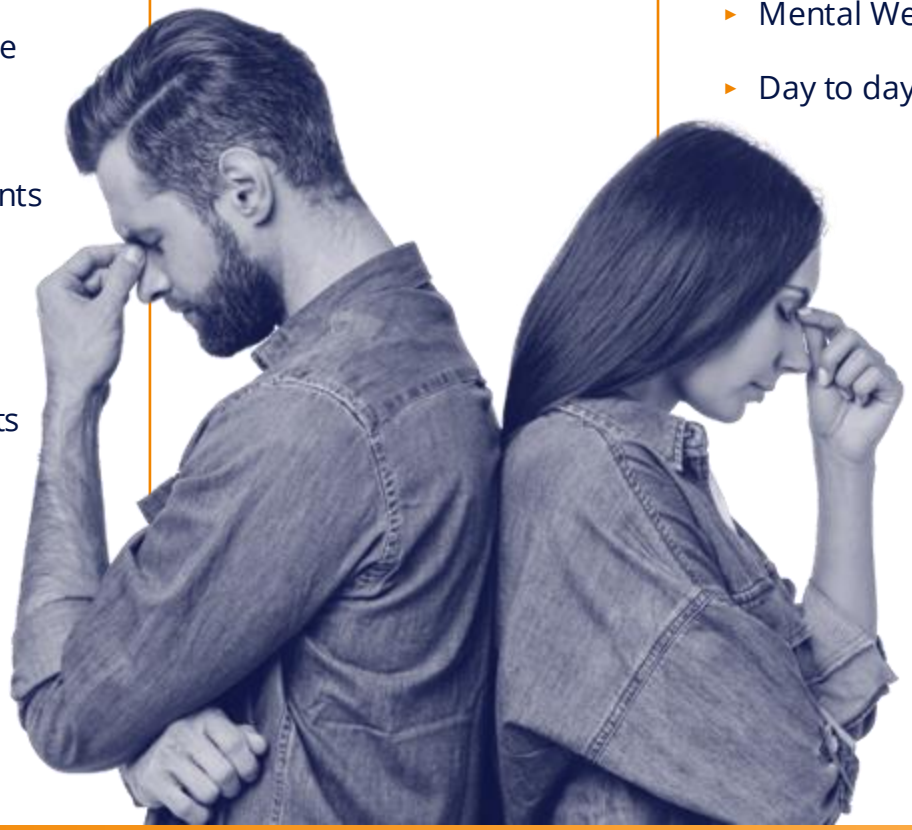
50% Stop purchasing PDE5 tablets[1]

60% Of men over 45 experience ED[2]

Growing prevalence with **age impacts quality of life**

Physical causes

- Heart Health
- Hormone Balance
- Diabetes
- Medical Treatments
  - Hair loss
  - Weight loss
  - Antidepressants



Psychological Impact

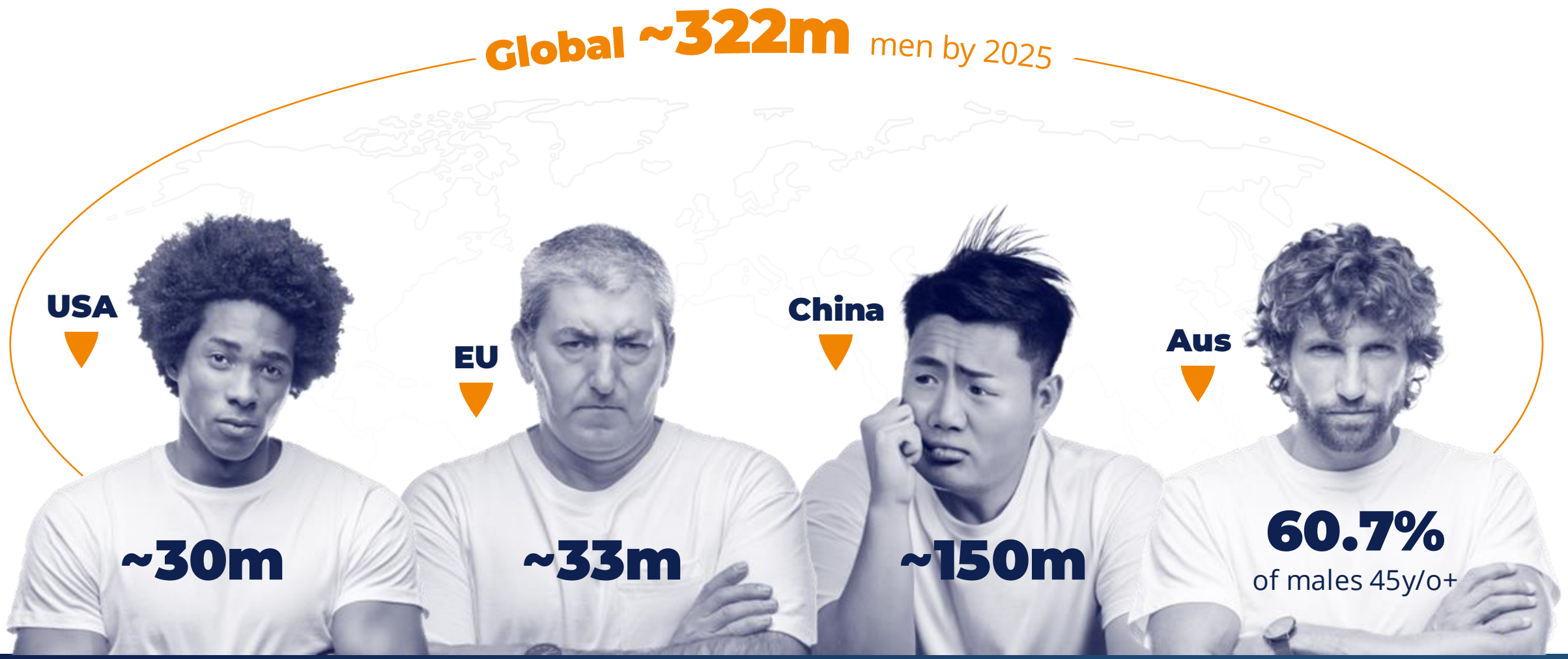
- Relationship problems
- Mental Wellbeing
- Day to day stress

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

Prevalence in key markets

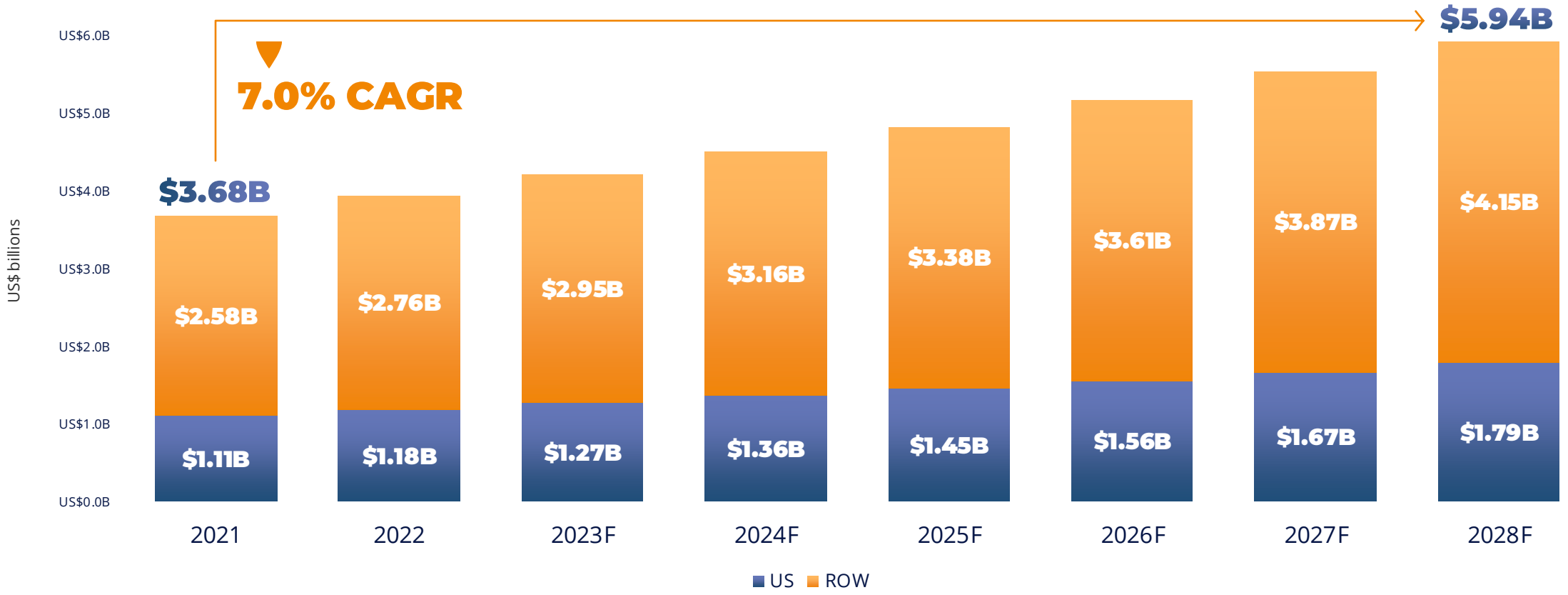
As risk factors become more prevalent, so does ED



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

Estimated Market size

Forecast to be US$6.0B market by 2028



Online sales expansion

Majority of ED medication is now sold through online channels

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 up to 35% of patients

= High discontinuation rate

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 a 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

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Solution

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Nasal Administration

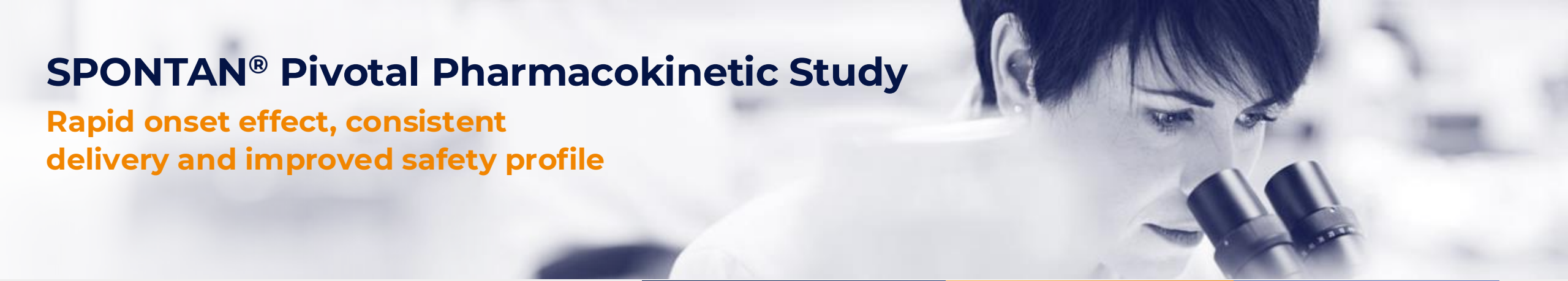
Delivery mechanism can solve many of issues facing PDE5 inhibitors

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

SPONTAN® Pivotal Pharmacokinetic Study

Rapid onset effect, consistent delivery and improved safety profile



- SPONTAN® nasal spray achieved rapid absorption and faster onset 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.
- Data to be used in regulatory filings in US, Australia and other key markets.

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 Fast-Acting Solution

Transforming ED treatment with speed and confidence

Speed Matters

Peak concentration in as little as
9 mins, 470% faster than oral tablets
Average onset: 12 mins vs 56 mins

Less is More

Half the dose
Similar effectiveness
Better delivery consistency

Proven Safety

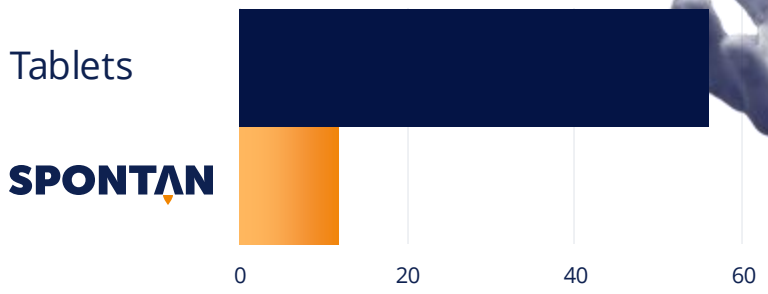
Validated safety profile
No severe events
Clinically proven

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
(minutes)



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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

2023

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

Initial Public Offer (IPO)
Completed an oversubscribed IPO. Listed on the ASX on 11 December 2023 and raised AU $7M.

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

Adopted Mayne Health as a **commercial manufacturing partner** to produce SPONTAN® to GMP standards

2024

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

Study results released
SPONTAN®'s clinical study to support regulatory filings, enable early Australian market access and preparation for licensing and partnering discussions

Australian Early Access Scheme commencement
Provision of SPONTAN® for unmet needs

Co-development with Aptar Pharma
Partnership for the commercialisation of SPONTAN in the USA and other key markets

Online Platform (Q1 CY25)
Increasing access through telehealth

Global Co-Development Agreement - Nasdaq listed Aptar Pharma

Strategic partnership driving regulatory success and market readiness

Partnership Foundations

- Focuses on commercialisation in the US and other key markets
- Utilises Aptar's VP7 model nasal spray technlogies
- Potential to develop additional next-gen nasal spray products

Strategic Benefits

- Access to Aptar's comprehensive regulatory services
- Supports 505(b)(2) expedited pathway
- De-risks regulatory submissions
- Foundation for future collaborations with global leader in nasal spray products

Regulatory & Development Activities

Extractables & Leachables (E&L) studies

- Validating FDA compliance standards
- Essential for regulatory submission

Human Factors Study program

- Evaluating user experience
- Optimising product usability

Regulatory Documentation

- FDA-compliant instructional videos
- Instructions For Use (IFU) development
- Supporting educational materials


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Clear path
to market

Expedited path to market

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

(US)

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**

(AUS)

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**

Milestones for FDA

- Preparation of regulatory documentation
- E&L Studies (with Aptar)
- Human Factors Studies (with Aptar)
- Pre-IND submission meeting (Q1 CY 25)*
- Animal Toxicology studies
- New Drug Application (NDA)

Milestones for TGA

- Preparation of regulatory documentation
- Targeting pre submission meeting (Q2 CY 25)

SPONTAN

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

*FDA may require additional studies. To be confirmed after Pre-OND meeting

TGA Early Access Pathways

Building real-world evidence to support regulatory submissions

Current Programs

Special Access Scheme (SAS)

- (Individual patient access)

Authorised Prescriber Scheme (APS)

- (Blanket approval per provider)

Strategic Benefits

- Early patient access before full approvals
- Real-world data collection
- Aids in future product education, product training preparations, future variations to develop and future product launches

Strategic Value Drivers

Clinical Validation

- Supporting regulatory submissions
- Strengthening partnership discussions
- Building successful clinical patient profiles

Market Development

- Building prescriber awareness before full approvals
- Aids in greater market uptake post-approval*
- Foundation for digital/online access

Fast acting → **Meeting unmet needs** → **Growing network** → **Building online prescribing** Q1 2025

*Ref: Patil, S. (2024). PMC4763516. Early access programs: Benefits, challenges, and key considerations for successful implementation.

Commercialisation Pathways

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

1 Australia's TGA SAS & APS early access

- The successful clinical study results outlining the strong efficacy and safety profile enables access in Australia through the TGA's early access schemes, SAS and APS
- Early access schemes permit the supply of SPONTAN through healthcare professionals on a compassionate use basis

2 Partnering / Licensing

- Exploration of partnership/licensing opportunities with significant global pharmaceutical industry participants has begun
- LTR Pharma will advance these discussions in conjunction with progressing regulatory approval pathways

3 Sales post Regulatory Approval

- Targeting an expedited path to market in the US, Australia and other key markets
- Following regulatory approval, SPONTAN will be a new branded erectile dysfunction drug leveraging online sales channels and partner networks

Capturing the Digital Health Revolution

Building tomorrow's ED treatment platform today

Explosive Growth of telehealth

US$140B+ **market size by 2032***

Digital health revolution transforming patient care

22% CAGR outpacing traditional healthcare*

Strategic Position

Positioning SPONTAN for online access

1st test market in Australia early 2025 – replicate success globally

telehealth integration and electronic prescribing

Partner with other online prescribers in 2025

Commercial Pathway

Online Prescribing Q1 CY25

Platform development – Q4 CY24

Test rollout in Q1 CY25

Direct patient access through experts in ED

Key Differentiators

Specialist sexual health practitioners providing personalised care

Comprehensive medical assessment, not just medications

Telehealth platform complementing established clinical expertise

Privacy-focused patient solution

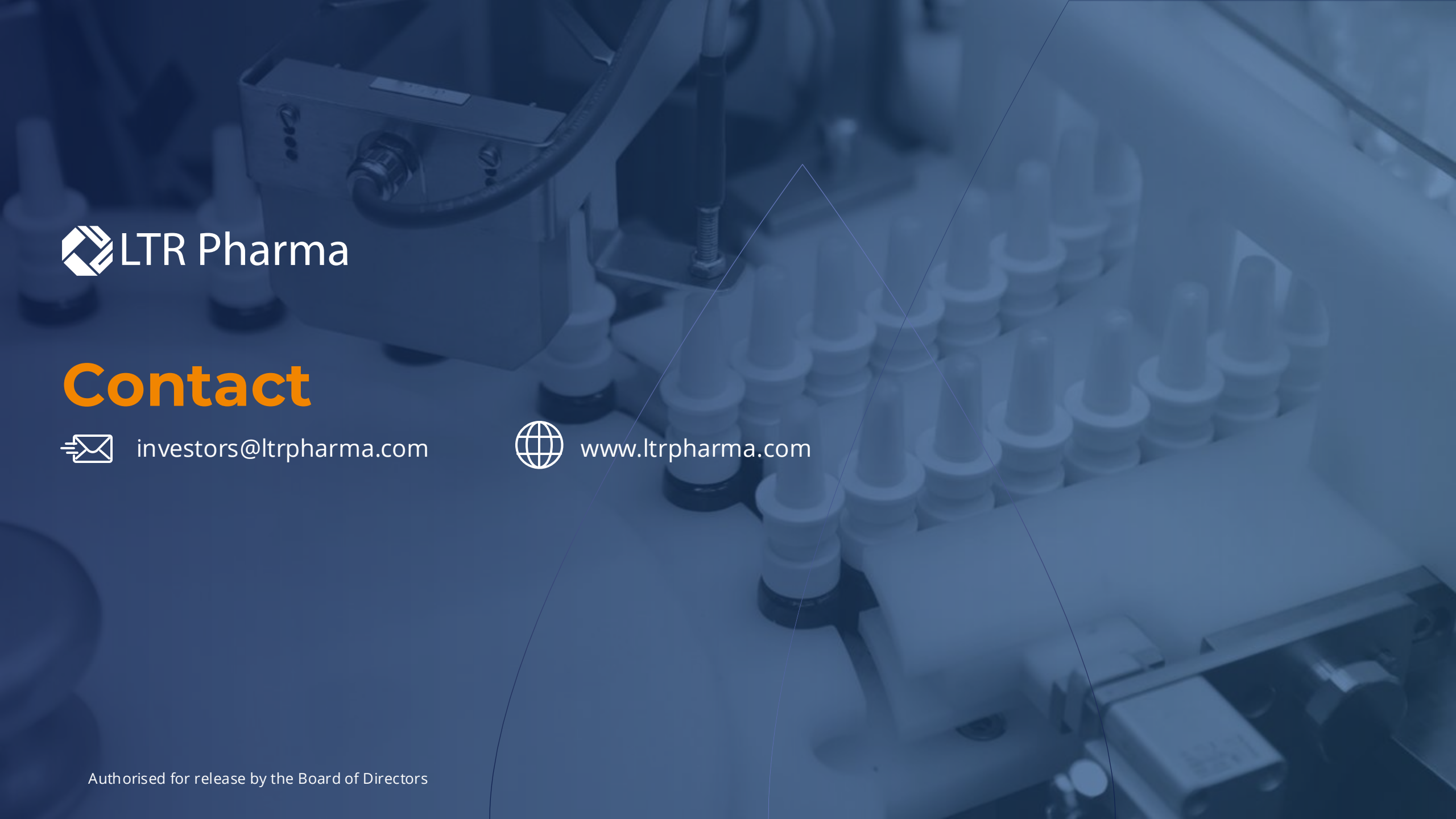
* Source: Fortune Business Insights, Global Telehealth Market Report 2024-2032

Corporate Overview

Strong Funding to Commercial Outcomes

(ASX:LTP) Public Market Overview (14 November 2024)	
Share Price	A$1.36
52-week range	A$0.24 – A$2.15
Market Cap	A$209.17M
Cash equivalents (31 July 2024)	A$12.05M
Top 20 shareholder percentage	52.59%

1. As at market close Thursday, 14 November 2024



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Contact

investors@ltrpharma.com

www.ltrpharma.com

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