LTR Pharma

ASX:LTP

SPONTAN®

Fast-acting nasal spray treatment for Erectile Dysfunction

Investor Presentation | 11 December 2023

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LTR Pharma Limited ACN 644 924 569

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INTRODUCTION

EXECUTIVE SUMMARY

Bringing to market the first nasal spray for ED

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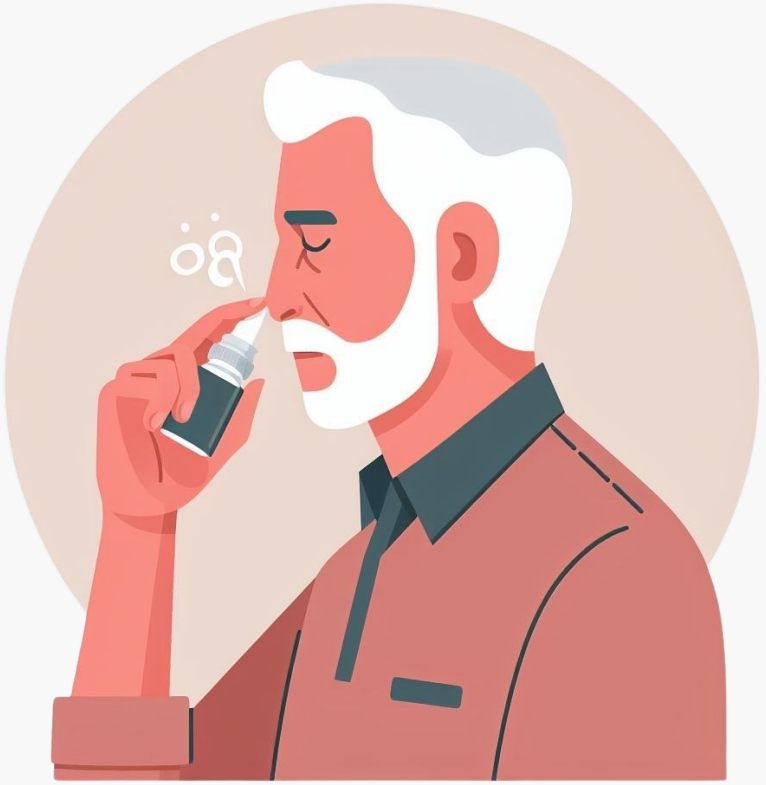
LTR Pharma is commercialising SPONTAN®
A 'First in Class' rapid, on demand nasal spray treatment for Erectile Dysfunction (ED)

Successful Phase I Human Proof of Concept
Indicating 6x faster than oral administration of PDE5 inhibitors (i.e. Viagra)

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
Progressing to bioequivalence study with expedited regulatory filings in the US and Australia within 1-2 years

Funding to progress the business
Raising up to $7 million as part of its IPO on the ASX



INVESTMENT HIGHLIGHTS

LTR Pharma positioned in a clear gap in the market

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Expedited path to market

Repurposed drugs with novel delivery methods can reach the market in the US and Australia quickly

Promising proof of concept

Demonstrated 6x faster than oral administration of competitor PDE5 inhibitors

Blockbuster market with issues

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

Blue chip partners

Drug development, device and manufacturing partnerships with APTAR and Mayne Health

Multiple upcoming value inflection points

Progress of both FDA and TGA applications

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INDUSTRY OVERVIEW

ED AND ITS CAUSES

A major factor in relationship breakdown

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

Physical causes	Psychological causes
Cardiovascular issues	Relationship problems
Hormonal issues	Stress/anxiety
Injury	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

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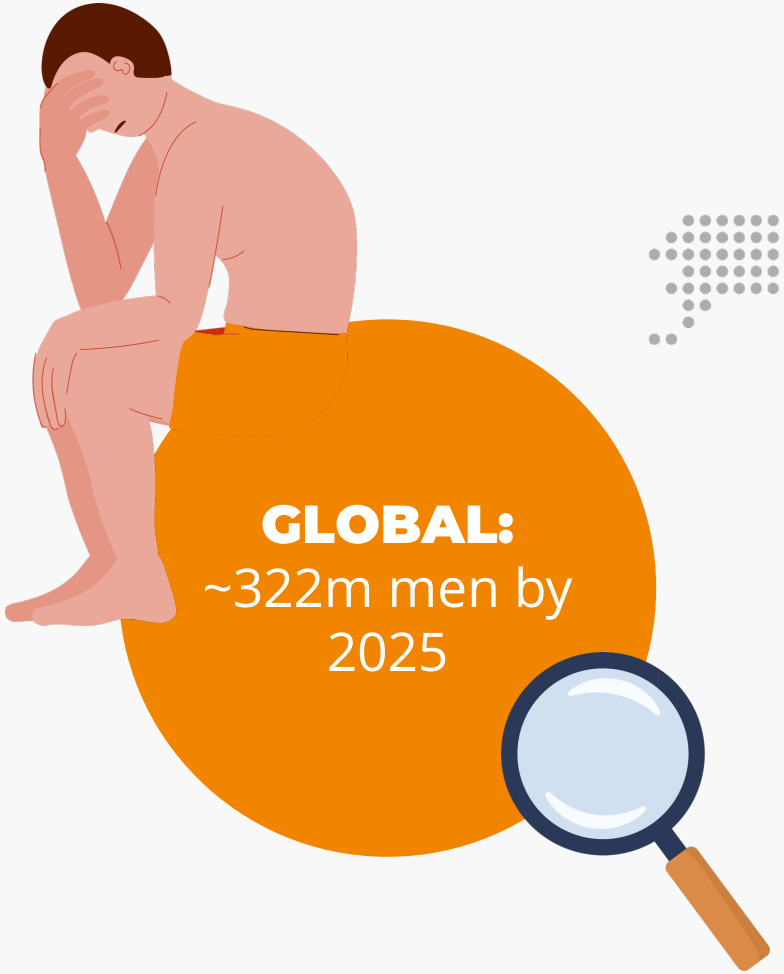

GLOBAL:
~322m men by 2025

USA:
~30m

EU:
~33m

CHINA:
~150m

AUS:
60.7% of males 45y/o+

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

CURRENT TREATMENTS

Gold standard are PDE5 inhibitors which have several drawbacks

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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 35% of patients

= high discontinuation rate

ESTIMATED MARKET SIZE

Forecast to be US$6.0B market by 2028

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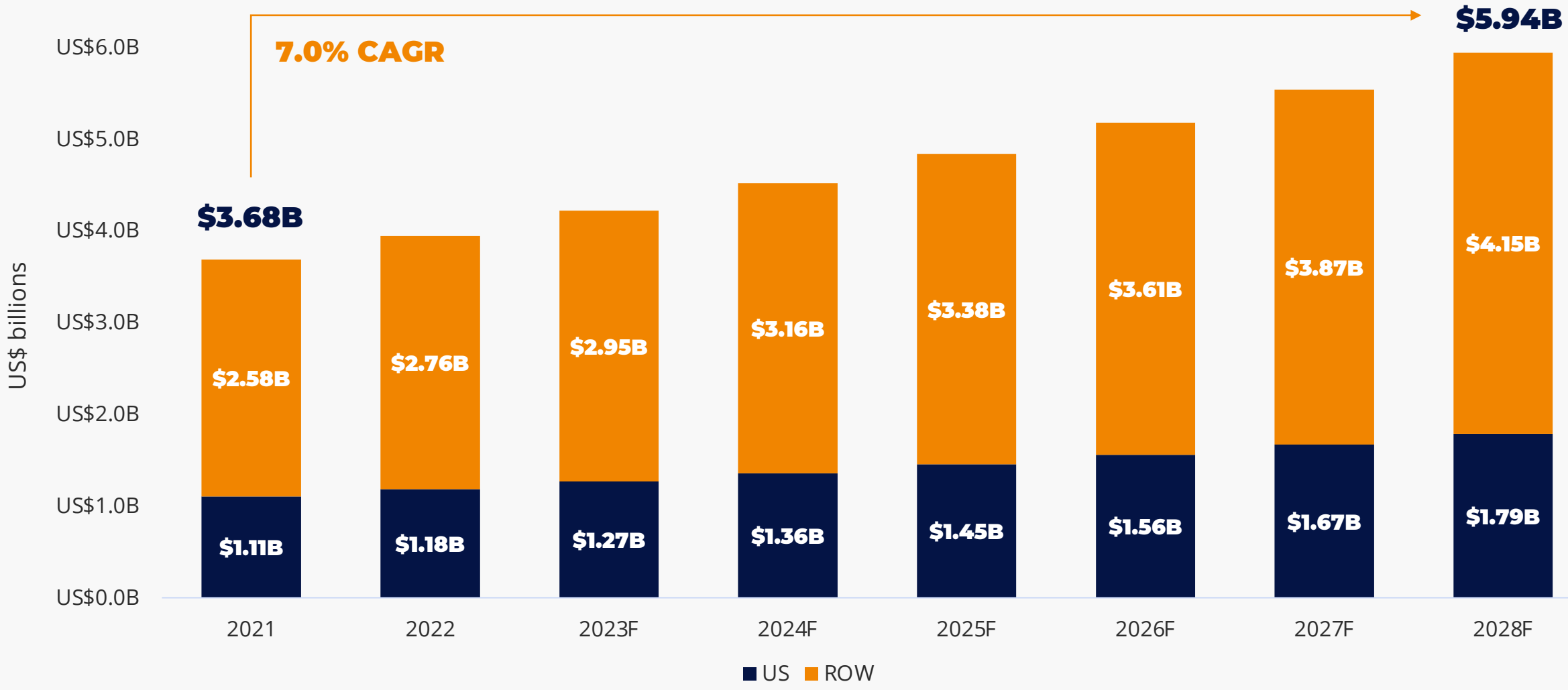

NASAL ADMINISTRATION

Delivery mechanism can solve many of issues facing PDE5 inhibitors

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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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COMPANY OVERVIEW

COMPANY HISTORY

Progressed company substantially derisking the proposition

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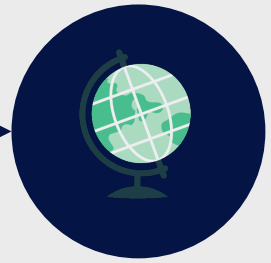
2020-21

Acquired exclusive worldwide rights to develop, manufacture and market SDS-089 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, APTAR

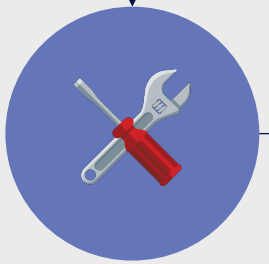
Adopted Mayne Health as a high-quality commercial manufacturing partner to product SPONTAN to GMP standards

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

2023

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

SPONTAN® OVERVIEW

A novel delivery of a proven ED drug

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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, SDS-089, 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 applications

COMPETITIVE ADVANTAGES

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

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	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	✓	✗	✗	✗	✗

PROOF OF CONCEPT TRIAL DATA

Confirmation of rapid onset effect

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12 patients in a randomised, single dose cross-over study of males aged between 24 -45

The delivery of the SDS-089 nasal spray solution used a 100 ul per dose nasal spray device manufactured by Aptar Pharma

The trial compared Vardenafil HC1 as SDS-089 nasal spray (4 mg) and as an oral tablet (10 mg)

Confirmation rapid onset of effect for SDS-089 of ~10 mins compared to 60 mins of existing oral ED drugs

The trial was published in May 2023 with The Journal of Sexual Medicine confirmed:

- Peak concentration of drug in patient within 10 mins suggesting patient will respond shortly after administration
- No severe adverse events
- An acceptable safety profile

PROPOSED BIOEQUIVALENCE TRIAL

Results expedite NDA filing & ARTG registration in the US & Australia

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- **Trial objective:** To assess the relative bioavailability of Vardenafil following administration of SPONTAN® as a nasal spray compared to Levitra® 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 Levitra® tablet (10 mg Vardenafil)
- **Subjects:** 18 healthy adult male subjects under fasting conditions for approximately 4 weeks
- **Outcome:** Successful completion of the bioequivalence trial provides trial data in new drug applications with the FDA and the TGA for relevant regulatory approvals

EXPEDITED PATH TO MARKET

LTR requires FDA and TGA approval to operate in the US & Australia

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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 at beginning 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 at middle of CY 2025

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 TIMELINE

Multiple value inflection points

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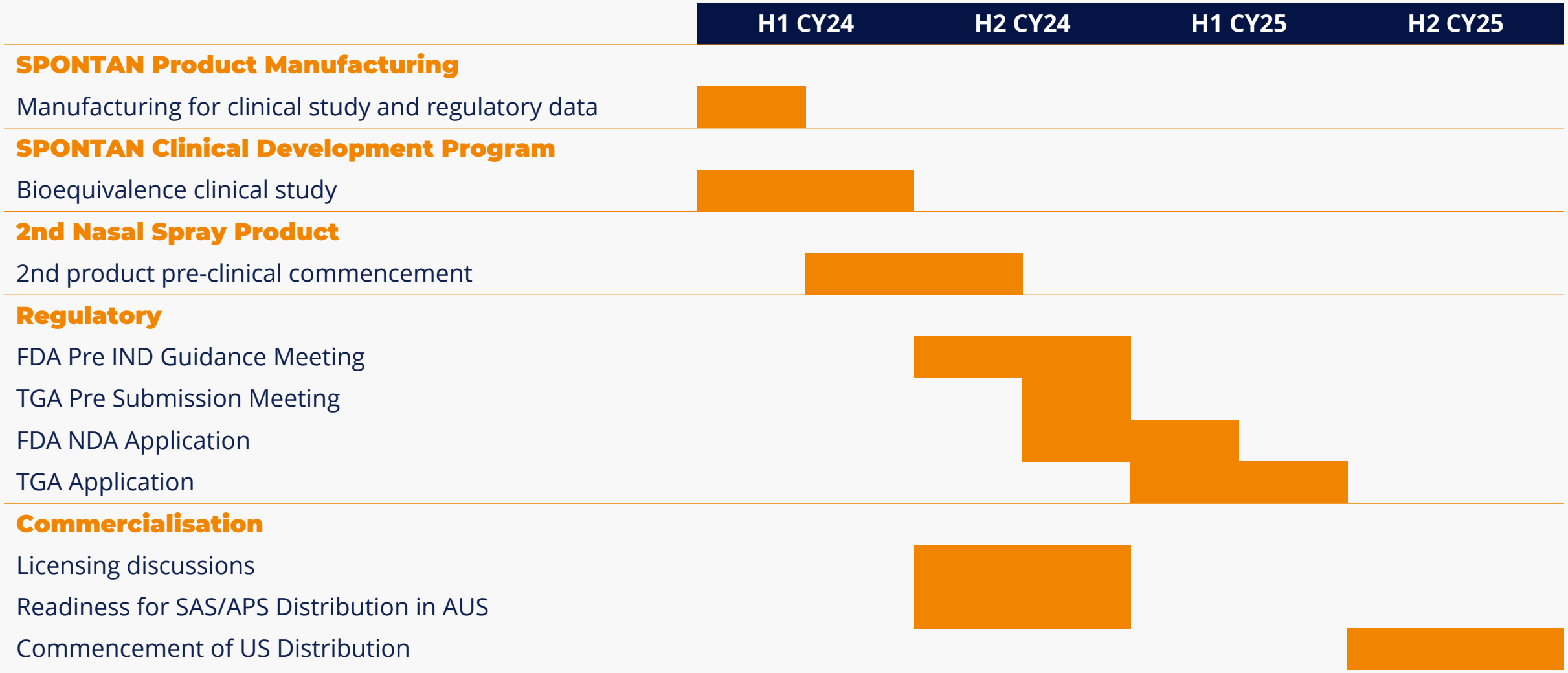

LONG TERM DEVELOPMENT PIPELINE

Repurposing existing oral drugs to intranasal delivery

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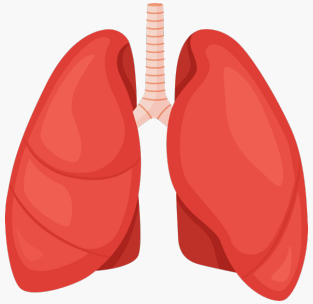
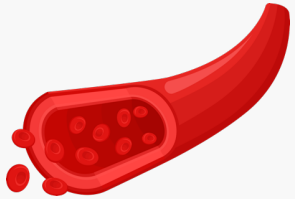
Additional ED products

Increasing range of ED products by dosage and using other PDE5 inhibitors



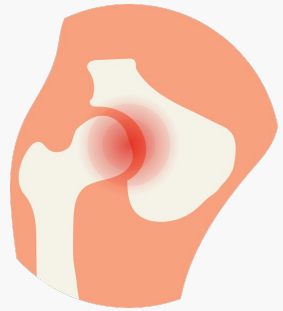
Pulmonary Arterial Hypertension (PAH)

A disorder characterised by high blood pressure in the arteries of the lungs



Scleroderma or systemic sclerosis

Immune disorder attacking healthy tissues, triggering the narrowing of blood vessels



Osteoporosis

Where bones become thin, weak and fragile and can lead to fractures for elderly patients

LTP intends to use its IP and intranasal delivery product to create additional products over the medium term

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BOARD & MANAGEMENT

BOARD OF DIRECTORS

Significant industry and listed company experience

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Lee Rodne
Executive Chairman

- Lee holds over 25 years' experience in healthcare and technology sectors in both public ASX and private enterprises, holding multiple executive leadership roles.
- Prior to joining LTR Pharma, Lee worked at Fortescue Metals group and was CEO and managing director for healthcare technology spin out Allied Medical, leading it to a valuation peak of $250m from $800k.
- Lee has a proven record of commercialising medical devices in Australia, North America, Europe and Asia with significant experience in Nasal Spray product sales.

Dr Julian Chick
Independent Non-executive Director

- Julian is an experienced healthcare executive with over 20 years' experience in board and senior management positions, including ASX listed companies Avexa (ASX.AVX), Admedus (ASX.AHZ), and is current Deputy Chairman of Cann Group Limited (ASX:CAN).
- Julian's experience includes working across investment banking transactions for over 8 years, focused on reviewing healthcare and biotechnology investment opportunities for private equity investors and venture capitalists.

Maja McGuire
Independent Non-executive Director

- Maja is a consulting lawyer and board director with a 15-year track record of providing strategic, corporate and compliance advice to public listed companies. This includes working with listed companies as a non-executive chair, non-executive director, general counsel, company secretary and in private practice.
- Prior to joining LTR Pharma, Maja was general counsel and company secretary of US based Alexium International Group Limited (ASX:AJC).
- Maja currently holds roles in multiple ASX listed companies, including non-executive chair of TechGen Metals (ASX.TG1), non-executive director of Kuniko (ASX.KNI), non-executive director of Indiana Resources Liimited (ASX.IDA).

KEY MANAGEMENT TEAM

High quality go-to-market team

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Danny Zannardo
VP, Commercial

Danny has over 25 years of commercial experience in Australian and global pharmaceuticals and medical devices. He has held executive positions in both private and ASX listed entities including Admedus Ltd, Roche and Actelion with a track record of successfully commercialising new medical technologies in Europe, North America, Asia Pacific and MENA.

Jacques Schipper
Chief Financial Officer

Jacques brings over 14 years of experience in Finance, Commercial Management & Controller roles. Prior to LTP he has been in senior financial roles at Lion Dairy & Drinks, Anteris Technologies, NL Food, First Quantum Minerals as well having successfully owned and managed several private businesses.

Mike Sweeting
VP, US Sales & Marketing

Mike has over 30 years of senior leadership roles in the pharmaceutical industry in commercial sales and market access. Mike currently serves early-stage pharmaceutical and biotech companies as an executive management consultant, most recently, building all functions related to Market Access for Scilex Pharmaceuticals, a San Diego-based startup.

Kip Vought
VP, Regulatory

Kip is a senior pharmaceutical R&D and regulatory executive with over 25 years of experience across major global markets. Successful leadership in preparation of agency meetings (PIND and equivalent, EOP1, EOP2, and PNDA/MAA and regional equivalents) all the way through to the preparation and submission of market applications.

Dr. Monil Shah
VP, Operations & Clinical Development

Monil has over 20 years of pharmaceutical and biotechnology industry experience in drug development. His most recent appointments include Chief Business Officer at Imugene and Chief Development Officer at WindMIL Therapeutics, and Chief Operating Officer of IRX Therapeutics. Previously, Medical Affairs Lead for Immuno-Oncology at Bristol Myers Squibb

Professor Geoffrey Strange
Medical Affairs Executive

Geoffrey is a senior executive and medical researcher with over 20 years' experience in the biopharmaceutical and medical industries. He's been an expert scientific advisor for numerous global pharmaceutical companies including Pfizer, Novartis, Bayer Pharmaceuticals Australia, Glaxo Smith & Kline (GSK) Australia and Edwards LifeSciences.

SCIENTIFIC ADVISORY BOARD

Providing expert guidance, expertise and credibility

LTR Pharma

Professor Eric Chung	Professor Russ Chess-Williams
Eric is a consultant urological surgeon at the AndroUrology Centre for Sexual, Urinary and Reproductive Excellence and holds professorial appointments at the University of Queensland and Macquarie University in Sydney. He is the Secretary-General of the Asia Pacific Society of Sexual Medicine (APSSUM). Eric has authored more than 130 peer-reviewed papers and book chapters.	Russ is the Director of the Centre for Urology Research and Professor of Pharmacology at Bond University. He has published greater than 170 papers that have received over 8500 citations and has authored over 600 conference abstracts. His published works include original papers in European Urology and Nature and his publications have been referenced in 26 patents.


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