

 LTR Pharma

SPONTAN

Fast-acting nasal spray
treatment for erectile
dysfunction



Investor Update | March 2025

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Executive Summary

Bringing to market the first nasal spray for ED



LTR Pharma is commercialising SPONTAN® and ROXUS®

'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



Multiple path to market

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



Compelling pivotal pharmacokinetic study data

5x 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
- ▶ Symbion – Australian distributor, owned by ASX listed EBOS Group



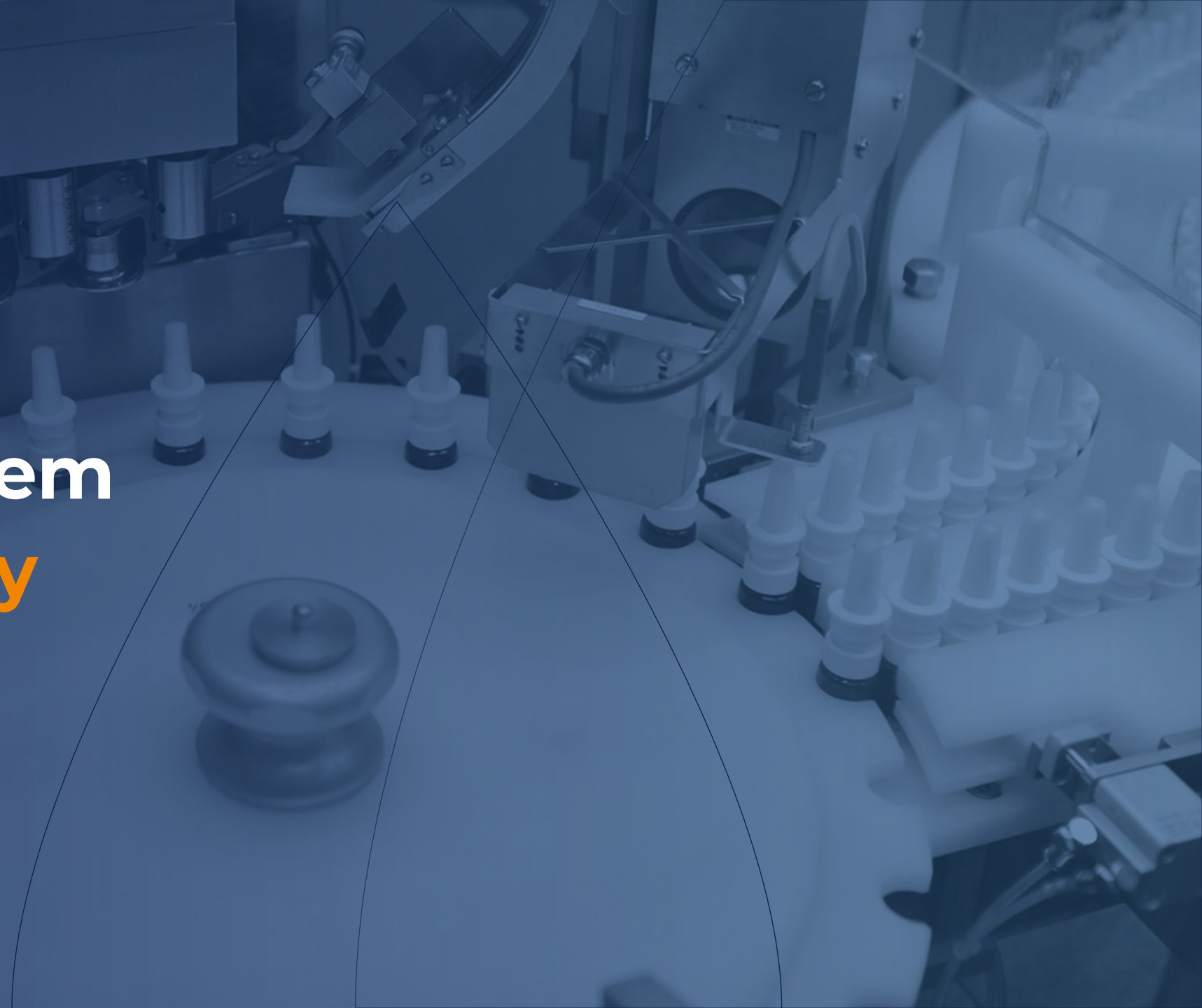
Multiple upcoming milestones

- ▶ Expanding product portfolio
- ▶ Manufacturing Scale up
- ▶ Roxus Product Development completion
- ▶ Growing Online Prescribing
- ▶ Regulatory studies & meetings
- ▶ Published data
- ▶ 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 tablets¹



60% Of men over 45 experience ED²



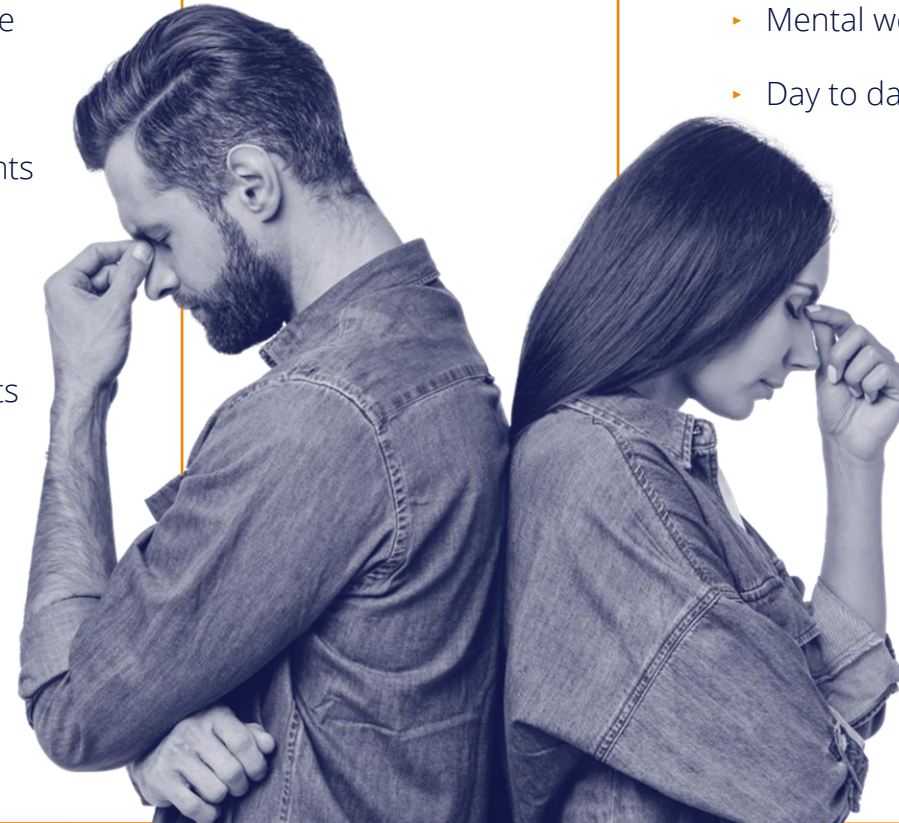
Growing prevalence with age impacts quality of life

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

USA



~30m

EU



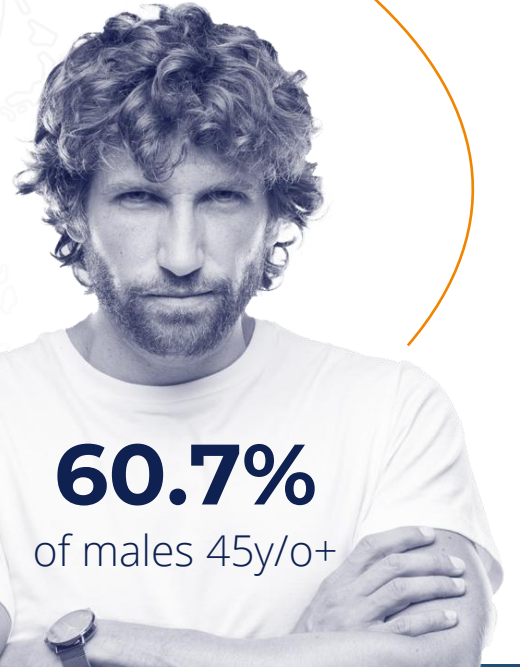
~33m

China



~150m

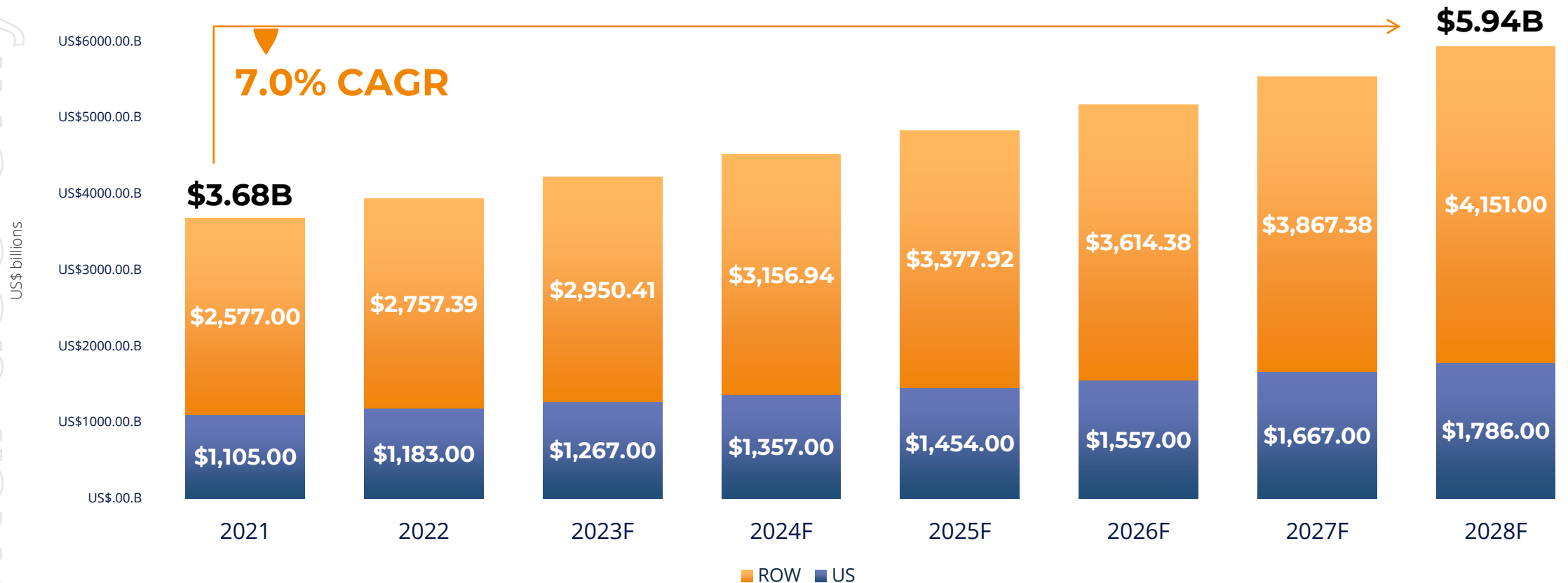
Aus



60.7%
of males 45y/o+

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

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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

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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



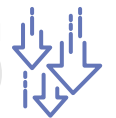
Less active
pharmaceutical
ingredients required



Higher rate
of absorption



Less drug degradation
due to bypassing the
digestive system



Lower adverse
reactions



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 (C_{max}) at half the dose of oral PDE5 inhibitors.
- ▶ Significantly faster (T_{max}) 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
▶ C _{max} (ng/ml).	▶ 13.0	▶ 16.7
▶ T _{max} (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

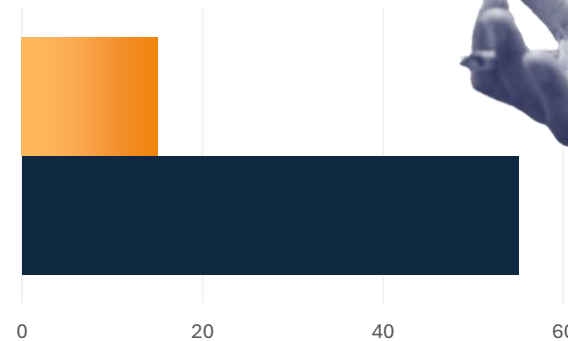
Patients can respond in **as little as 5 minutes**, well before peak concentration is reached*.

*Based on healthcare professional feedback

Time to peak concentration (minutes)

SPONTAN

Tablets



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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**



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



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.

< 2023



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



Adopted Mayne Health as a **commercial manufacturing partner** to product SPONTAN[®] to GMP standards



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

< 2022



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



Conducted crucial derisking activities before moving into clinical development

2024 >



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

2025 >



FDA pre-IND meeting complete
ROXUS Development initiated

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 technologies
- ▶ 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

SPONTAN - FDA Regulatory Milestone

Clear Path Forward

Pre-IND Meeting Completed

- ▶ FDA endorsement of overall development approach
- ▶ Alignment on streamlined clinical development plan
- ▶ Clear understanding of regulatory requirements

Key Development Components

- ▶ Access to Aptar's comprehensive regulatory services
- ▶ One pivotal safety and efficacy clinical trial
- ▶ Multi-dose pharmacokinetic (PK) study
- ▶ Chemistry, Manufacturing and Controls (CMC) plan
- ▶ Non-clinical (toxicology) program

Strategic Advantage

- ▶ Regulatory clarity enhances development efficiency
- ▶ Leveraging Aptar Pharma's established FDA relationships
- ▶ Expert team with track record in 505(b)(2) submissions
- ▶ Potential for global regulatory synergies with multi-market approach

Regulatory Program Check Points



Introducing ROXUS[®]

Personalised ED Care

Development Status

- ▶ Stability testing underway with Australian pharmaceutical partner
- ▶ Completion expected in next two quarters
- ▶ Targeting US market entry in early-mid 2026
- ▶ Initial focus on specialised clinics and personalised care groups
- ▶ Targeting top KOLs in US market



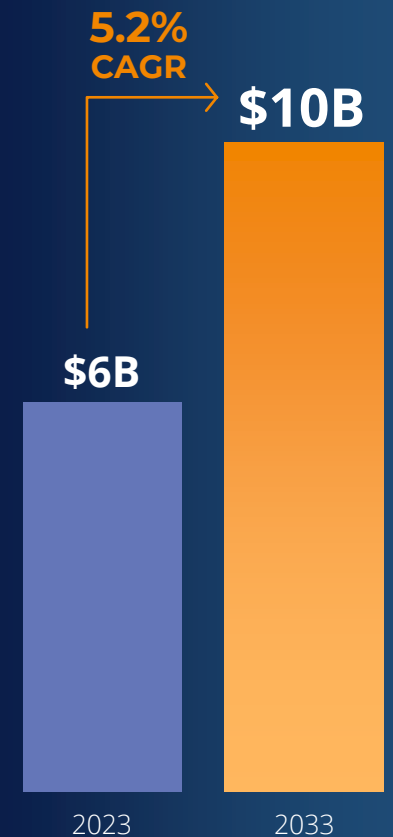
Product Features

- ▶ Vardenafil-based nasal spray
- ▶ Identical active ingredient to SPONTAN[®]
- ▶ Targeting the personalised medicine sector
- ▶ Positioned for fast-acting, on-demand ED relief
- ▶ Leveraging the established safety profile of SPONTAN[®]

Strategic Advantages

- ▶ Early entry into the US market
- ▶ Real-world patient and prescriber insights
- ▶ Market positioning validation
- ▶ Positioned for high growth

Personalised Care Compounding Pharmacy Market*



Accelerating US Market Entry

Dual-Track Strategy

Path 1: SPONTAN® > Full Approval

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

Path 2: ROXUS > Personalised Medicine

- ▶ US 503(a) pathway
- ▶ Early market entry in 2026
- ▶ Target: Personalised healthcare sector
- ▶ Accessing \$6B US compounding market

SPONTAN

ROXUS

- ▶ 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



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**Clear path
to Market**



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://kangaropointmedicalcentre.com.au/>



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. Pharmacokinetic (PK) Study
5. Safety and Efficacy Trial
6. Animal Toxicology study
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)

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

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. Personalised Healthcare Market

- ▶ ROXUS is expected to roll out to commercial pharmacies In 1H CY26
- ▶ LTR Pharma will advance these discussions in conjunction with progressing regulatory approval pathways

3. 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

4. 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



ROXUS to be launched in the US in early 2026 targeting the personalised medicine market

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

Multiple Value Inflection Points

Key milestones and catalysts anticipated in 2025/26

Early Access Expansion in Australia

- ▶ Growing Online prescribers
- ▶ General Practitioner awareness engagement
- ▶ Symbion coming online Q2 CY25
- ▶ Manufacturing Scale ups –bar coding / packaging
- ▶ Clinical data – publications

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)

Expanding Product Portfolio Range

- ▶ SPONTAN® derivatives (Multiple product versions for sale)
- ▶ New indications

Strategic Development

- ▶ FDA/TGA pre-submission meetings
- ▶ USA manufacturing & distribution preparations
- ▶ Potential partnerships/licensing
- ▶ ROXUS development for early US market entry

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