LTR Pharma

SPONTAN

Fast-acting nasal spray treatment for erectile dysfunction

Investor Overview | 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, consistency of delivery and confirmed safety profile

ASX IPO December 2023

Won IPO of the Year award at the Australian Broker Awards

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

SPONTAN's clinical study to expedite US and Australian regulatory filings within 1-2 years, enable early Australian market access, and clinical package preparation for licencing and regulatory discussions

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

Demonstrated rapid onset at a lower dose and confirmed safety profile

Blockbuster market with issues

Existing PDE5 inhibitors have a high discontinuation rate due to poor efficacy and side effects

Blue chip partners

Commercial manufacturing partnership with ASX listed Mayne Pharma

Multiple upcoming milestones

Final study results

Regulatory meetings

Preparations for early access in Australia

Potential partnerships/ licensing

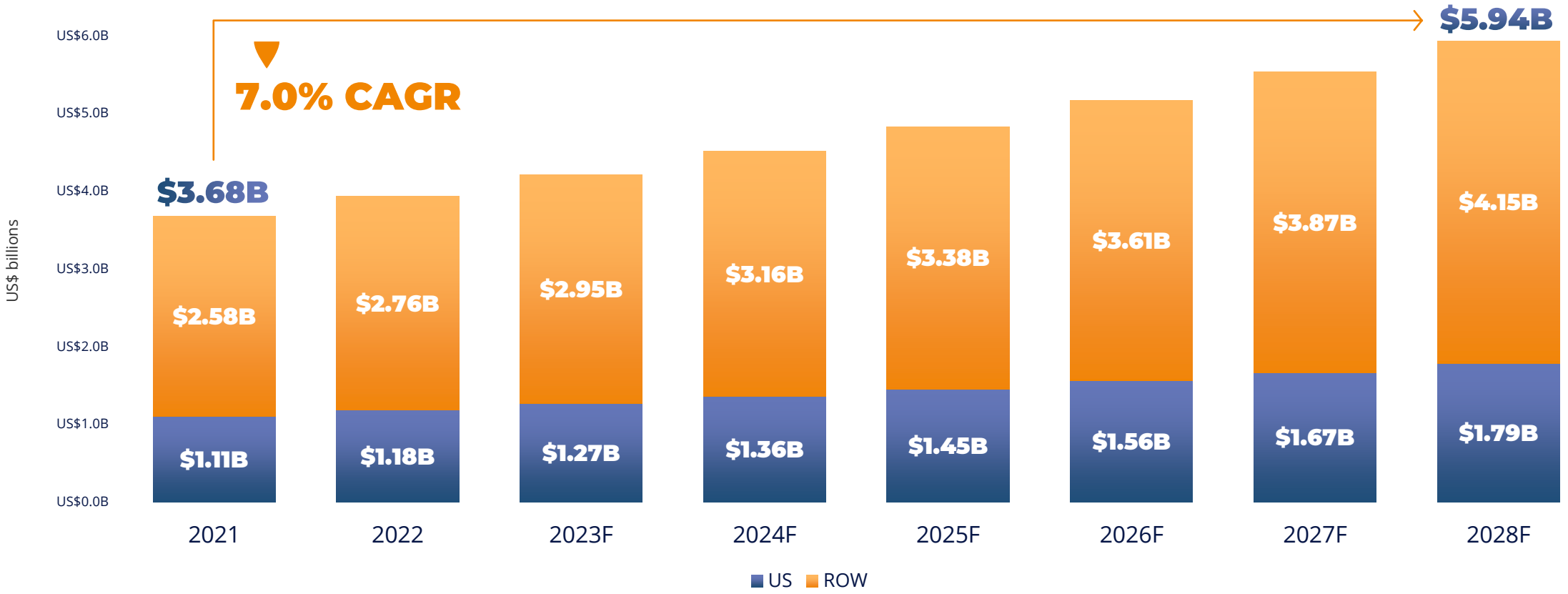
LTR Pharma

Industry overview*

*Frost & Sullivan, Market Report: (September 2023) The Erectile Dysfunction Medicines Market

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 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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Company Overview

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® Overview

A novel delivery of a proven ED drug

Drug repurposing

Focused on changing the method of administration of Vardenafil, an existing and approved drug already in global markets since 2003

Intra-nasal delivery

Intra-nasal Vardenafil formulation, SPONTAN®, is fast acting and low dose compared with the incumbent oral ED treatment products on market

Expedited path to market

Builds on Vardenafil's safety and efficacy data package with upcoming bioequivalence study in advance of FDA and TGA meetings

Proven Competitive Advantages

Distribution through partnering/licensing and direct-to-consumer models

A faster acting lower dose drug formulation with a better safety profile

	SPONTAN	Sildenafil	Tadalafil	Avanafil	Vardenafil
Mode of delivery	**Nasal**	**Oral**	**Oral**	**Oral**	**Oral**
Low dosage	✓	✗	✗	✗	✗
Rapid absorption	✓	✗	✗	✗	✗
Quick onset of action	✓	✗	✗	✗	✗
Higher bioavailability	✓	✗	✗	✗	✗
Fewer side effects	✓	✗	✗	✗	✗

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.[1]
- 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[2]	0	1

Note: [1] Final study report to be released mid-2024. [2] Adverse Events refers to FDA serious adverse events classification.

Pivotal Pharmacokinetic clinical study

Results to support early access in Australia and regulatory pre-submission meetings

Trial objective

To assess the relative bioavailability of Vardenafil following administration of SPONTAN® as a nasal spray compared to Vardenafil tablets.

Trial design

A single-dose, randomised, open-label, 2-treatment, 2-period crossover study of SPONTAN® nasal spray (5 mg Vardenafil: a single 2.5 mg spray in each nostril) compared to Vardenafil tablets (10 mg Vardenafil) with 18 healthy adult male subjects.

Outcome

Successful completion will provide data for FDA and global regulatory pathways and early access in Australia and partnering and licensing discussions.

Expedited path to market

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

FDA (US)

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**

Targeting NDA filing 1st half of CY 2025

TGA (AUS)

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**

Targeting filing middle of CY 2025

SPONTAN

SPONTAN® may be made available to patients via the TGA's SAS or APS on an as needs basis and subject to the **relevant regulatory framework**

Commercialisation Pathways

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

1 Australia SAS Sales

- The successful clinical study results outlining the strong safety profile will enable near-term commercialisation in Australia through the early access schemes, SAS and APS
- Approval under early access schemes will permit the supply of SPONTAN through healthcare professionals on a case-by-case basis
- LTR Pharma expects to commence first sales under this process in the coming quarter post completing the clinical study

2 Partnering / Licensing

- LTR Pharma have already begun exploring partnership / licensing opportunities with significant offshore pharmaceutical industry participants:
  - **Partnerships**: opportunity to partner with a large pharmaceutical company to leverage their resources, expertise & market access
  - **Licensing**: opportunity to license SPONTAN to a large pharmaceutical company in exchange for upfront payments, milestone payments and royalties on sales
- LTR Pharma will advance these discussions in conjunction with progressing regulatory approval pathways

3 Direct Sales post Regulatory Approval

- LTR Pharma are targeting an expedited path to market in key markets including the US and Australia
- Following regulatory approval, LTR Pharma will bring SPONTAN to market as a new branded erectile dysfunction drug with an improved therapeutic profile
- Market entry will focus on leveraging online sales channels, with a majority of scripts being fulfilled online

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 (3 September 2024)	A$12.05M
Top 20 shareholder percentage	52.59%

1. As at market close Thursday, 14 November 2024

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Appendix

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

Adopted Mayne Health as a **high-quality commercial manufacturing partner** to product SPONTAN to GMP standards

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

2023

Initial Public Offer (IPO)
Successfully completed an oversubscribed IPO. The Company listed on the ASX on 11 December 2023 and raised AU $7M.

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

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

2024

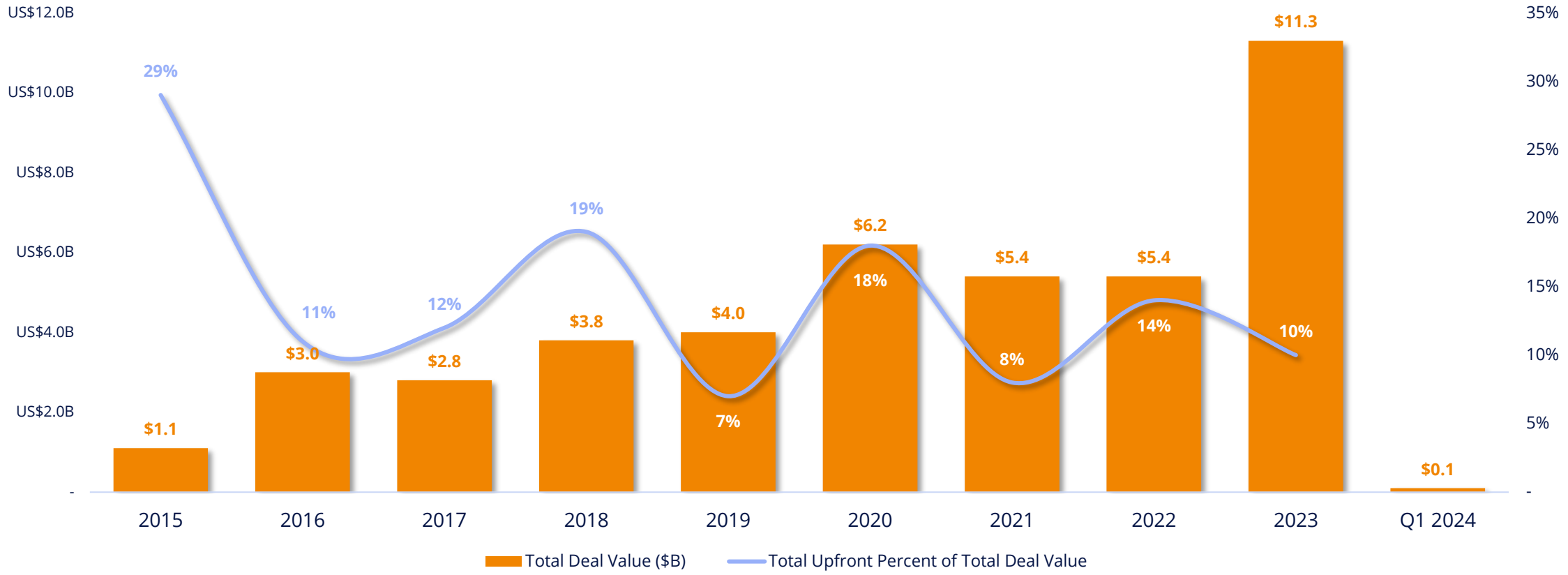
Initial study results released[1]
SPONTAN's clinical study to support regulatory filings, enable early Australian market access and preparation for licensing and partnering discussions

Note: [1] Final study report to be released mid-2024

Medtech R&D Partnership & Licensing

Partnership and licensing deals continue to grow, remaining tilted towards milestone-based payments

Medtech: R&D Partnership & Licensing Totals and Percentage Up Front[1]



ED and its Causes

A major factor in relationship breakdown

Erectile disfunction (ED) is a medical condition wherein an individual is unable to get or keep an erection for satisfactory sexual intercourse

Physical causes

Cardiovascular issues

Hormonal issues

Diabetes

Injury

Side effects from Medications for

- Weight loss
- Hair loss
- Anti-depressants

Psychological causes

Relationship problems

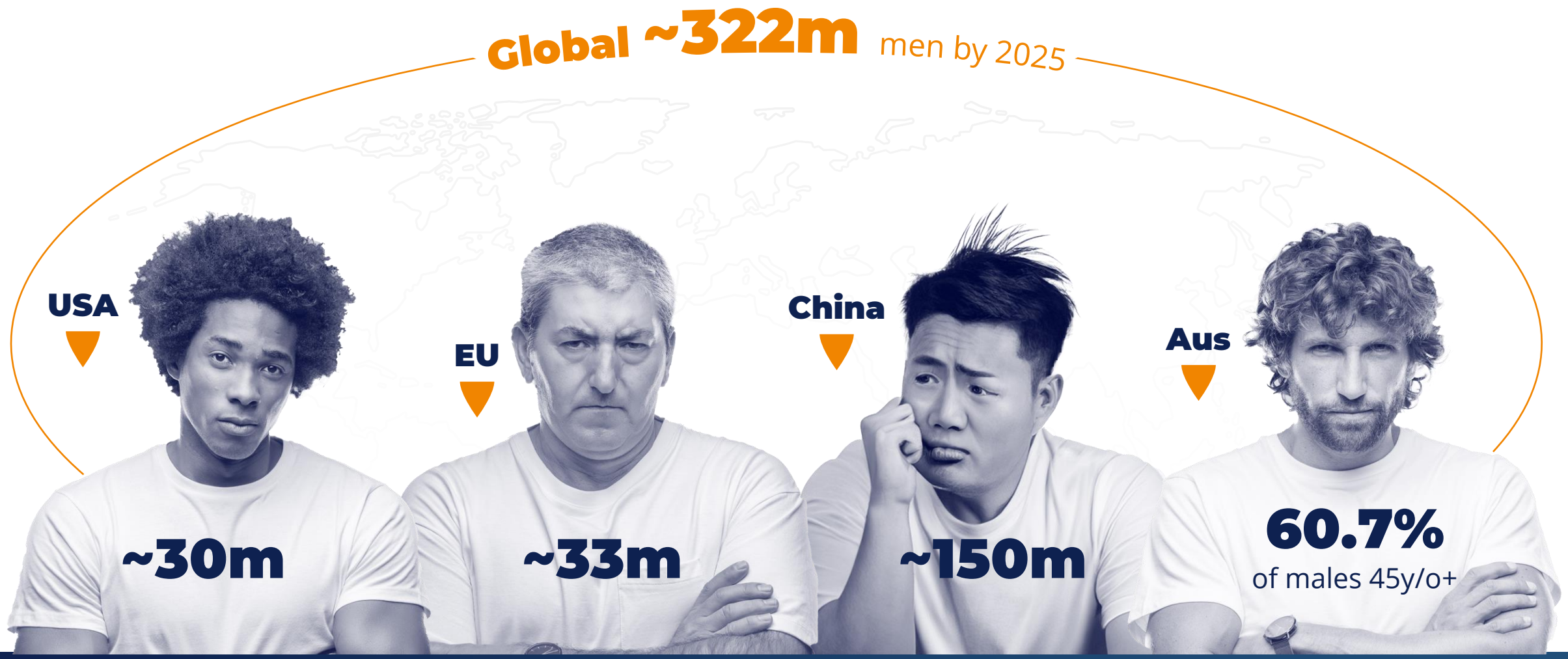
Stress / anxiety

Depression

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



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

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