



Building a Portfolio of Differentiated Specialty Therapies

Investor Update | May 2026

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Executive Summary

LTR Pharma: Late-Stage Pharmaceutical Platform with Validated Early Market Access



Differentiated Lead Program – SPONTAN / ROXUS

Rapid-acting intranasal PDE5 therapy demonstrating 5x faster absorption versus oral tablets at half the dose, with a validated safety and tolerability profile.



Dual U.S. Pathway Strategy

Advancing SPONTAN via the 505(b)(2) regulatory pathway following successful Pre-IND engagement. In parallel, progressing commercial discussions to support U.S. launch of ROXUS through the personalised medicine (503A) channel.



Early Commercial Validation (Australia)

1,000+ prescriptions under the TGA Special Access Scheme (SAS), supporting prescriber adoption and expanding real-world safety and efficacy data.



Strategic Partnerships

Co-development agreement with Aptar Pharma (Nasdaq). Commercial manufacturing with Mayne Pharma (ASX). National distribution via EBOS/Symbion (ASX).



Funded Through Key Milestones

\$24.1M cash, zero debt, funding Phase II data readout and continued regulatory and commercial advancement.¹



**Market Inefficiency:
High Discontinuation
and Delayed Onset**

Global Erectile Dysfunction Treatment Market



Global ED drug market estimated at **~US\$5B annually**¹



Oral PDE5 inhibitors currently dominate prescribing



High discontinuation rates (>50%) reported with oral PDE5 inhibitors due to delayed onset, inconsistent response and tolerability²



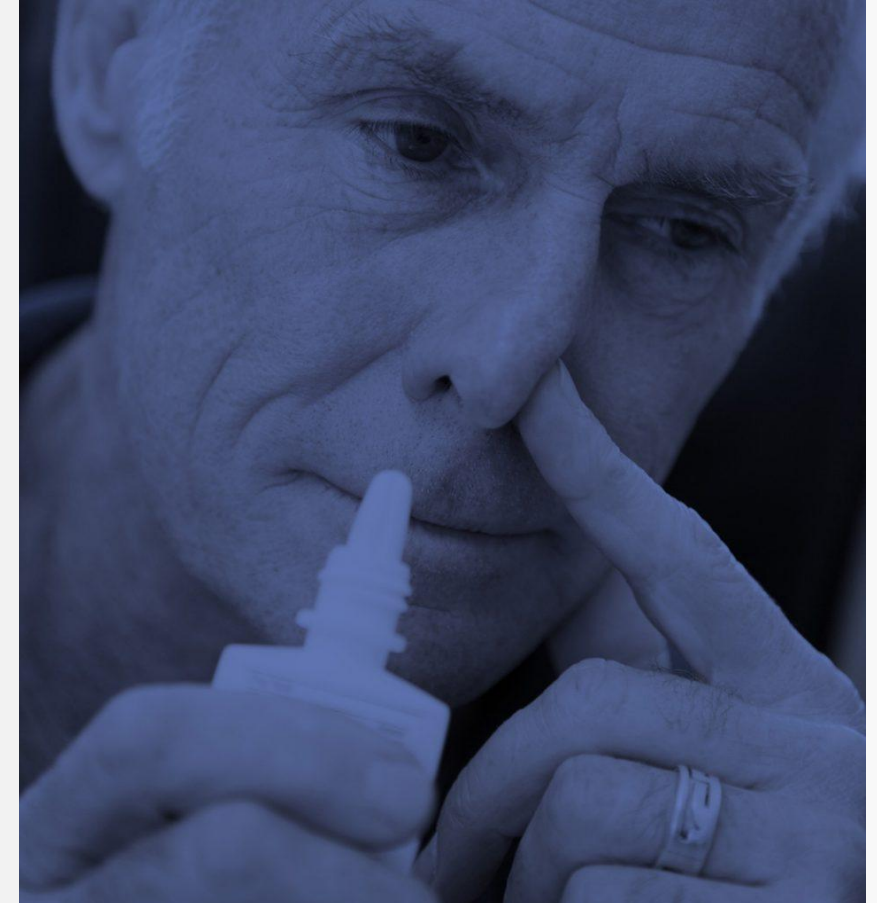
Rapid growth in telehealth prescribing channels



Opportunity for differentiated therapies with faster onset and alternative delivery




Potential adoption in difficult-to-treat ED segments (e.g., post-prostatectomy, performance anxiety, BPH)



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
- ▶ 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%**

Current Treatments

Oral PDE5 inhibitors and 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
Vardenafil	Levitra, Staxyn	1 hour+	2003	Yes
Avanafil	Stendra	30 minutes+	2012	No

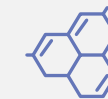
Issues with oral PDE5 inhibitors



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.

Where SPONTAN Fits in the ED Treatment Landscape



Current first-line therapy: Oral PDE5 inhibitors (Viagra, Cialis, Levitra)



Limitations of oral therapies include delayed onset, food interactions, and high discontinuation rates



SPONTAN® intranasal delivery bypasses first-pass metabolism and enables faster systemic absorption



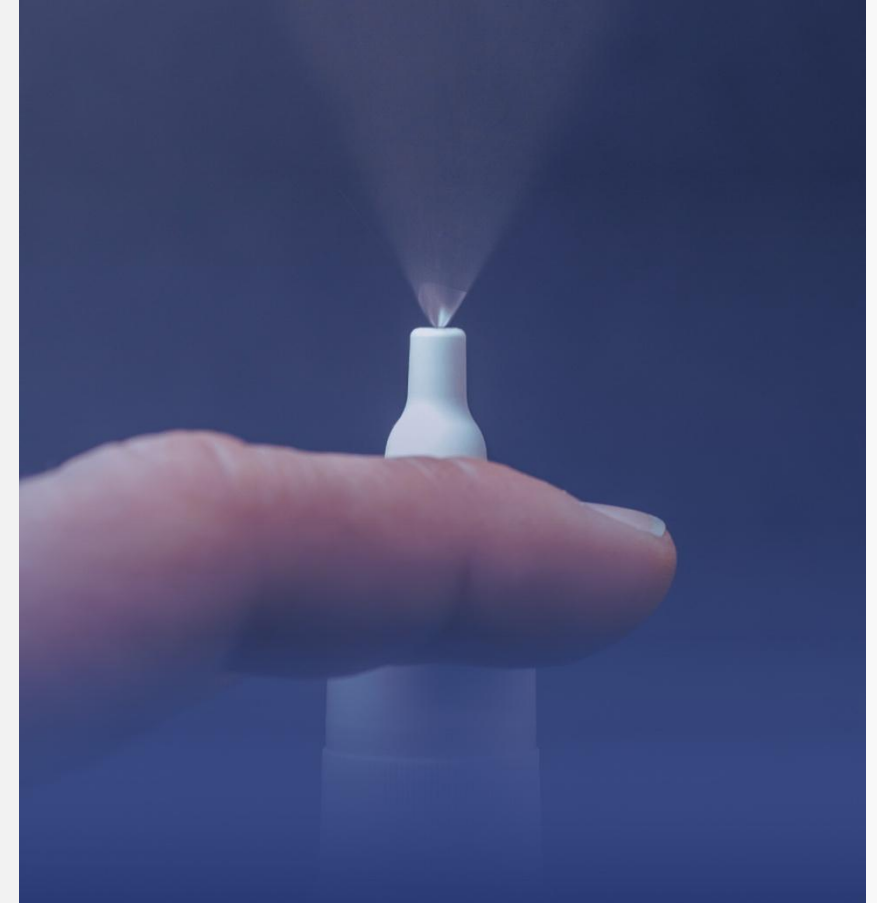
Rapid onset potential supports more spontaneous use compared with traditional oral treatments



May offer **advantages for patients** who do not respond optimally to oral PDE5 inhibitors



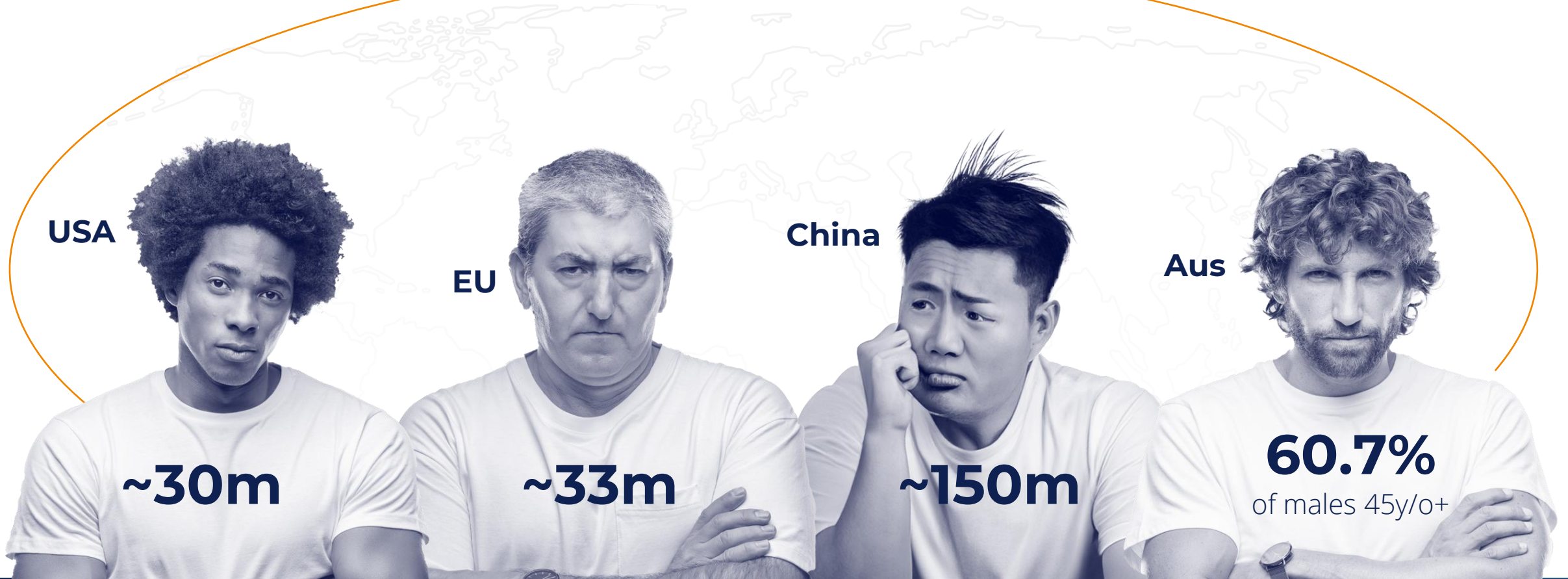
Applicable across the broad ED population, particularly for patients seeking faster onset and improved spontaneity, with potential advantages in difficult-to-treat segments such as post-prostatectomy and performance-related ED.



Prevalence in Key Markets

As risk factors become more prevalent, so does ED

Global ~322m men by 2025





LTR Pharma

Solution
SPONTAN

SPONTAN[®]

Phase I 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.
- ▶ **Phase I findings reproduced and extended in the Phase II interim dataset.**

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 Science of Superior Delivery

Faster and more potent



Speed Superiority

- ▶ Tmax: 5x 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 C_{max} is 155.6% higher than orals
- ▶ Consistent effectiveness
- ▶ Direct bloodstream delivery bypasses liver metabolism



Proven Safety

- ▶ Validated safety profile
- ▶ No severe events
- ▶ Clinically proven

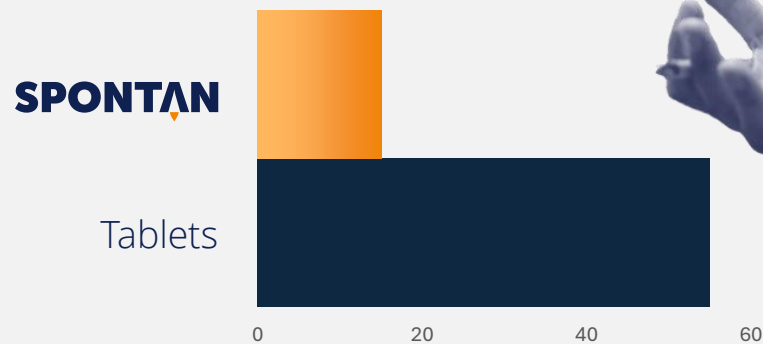
Healthcare Professional Insight

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

*Based on healthcare professional feedback



Time to peak concentration (T_{max}) (minutes)



Phase II Interim Data Reinforce Rapid-Onset Profile and Expand Dataset

Key Highlights



Rapid Absorption Profile

- ▶ Median Tmax ~10 minutes for SPONTAN® (5 mg)
- ▶ Compared with ~60 minutes for 20 mg oral vardenafil



Consistent Pharmacokinetic Profile

- ▶ Comparable PK observed across adult and ≥65-year cohorts in the interim dataset



Repeat Dosing Behaviour

- ▶ No evidence of drug accumulation observed following 5 days of dosing (5 mg)
- ▶ Supports predictable exposure with repeat dosing



Favourable Safety Profile

- ▶ No serious adverse events
- ▶ No Grade 3 or 4 treatment-emergent adverse events
- ▶ No treatment-related discontinuations

Study designed in accordance with FDA Pre-IND guidance
Dataset includes key PK parameters (absorption, repeat dosing, age effects)

Phase II Interim Pharmacokinetic Profile

SPONTAN[®] vs Oral Comparator

- ▶ **Faster onset** profile observed with intranasal SPONTAN[®] compared with oral vardenafil.
- ▶ **Comparable PK** observed across adult and ≥65-year cohorts in the interim dataset.
- ▶ **No accumulation** observed following 5 days of repeat dosing.
- ▶ **Favourable safety** with no serious or severe treatment-emergent adverse events.

Parameter	SPONTAN 5 mg (Intranasal)	Vardenafil 20 mg (Oral)
▶ Median Tmax	▶ ~10 minutes (10–15 min)	▶ ~60 minutes (30–180 min)
▶ Onset profile	▶ Rapid and consistent	▶ Slower, variable
▶ Repeat dosing	▶ No accumulation observed	▶ Not assessed
▶ Safety (interim)	▶ No serious or severe TEAEs	▶ No serious or severe TEAEs

Commercial Relevance: Faster onset aligns with on-demand patient use, Consistent PK supports a predictable profile with repeat use, Applicable across a broad patient population including ≥ 65

Australian Early Access Program: Real-World Clinical and Prescriber Validation

**TGA Special Access Scheme - 1,000+ prescriptions
supporting real-world clinical and prescriber validation**



Prescriber Adoption

- ▶ 1,000+ prescriptions and growing
- ▶ Expanding prescriber base
- ▶ Repeat prescribing behaviour observed



Real-World Clinical Data

- ▶ Published case series (APCC 2025)
- ▶ Positive patient preference versus oral PDE5 in post-prostatectomy cohort¹
- ▶ Positive outcomes in performance-related ED²
- ▶ Growing real-world safety and efficacy dataset



Commercial Infrastructure Established

- ▶ 600+ pharmacies via Symbion / TerryWhite Chemmart
- ▶ Telehealth integration underway
- ▶ Distribution and fulfilment processes operational

Why LTR Pharma Can Win in the ED Treatment Market



Clinically differentiated product: SPONTAN demonstrates ~5x faster absorption versus oral PDE5 tablets



Intranasal delivery bypasses first-pass metabolism, enabling rapid systemic exposure



Real-world validation: 1,000+ prescriptions under the Australian TGA Special Access Scheme



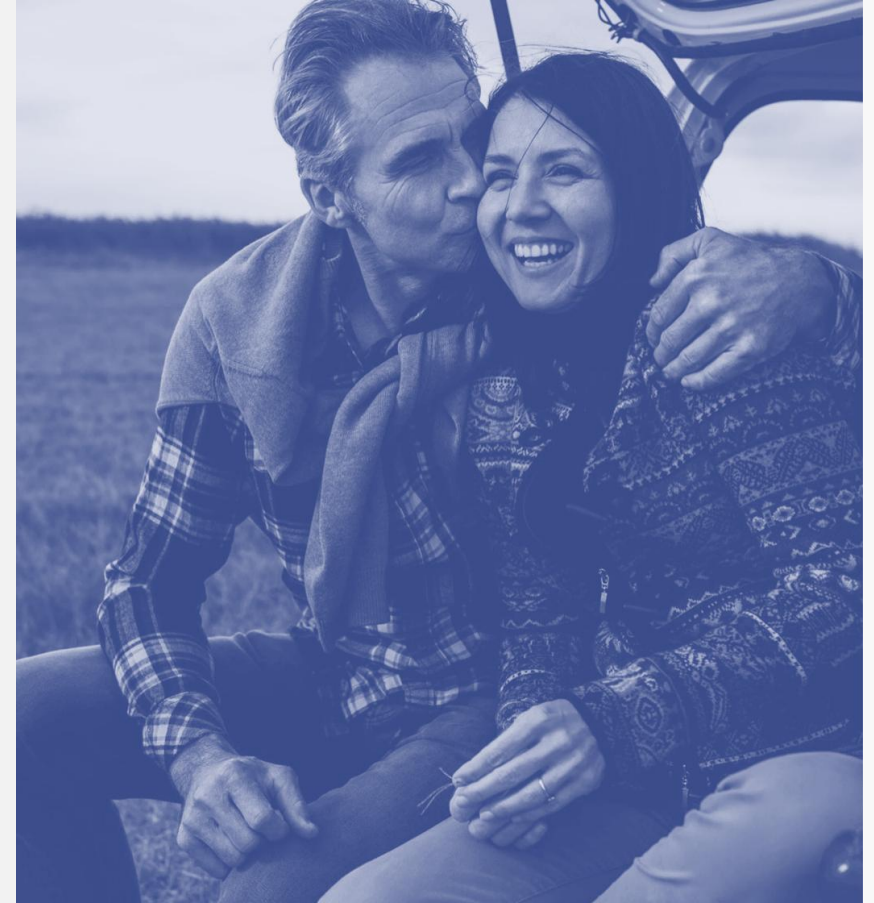
Efficient regulatory strategy via the FDA 505(b)(2) pathway



Strategic partnerships supporting development and commercialisation (Aptar, Mayne, EBOS/Symbion)



Potential early U.S. market entry via personalised medicine (503A) pathway while advancing toward **FDA approval**



US Market Strategy

Dual Pathway Approach

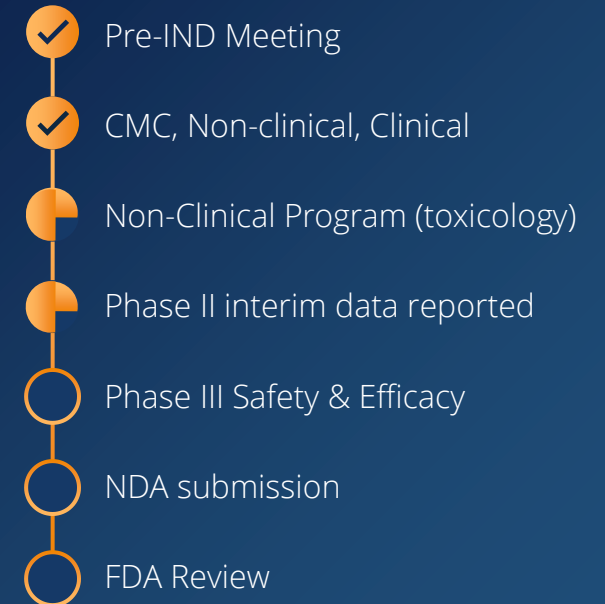
Primary Value Pathway – FDA 505(b)(2)

- ▶ Pre-IND meeting completed with FDA
- ▶ Agreed development framework
- ▶ Phase II PK study underway
- ▶ Single pivotal Phase III Safety and Efficacy study required
- ▶ CMC and human factors programme progressing with Aptar
- ▶ Designed to support NDA submission under the 505(b)(2) pathway

Complementary Commercial Pathway – ROXUS (503A)

- ▶ Progressing commercial discussions with U.S. personalised medicine pharmacies and telehealth
- ▶ Intended to support early market presence
- ▶ Generates commercial experience and real-world insights
- ▶ Complementary to the FDA regulatory programme

FDA Regulatory Program Check Points



Portfolio Overview and Development Focus

Validated Platform Supporting Multiple Indications



Lead Clinical Program

SPONTAN **ROXUS**

*Intranasal Sprays for Erectile
Dysfunction*

- ▶ TGA Early Access – ACTIVE
- ▶ FDA 505(b)(2) regulatory pathway
 - ▶ Phase II PK Study – interim data released
 - ▶ 503A Commercial Discussions Progressing

Early Development

OROFLOW – Platform Expansion

*Intranasal Spray for
Oesophageal Motility Disorders (OMD)*

- ▶ Pre-clinical / proof-of-concept Stage
- ▶ Evaluating additional intranasal indications
- ▶ Capital prioritised to lead program

Strategic Investment LevOmega

Nature-Identical omega-3 Products

- ▶ Equity Investment – 43%
- ▶ Focused on development of nature-identical omega-3 products
- ▶ Separate development pathway and capital structure
- ▶ Complementary to LTR's core intranasal programs



Strategic Execution

Milestones, Partnerships
and Regulatory Progress

Global Co-Development Agreement Aptar Pharma

Strategic partnership driving regulatory success and market readiness



Combination product expertise

- ▶ Co-development agreement with Aptar Pharma (Nasdaq)
- ▶ VP7 multidose nasal spray platform
- ▶ Integrated drug-device development programme



Regulatory and development

- ▶ Extractables study completed
- ▶ Leachables study underway
- ▶ Human factors studies progressing
- ▶ Supporting FDA combination product requirements



Strategic significance

- ▶ Global supply and FDA expertise
- ▶ Alignment with 505(b)(2) development pathway
- ▶ Established pharmaceutical partner

Financial Position

Disciplined capital management supporting clinical and commercial execution



Cash in Bank

\$24.1 million



Quarterly Operation Cash Outflow

\$1.8 million



Debt Position

Zero debt

Funded Value Inflection Points

Completion of Phase II PK Study

● Interim data reported; final results Q3 CY2026



Human factors programme

● Underway



Non-clinical toxicology programme

● Progressing

US Market Entry Preparations

Ongoing

Funded to deliver near-term clinical milestones

Key Milestones

Executing across clinical, regulatory and commercial programmes



Achieved

- ▶ Phase II PK interim data reported
- ▶ Pre-IND meeting completed with FDA endorsement
- ▶ Extractables study completed — all compounds below ICH thresholds
- ▶ 1,000+ prescriptions under TGA early access
- ▶ Clinical data published in European Journal of Pharmaceutical Sciences



Near-Term (H1 2026)

- ▶ Human factors study completion
- ▶ Leachables study completion
- ▶ Progression of commercial discussions in support of entering the U.S. personalised medicine (503A) pathway



Development Progression (H2 2026+)

- ▶ Full Phase II data set
- ▶ Animal toxicology completion
- ▶ Phase III planning
- ▶ OROFLOW® proof-of-concept progression
- ▶ Strategic partnership discussions

\$24.1M cash | Zero debt | Supporting key clinical and regulatory milestones

Why Invest in LTR Pharma

Clinical proof. Contracted partners. Funded to deliver



Clinical Differentiation

- ▶ SPONTAN / ROXUS demonstrates 5x faster absorption at half the dose versus oral PDE5 tablets, reinforced by Phase II interim data confirming rapid onset and consistent safety in adult and ≥65 populations.



Clear and Efficient Regulatory Pathway

- ▶ Advancing via the FDA 505(b)(2) framework following successful Pre-IND engagement, requiring a single Pivotal Phase III study.



Early Validation and U.S. Strategy

- ▶ 1,000+ prescriptions under Australia's SAS programme supporting prescriber adoption.
- ▶ Dual U.S. approach: FDA pathway complemented by potential personalised medicine (503A) entry.



Capital and Strategic Position

- ▶ \$24.1M cash, zero debt, disciplined capital allocation.
- ▶ Partnerships with Aptar (Nasdaq), Mayne (ASX), and EBOS/Symbion (ASX).



Contact

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