LTR Pharma

SPONTAN

Fast-acting nasal spray treatment for erectile dysfunction

Capital Raising Presentation | 10 December 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

Capital Raising

LTR Pharma has raised A$25.0 million via Placement which will fully fund the Company through until the end of 2026, including commercial launch in the US

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]

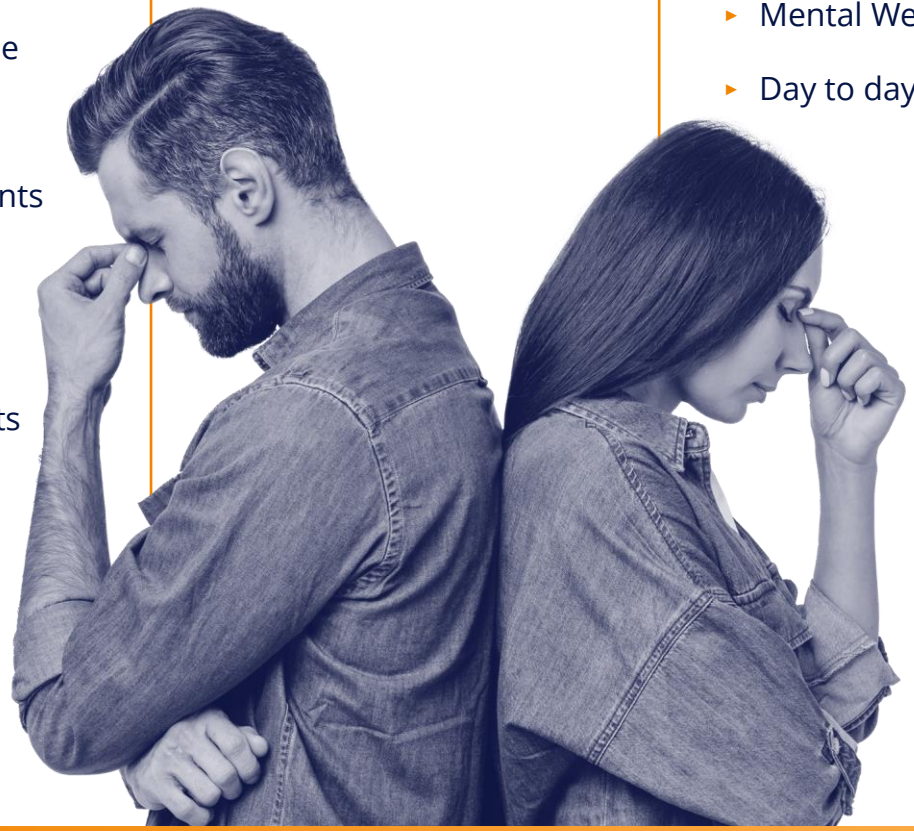
Growing prevalence with **age impacts quality of life**

Physical causes

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

Psychological Impact

- Relationship problems
- Mental Wellbeing
- Day to day stress

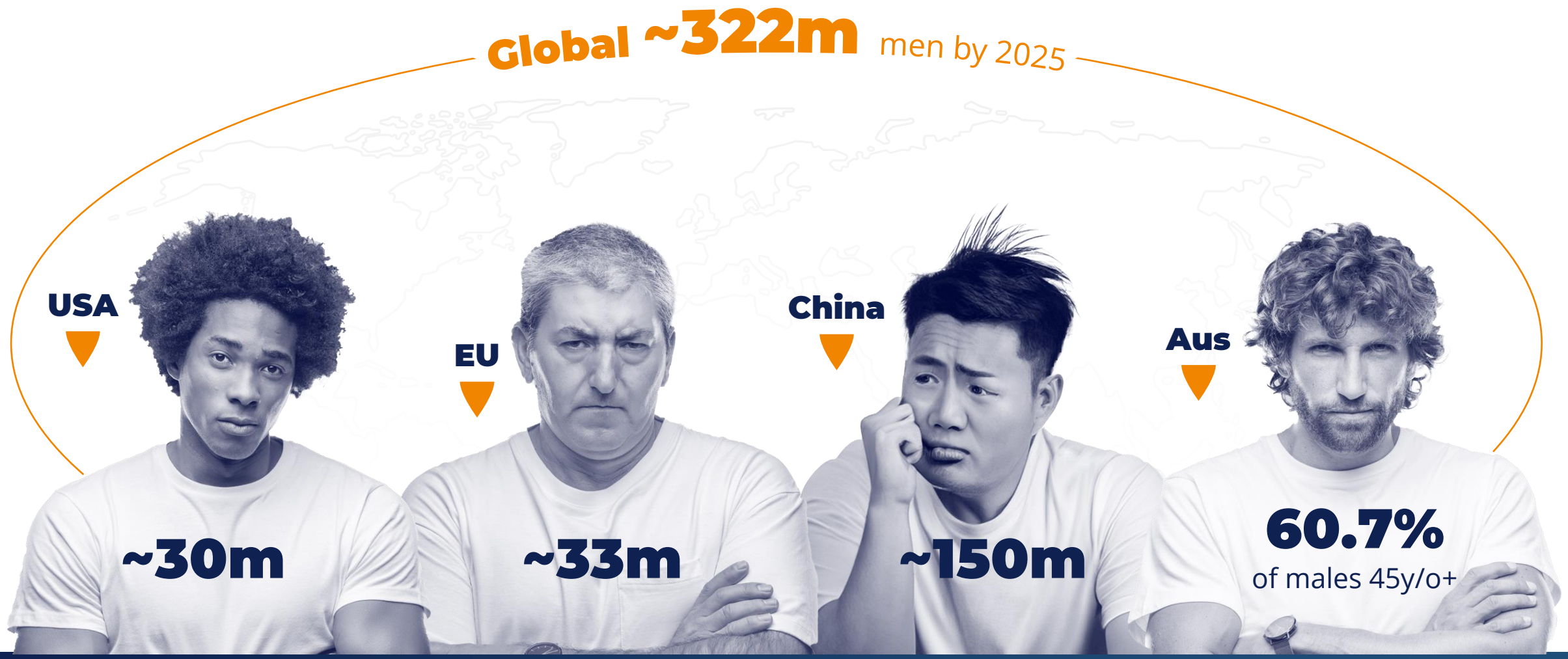


Prevalence of ED with individuals with cardiovascular risk factors, hypertension and diabetes, is reported as high as 50%

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

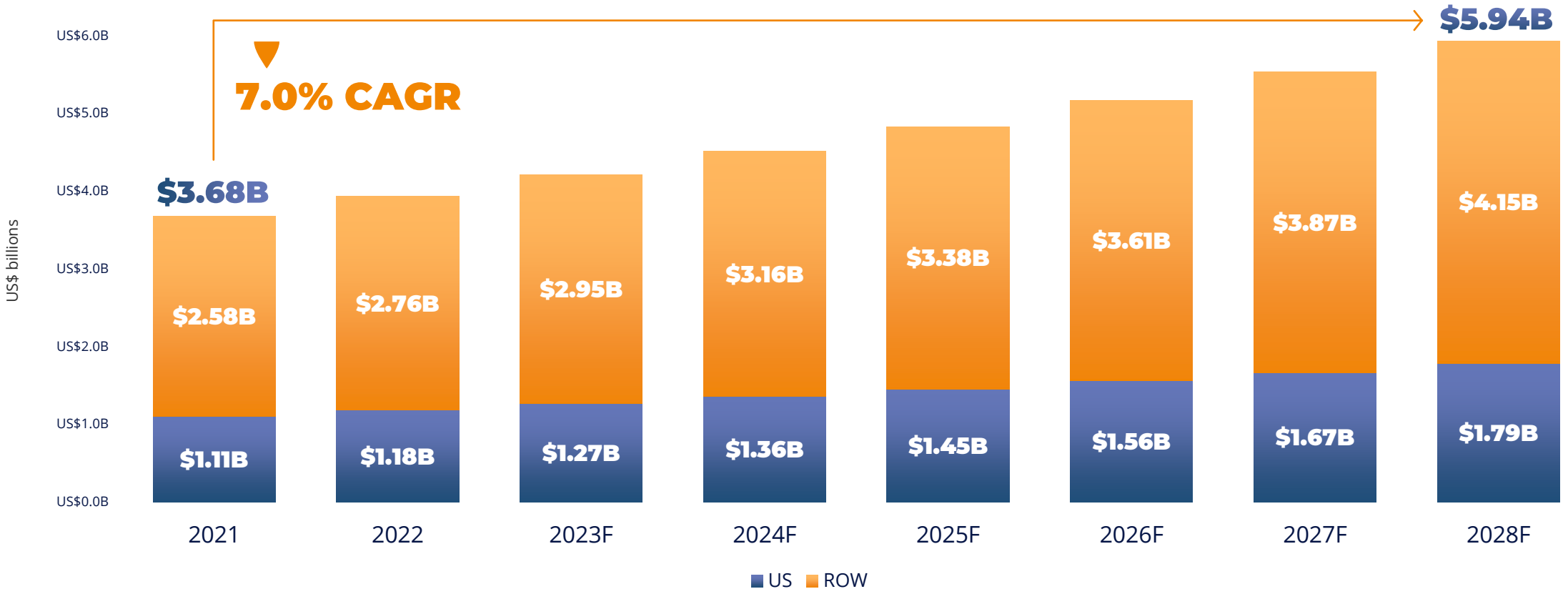
As risk factors become more prevalent, so does ED



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

SPONTAN

Nasal Administration

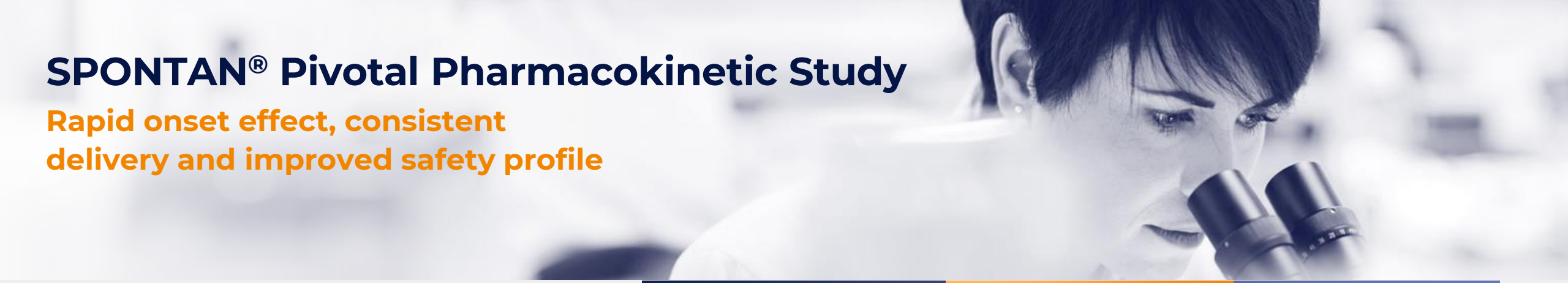
Delivery mechanism can solve many of issues facing PDE5 inhibitors

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

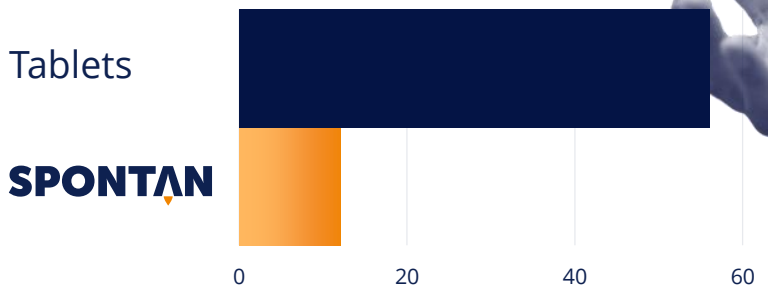
Validated safety profile
No severe events
Clinically proven

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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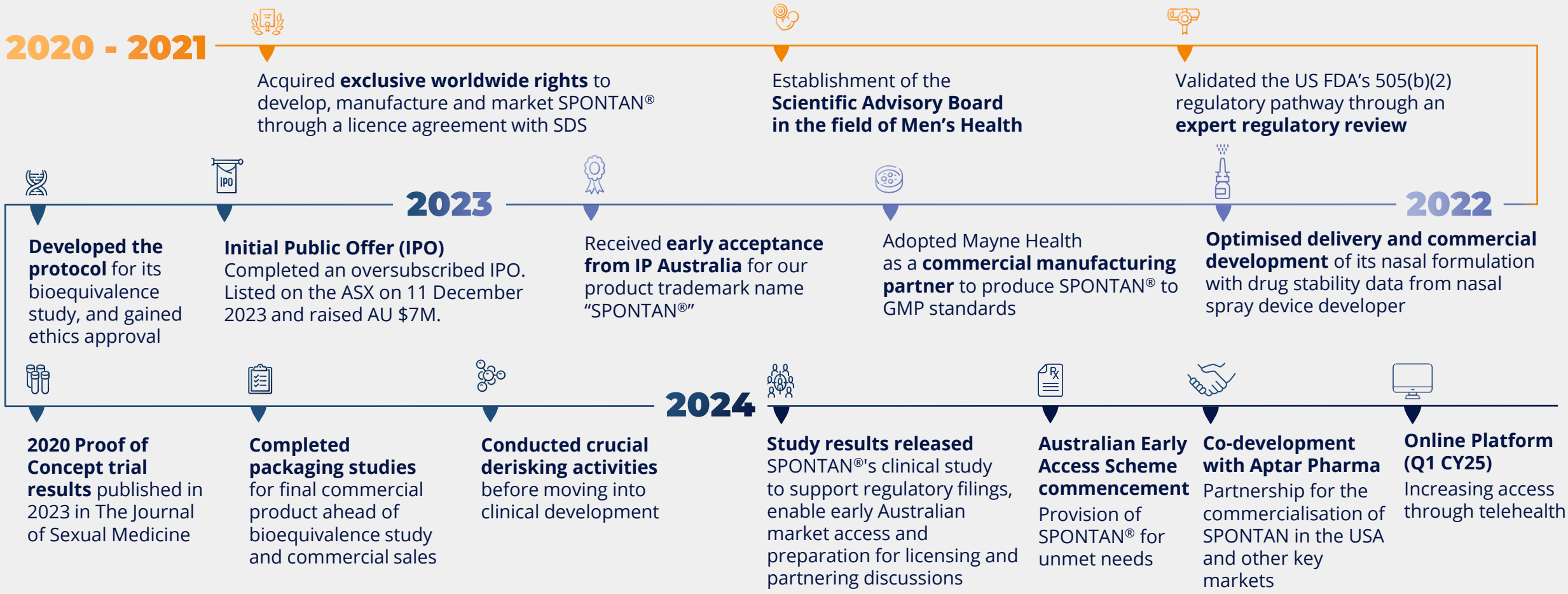
Company Overview

Company History

Progressed company substantially derisking the proposition



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

Multiple Value Inflection Points

Key milestones and catalysts anticipated in H1 2025 (CY)

Early Access Expansion in Australia

- Online prescribers, additional men's health experts
- General Practitioner awareness engagement

Expanding Product Portfolio Range

- SPONTAN derivatives
- New indications

Regulatory/Marketing Studies

- Chemistry, manufacturing and Control (CMC) studies (i.e., extractable and leachables)
- Animal toxicology studies
- Clinical – registration/marketing study
- Investigator initiated led studies (i.e. post prostate cancer, etc)

Strategic Development

- FDA/TGA pre-submission meetings
- USA manufacturing & distribution
- Potential partnerships/licensing

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Offer Overview and Timetable

Capital Raising Overview

LTR Pharma has raised approximately $25.0 million via a Placement which will fully fund the Company through until the end of 2026, including commercial launch in the US

Placement	• A single tranche Placement to sophisticated and institutional investors to raise approximately $25.0 million under the company's existing placement capacity per LR7.1 and LR7.1A ("**Placement**") • Approximately 27.2 million new fully paid ordinary shares in LTP ("**New Shares**") to be issued under the Placement, representing approximately 17.7% of LTP current shares on issue
Offer Price	• New Shares issued under the Placement will be issued at a price of $0.92 per new share ("**Offer Price**"), representing a: – 12.4% discount to the last close price on Thursday 5th December 2024 of $1.05 – 19.8% discount to the 5-day VWAP up to and including Thursday 5th December 2024 of $1.147 – 21.6% discount to the 10-day VWAP up to and including Thursday 5th December 2024 of $1.173
Ranking	• All new shares issued under the Offer will rank equally with existing LTP shares from the date of issue
Joint Lead Managers	• Bell Potter Securities Limited ("**Bell Potter**") and Alpine Capital Pty Limited ("**Alpine Capital**")

Offer Timetable and Use of Funds

Indicative capital raising timetable[1]	Date (AEDT)
Trading Halt, Bookbuild Opens	Friday, 6th December 2024
Trading Halt Lifted and Announcement of Capital Raising	Tuesday, 10th December 2024
Settlement of Institutional Placement	Friday, 13th December 2024
Allotment of New Shares under Institutional Placement	Monday, 16th December 2024

[1] The timetable is indicative only and subject to change by the Company and Joint Lead Managers, subject to the Corporations Act and other applicable laws.

Use of Funds	A$m
US commercial preparations	$10.5m
Regulatory activities and animal toxicity studies	$2.0m
SPONTAN derivatives and variations development	$1.0m
Marketing studies and website development	$4.0m
Working capital	$6.0m
IR/Costs of offer	1.5
Total	**$25.0m**

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Key Risks

Key Risks

Early clinical state of development	LTP's candidate product has completed a pharmacokinetic clinical trial. No guarantee can be provided that the clinical work will be successful or result in a product approved for use by a regulatory agency and further clinical development may be necessary beyond the pharmacokinetic trial completed by the LTP in order to commercialise LTP's candidate product.
Competition	The biotechnology and pharmaceutical industries are highly competitive, and include companies with significantly greater financial, technical, human, research and development, and marketing resources than LTP. There are companies that compete with LTP's efforts to discover, validate and commercialise therapeutic uses for products or product candidates. LTP's competitors may discover and develop products in advance of LTP and/or products that are more effective than those developed by LTP. As a consequence, LTP's current and future products may become obsolete or uncompetitive, resulting in adverse effects on revenue, margins and profitability. LTP anticipates market exclusivity protection in the United States for SPONTAN® for a period of 3 years subject to receiving regulatory approval by the FDA.
Healthcare insurers and reimbursement	In both domestic and foreign markets, a component of LTP's product sales may depend in part upon the availability and amounts of reimbursement from third party health care payer organisations, including government agencies, private health care insurers and other health care payers such as health maintenance organisations and self-insured employee plans. No assurance can be given that reimbursement will be provided by such payers at all or without substantial delay, or, if reimbursement is provided, that the approved reimbursement amounts will be sufficient to enable LTP to sell its products on a profitable basis.
Reliance on key personnel	LTP currently employs a number of key management and scientific personnel and consultants, and its future depends on attracting and retaining suitably qualified personnel. LTP has included, in its terms of employment, provisions aimed at offering competitive remuneration and incentives, assisting in the recruitment and retention of such key personnel. It has also established contractual mechanisms through employment and consultancy contracts to limit the ability of key personnel to join a competitor or compete directly with the Company. Despite these measures, however, there is no guarantee that LTP will be able to attract and retain suitably qualified personnel, and a failure to do so could materially and adversely affect the Company's business, operating results and financial prospects
Regulatory requirements	LTP plans to seek approval from the US FDA and Australia TGA to commercialise and market its product, as well as equivalent regulatory authorities in other foreign jurisdictions to commercialise in those regions. There is a risk that these regulatory authorities may not approve LTP's proposed regulatory approval application or may require LTP to undertake more trials and cause a delay in the LTP's product launch.

Key Risks Cont.

Product Liability	As with all new biotechnology products, even after the granting of regulatory approval, there is no assurance that unforeseen adverse events or manufacturing defects will not arise. Adverse events could disrupt the supply chain and expose LTP to product liability claims or litigation, resulting in the removal of the regulatory approval for the relevant products and/or monetary damages being awarded against LTP. In that event, the Company's liability may exceed the Company's insurance coverage.
Intellectual Property	There is no guarantee that LTP's intellectual property, whether owned or licensed from others, comprises all of the rights that LTP may require to freely commercialise its product candidates. Patent applications in significant markets have been lodged in respect of LTP's product candidate. However, there is no assurance that those patent applications will result in granted patents in all desired jurisdictions. Further, LTP's intellectual property rights (or the intellectual property rights of third parties licensed to LTP) may be challenged. If these intellectual property rights are ever challenged LTP may not have the funds to oppose the challenge which may have a significant detrimental effect on LTP's operations. Lastly, the Company's right to exploit the nasal delivery of Vardenafil is subject to its licensing arrangements. If these licensing arrangements were to be jeopardised, it could have significant detrimental effects on the Company's business.
Trade secrets	LTP relies in-part on trade secrets, which include information relating to the manufacture, development and administration of its products. While LTP has taken protective measures in that regard, they may not provide adequate protection for those trade secrets. This could erode LTP's competitive advantage and materially harm its business. LTP cannot be certain that others will not independently develop the same or similar technologies on their own or gain access to trade secrets or disclose such technology.
Infringements of third-party IP	If a third party accuses the Company of infringing its intellectual property rights or if a third party commences litigation against LTP for the infringement of patent or other intellectual property rights, the Company may incur significant costs in defending that action, whether or not it ultimately prevails. Costs that the Company incurs in defending third party infringement actions would also include diversion of management's and technical personnel's time.
Disruption of business operations	The Company is exposed to a large range of operational risks relating to both current and future operations. Such operational risks include fraud / dishonesty by its employees or service providers, industrial action or disputes and natural disasters. While the Company endeavours to take appropriate action to mitigate these operational risks and, where the Directors consider it practicable, insure against them, the Company cannot remove all risks of disruption to its operations.

Key Risks Cont.

Dependence on service providers	The Company intends to operate a significant amount of its key clinical activities through a series of contractual relationships with independent contractors and suppliers. The Company relies on and will continue to rely on a number of its contractors for their expertise in manufacture and clinical development. All of the Company's contracts carry a risk that the third parties do not adequately or fully comply with its or their respective contractual rights and obligations.
Currency risk	Revenue and expenditures in overseas jurisdictions are subject to the risk of fluctuations in foreign exchange markets. Accordingly, payment will be made in those countries' currencies, and may exceed the budgeted expenditure if there are adverse currency fluctuations against the Australian dollar.
Contractual and counterparty risks	The Company will have various contractual rights in the event of non-compliance by a contracting party. However, no assurance can be given that contracts will be fully performed by all contracting parties and that the Company will be successful in securing compliance with each contract by the counterparties to its contracts.
Expenditure program and sufficiency of funding	It is possible that LTP's actual expenditure may be more than currently estimated by LTP, depending on the difference in actual costs, require LTP to seek to raise additional funding. LTP has finite financial resources and may need to raise additional funds from time to time to finance the complete development and commercialisation of its products and achievement of its longer-term objectives. LTP's ability to raise additional funds will be subject to, among other things, factors beyond the control of LTP and its board, including cyclical factors affecting the economy and share markets generally.
General risks	LTP also faces many general risks that are outside of its control, including stock market volatility, general economic conditions (such as international and domestic economic activity, inflation and interest rates), taxation, insurance risks, government actions, global events, foreign regulatory structures and laws which may have an impact on LTP's operations.

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