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 tablets[1]

60% Of men over 45 experience ED[2]

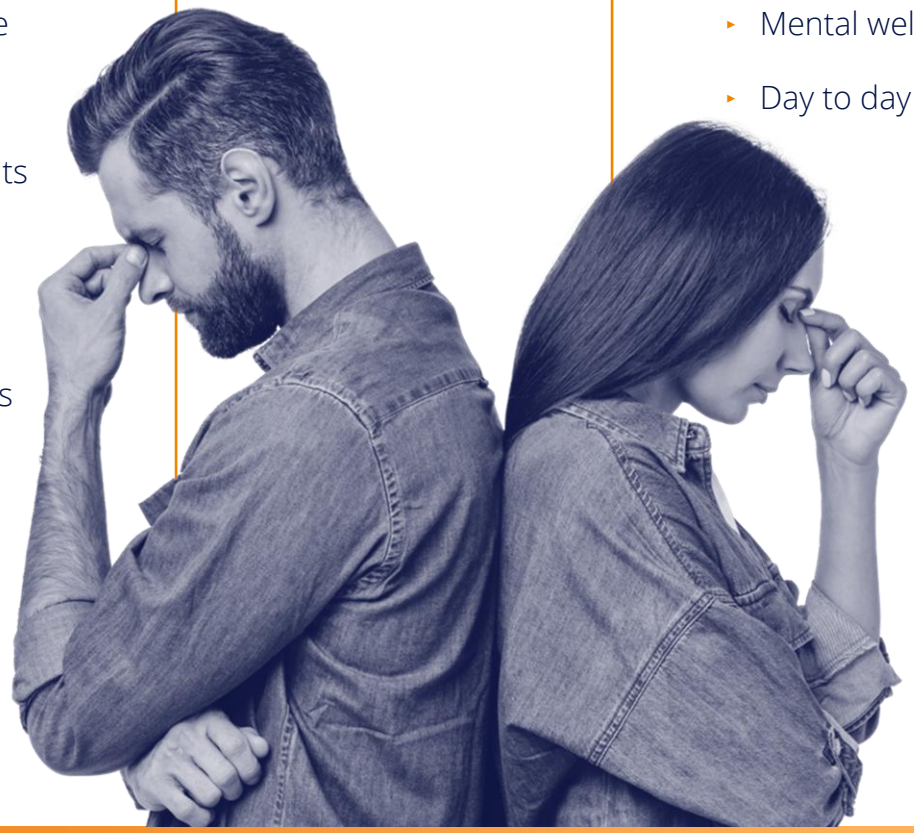
Growing prevalence with age impacts quality of life

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

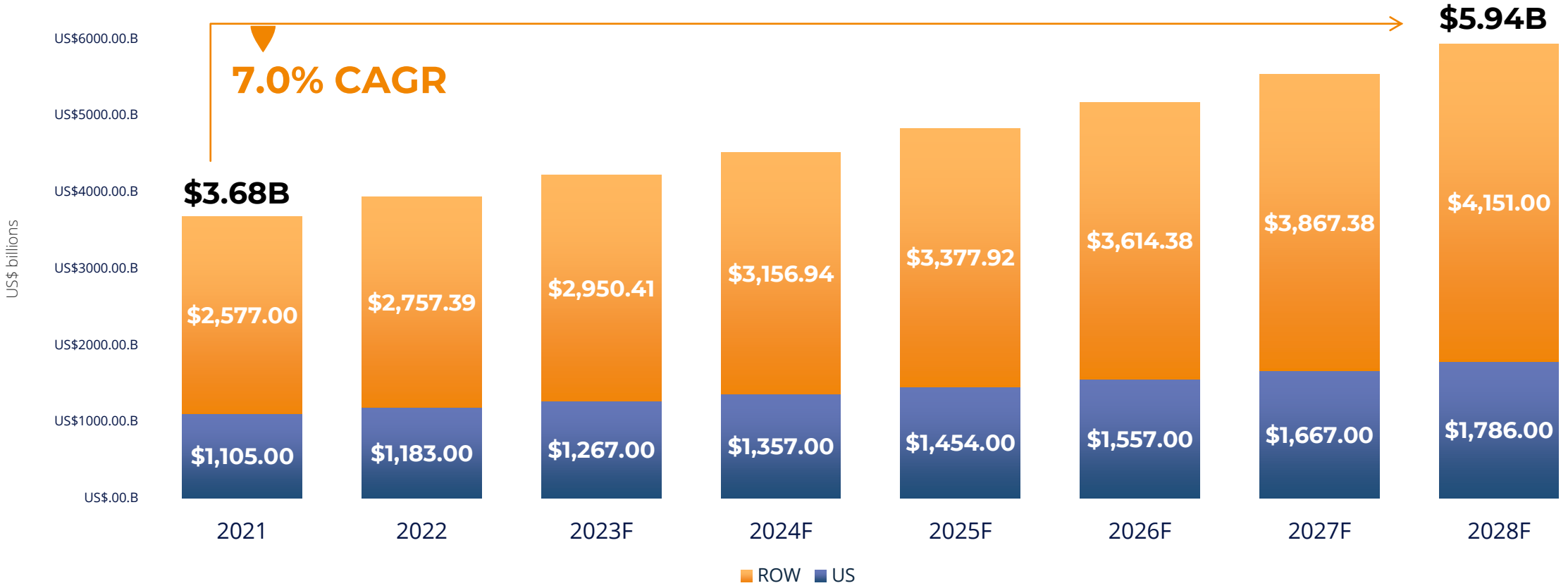
Prevalence In Key Markets

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
Varendafil	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

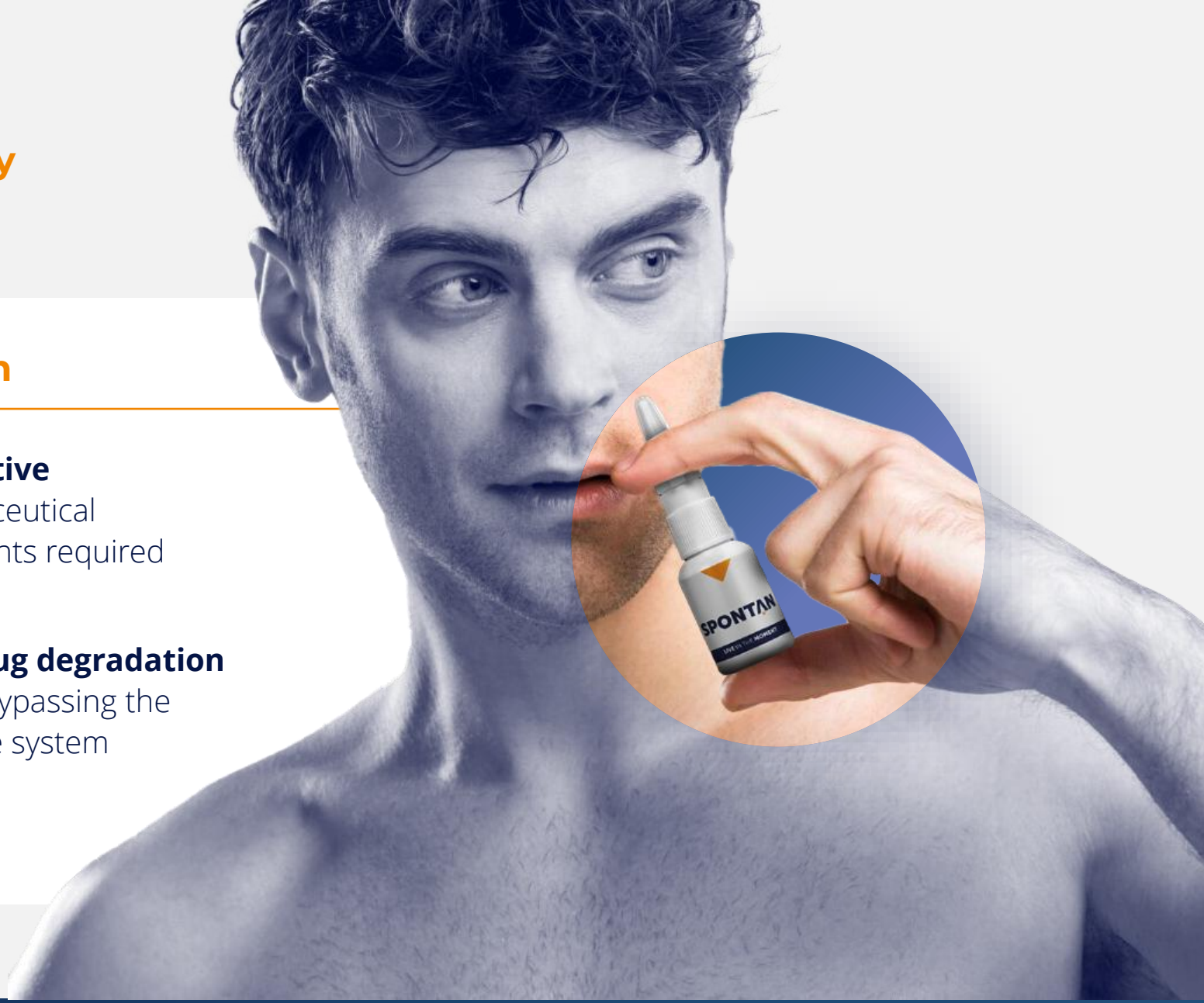
More rapid
onset of action

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

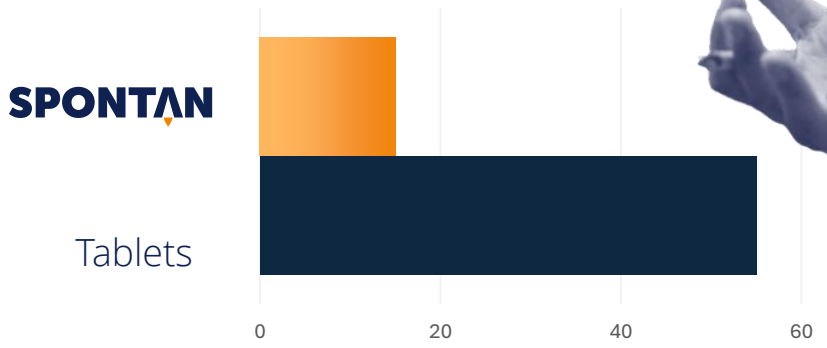
- Validated safety profile
- No severe events
- Clinically proven

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

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

- ✓ Pre-IND Meeting
- Development Plan (CMC, Non-clinical, Clinical)
- NDA Submission
- FDA Review
- Market Approval

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

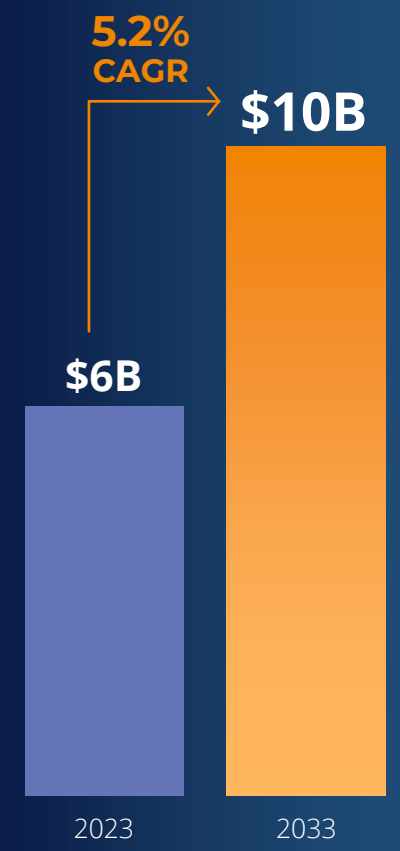
Product Features

- 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*



*Source: Nova1Advisor: Compounding Pharmacies Market Size, Share & Trends Analysis.

Accelerating US Market Entry
Dual-Track Strategy

Path 1: SPONTAN® > Full Approval

SPONTAN

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

Path 2: ROXUS > Personalised Medicine

ROXUS

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

- 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://kangaroopointmedicalcentre.com.au/

Expedited path to market

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

FDA
United States

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

TGA
Australia

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)

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

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

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

Expanding Product Portfolio Range

- SPONTAN® derivatives (Multiple product versions for sale)
- 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 preparations
- Potential partnerships/licensing
- ROXUS development for early US market entry

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