LTR Pharma

Lead nasal spray portfolio

Investor Update | October 2025

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Executive Summary

LTR Pharma:

Late-Stage Pharmaceutical Platform with Validated Early Market Access

Rapidly commercialising SPONTAN® and ROXUS®

First-in-class rapid, on-demand nasal spray treatment for Erectile Dysfunction (ED)

Clinically validated platform with early prescriber adoption

Demonstrated rapid onset and consistency of delivery

SPONTAN now available under TGA SAS

SPONTAN is available now through Australia's controlled early access programs – reaching patients in need, now

ROXUS addressing the US personalised medicine market

Targeting to launch in H1 2026

Growing pipeline of novel nasal spray products

Developing additional SPONTAN® products for ED – **different variations, price points and other indications - together with OROFLOW® for oesophageal motility disorders**

Investment Highlights

LTR Pharma positioned in a clear gap in the market

Multiple path to market

- SPONTAN® active in Australia via SAS
- ROXUS® targeting US personalised medicine H1 CY2026
- Regulatory approvals expanding market access

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

- SPONTAN Phase II PK Study
- ROXUS® development completed
- ROXUS launch H1 CY 2026
- Growing Online Prescribing
- SPONTAN Animal Tox Study
- Published data
- Partnership discussions
- OROFLOW® development for OMD

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Market Problem
& Opportunity

Understanding the Market Need

A significant healthcare challenge affecting relationships and quality of life

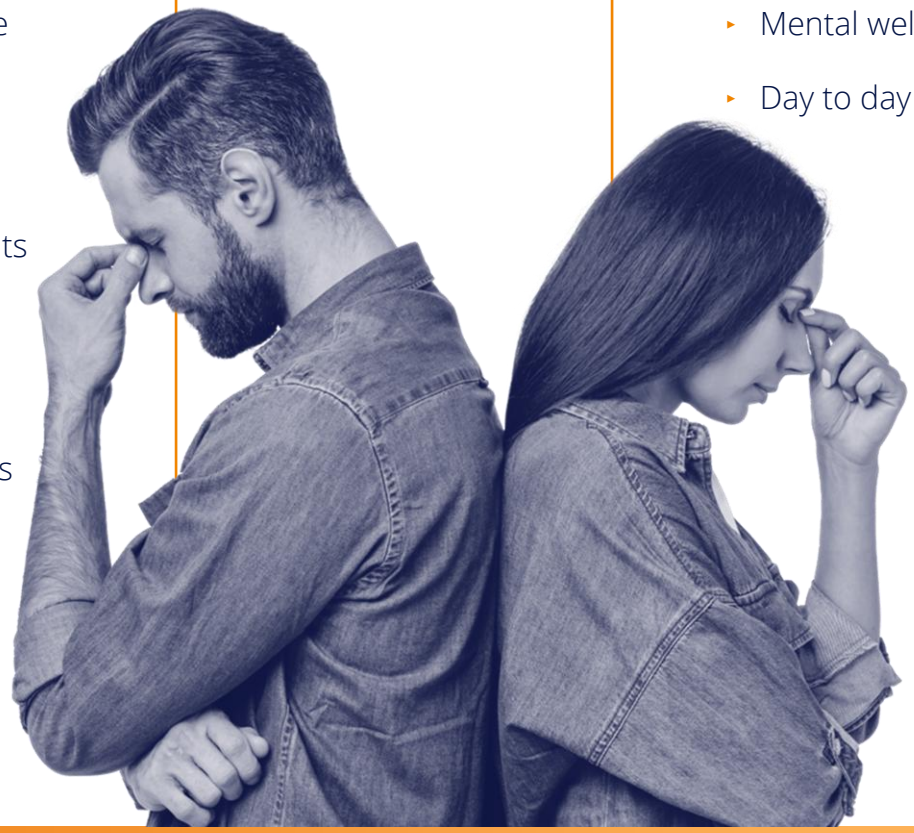
50% Stop purchasing PDE5 tablets[1]

60% Of men over 45 experience ED[2]

Growing prevalence with age impacts quality of life

Physical causes

- Heart health
- Hormone balance
- Prostate Cancer
- Diabetes
- Medical treatments
  - Hair loss
  - Weight loss
  - Antidepressants



Psychological Impact

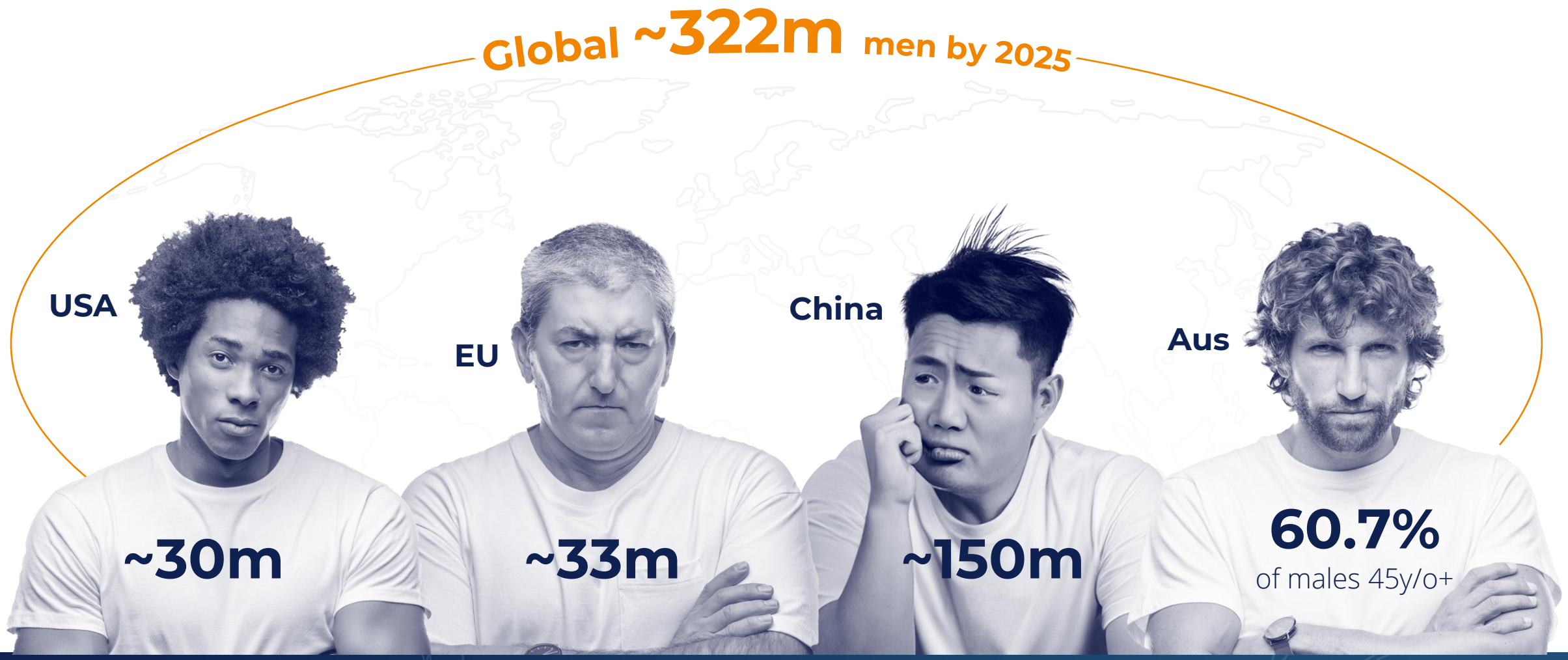
- Relationship problems
- Mental wellbeing
- Day to day stress

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

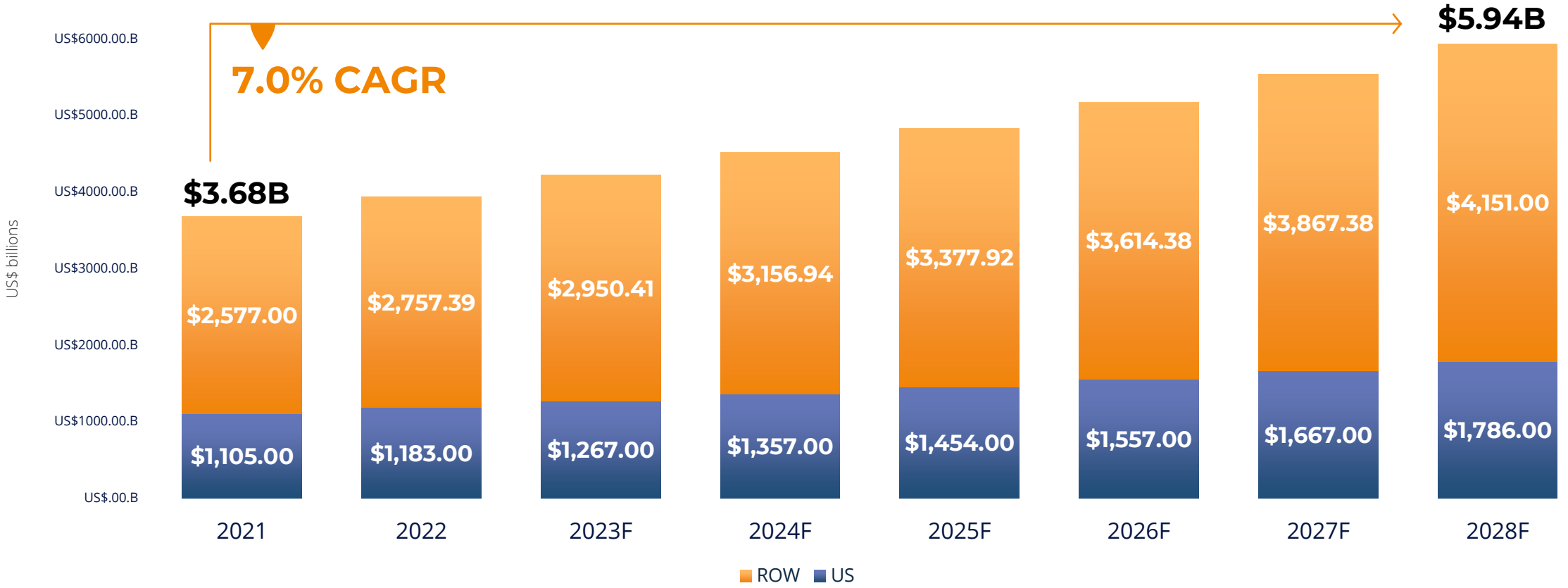
As risk factors become more prevalent, so does ED



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

Oral PDE5 inhibitors & SPONTAN® Nasal Spray

Oral 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 oral 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

SPONTAN First and only PDE5 nasal spray, available now in Australia under TGA early access.

Nasal Administration

Delivery mechanism can solve many of issues facing PDE5 inhibitors

Advantages vs oral administration

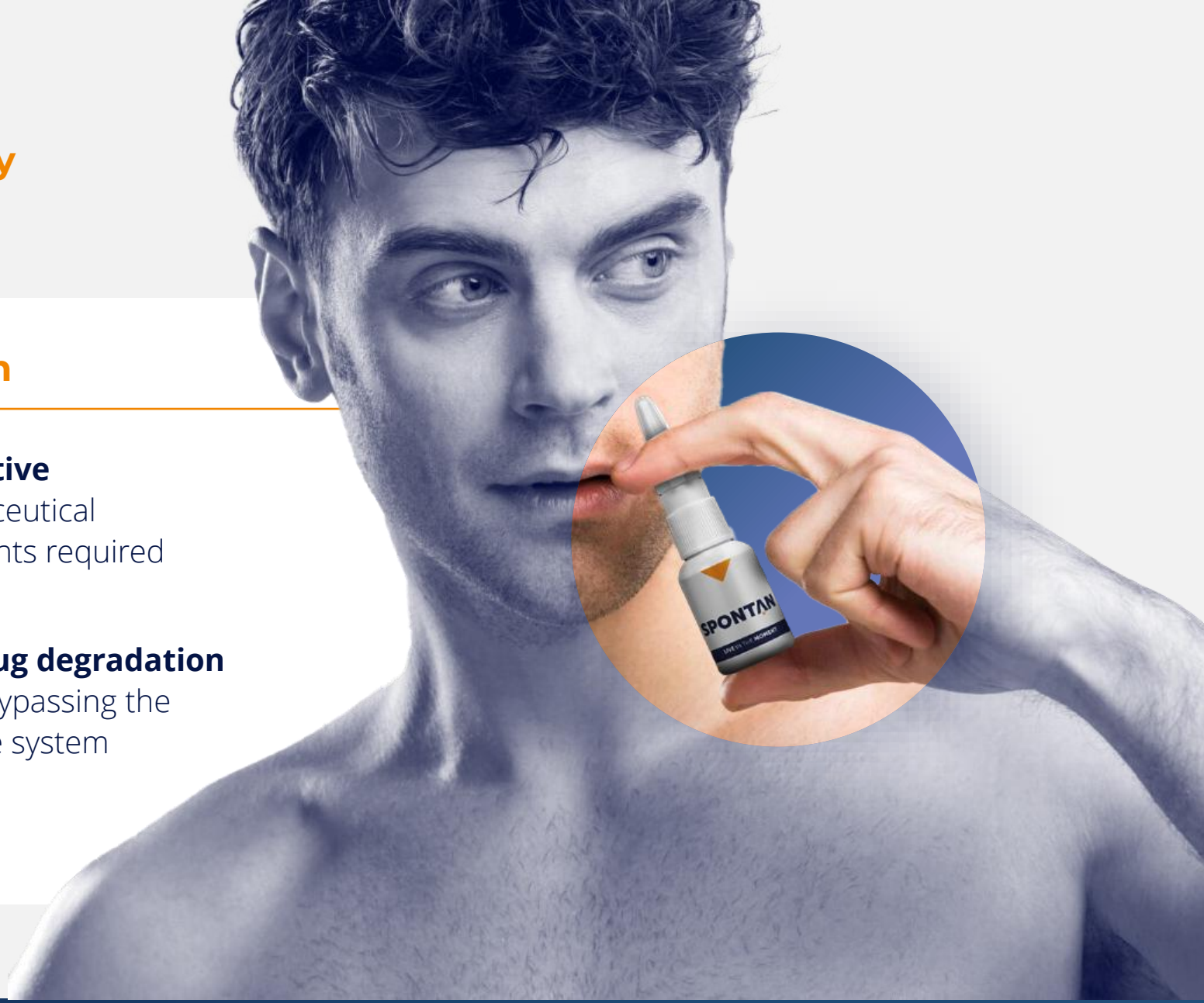
More rapid
onset of action

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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Solution

SPONTAN and roxus

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 Science of Superior Delivery

Faster and More Potent

Speed Superiority

- Tmax: 5 x faster than oral tablets
- Peak concentration in as little as 9 mins
- Average onset: 12 mins vs 56 mins

Potency Advantage

- Half the dose
- Dose-normalised Cmax is 155.6% higher than orals
- Consistent effectiveness
- Direct bloodstream delivery bypasses liver metabolism

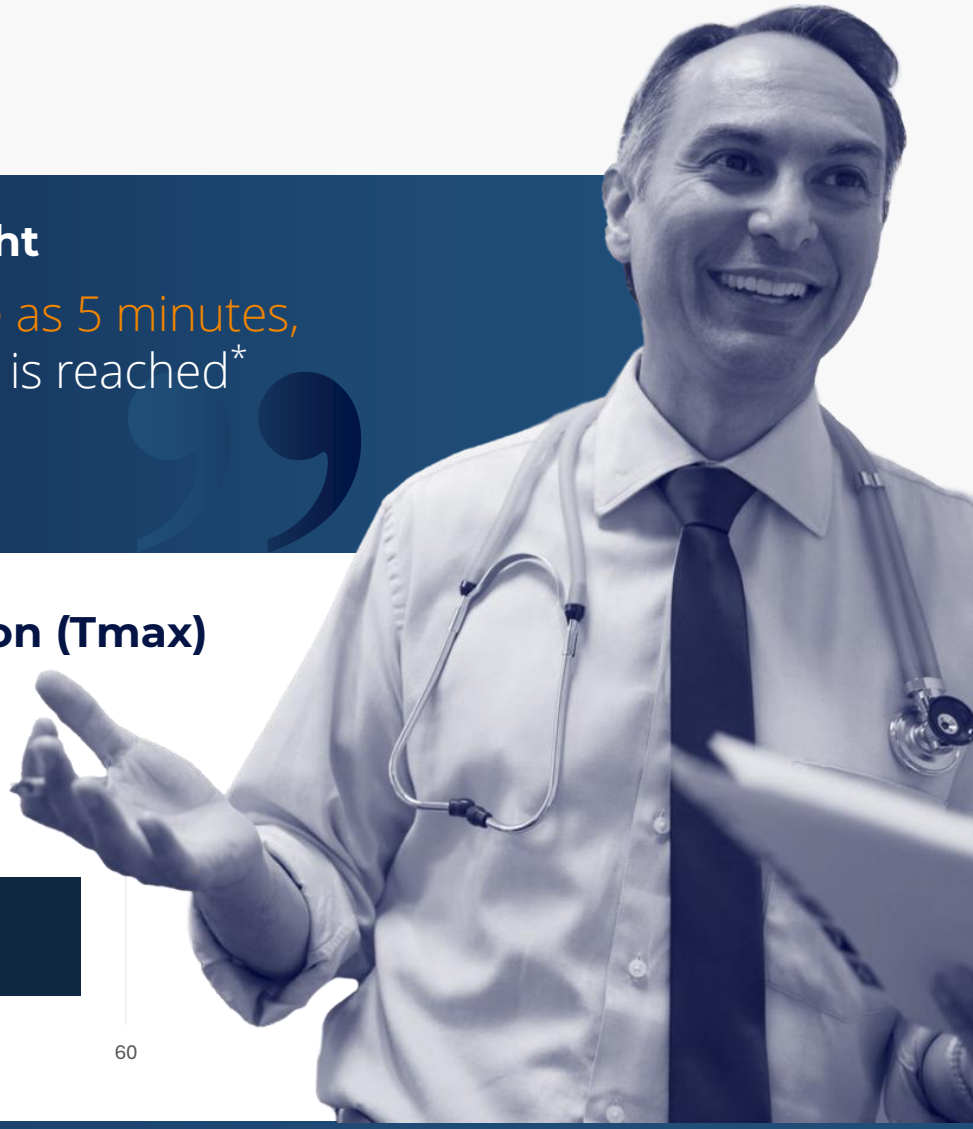
Proven Safety

- Validated safety profile
- No severe events
- Clinically proven

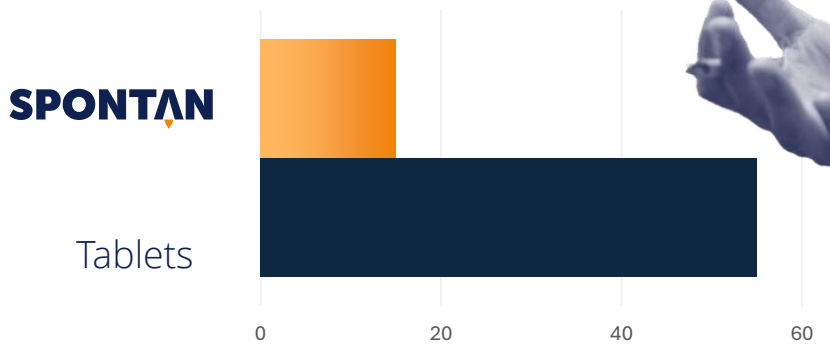
Healthcare Professional Insight

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

*Based on healthcare professional feedback



Time to peak concentration (Tmax)
(minutes)



In-Market NOW

Commercial Platform Active: Growing Prescriber Network

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)

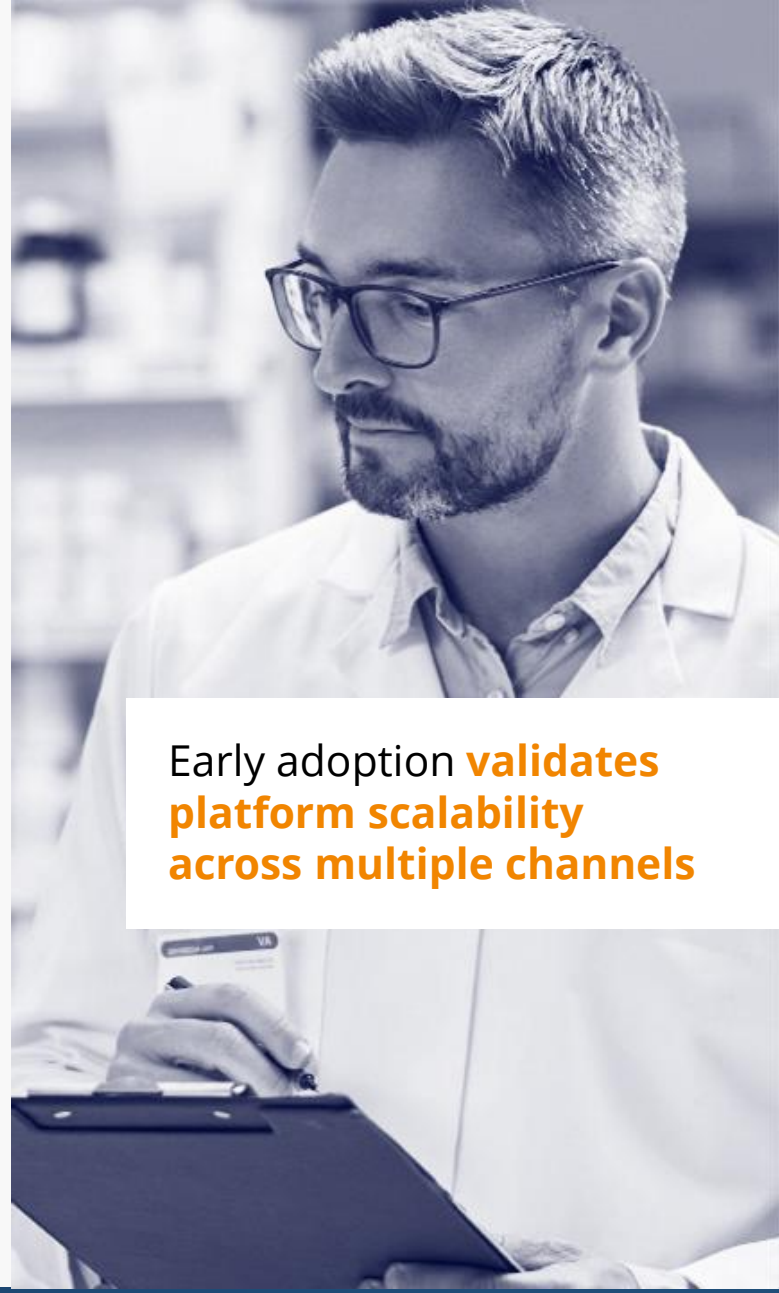
- Australia's largest men's health pharmacy clinic network
- Significant referral network of GPs, urologists, and sexual health clinics
- Online telehealth appointment / SPONTAN Nasal Spray prescribing on
- https://menshealthdownunder.com.au

3. Kangaroo Point

- Specialist GP Men's Health Services
- Online telehealth appointments on
- https://kangaroopointmedicalcentre.com.au

4. Pharmacy Networks

- Symbion pharmacy network of over 3900 pharmacies
- Terrey White Chemmart nationwide



Early adoption **validates platform scalability across multiple channels**

US Commercialisation

Multiple Active Routes to Market

ROXUS > Early Market Entry via Personalised Medicine

- ROXUS to be available via 503(a) personalised medicine pathway
- Market entry with 1st sales targeted for H1 CY2026
- Focus on urology/men's health prescribers and telehealth
- Builds US brand, relationships, and real-world use case data
- Accesses $6B+ US personalised healthcare market (2025), independent of SPONTAN FDA timeline

SPONTAN® > Broad Market Expansion

- FDA 505(b)(2) pathway
- FDA Approval enables broad market expansion
- Benefits from ROXUS commercialisation in the market
- Phase II PK study, enrolling January 2026 and then progressing to Phase III Safety and Efficacy study

Growing Pipeline of Novel Nasal Spray Treatments

Validated Platform Supporting Multiple Indications

Indication/ Program	Pre-clinical	Proof of Concept	Phase 1 (PK study)	Phase 2 (PK study)	Phase 3
Erectile Dysfunction (ED)					
SPONTAN / TGA early access	Available now				
roxus / FDA 503(a) Personalised Medicine	Current	Launch in US via personalised healthcare market			
SPONTAN / FDA 505(b)(2)	Completed	Completed	Completed	Current	Planned
Expanding Pipeline & Strategic Investments					
OROFLOW	Completed	Current			
omega-3	Current	Planned			

Platform scalability demonstrated through successful clinical validation

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Strategic Execution

Milestones, Partnerships and Regulatory Progress

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

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

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

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**

Commercial platform activation through the Australian early access

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 US market preparation through ROXUS development

Platform expansion into OMD with OROFLOW development

Secured 33% stake in LevOmega Nature-identical omega-3 platform addressing $10B+ market

Global Co-Development Agreement Nasdaq listed Aptar Pharma

Strategic partnership driving regulatory success and market readiness

Partnership Foundations

- Strategic partnership supporting validated commercial platform
- 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

- Extractables study completed
- Leachables study underway
- Supporting FDA compliance standards and regulatory submission

Human Factors Study program

- User experience evaluation in progress
- Completion targeted H1 2026
- Optimising product usability

Regulatory Documentation

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

SPONTAN - FDA Engagement

Validates Commercial Platform

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

2025-2026
Key Milestones

Calendar Year

Q1 2026	H1 2026	2026
Phase II Clinical Study enrolment	ROXUS 1st US Sales	Published data
ROXUS Development Completed	Phase II completion and data read out	OROFLOW development
Human factor study completion		Partnerships discussions
		Animal Toxicology Program

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