LTR Pharma

Building a Portfolio of Differentiated Specialty Therapies

Investor Update | September 2026

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Executive Summary

LTR Pharma: Late-stage pharmaceutical platform approaching U.S. commercialisation

Differentiated Lead Program – SPONTAN / ROXUS

Rapid-acting intranasal PDE5 therapy demonstrating ~6x faster absorption versus oral tablets[1] with a favourable safety and tolerability profile.

U.S. Commercial Launch & FDA Value Pathway

ROXUS® U.S. commercial launch targeted for H2 CY26, with definitive agreements with Shed and Strive supporting the planned commencement of first U.S. commercial revenues. In parallel, SPONTAN® is advancing through the FDA 505(b)(2) pathway toward a single pivotal Phase III study.

Early Real-World Validation (Australia)

1,000+ prescriptions[2] 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 (NYSE). Commercial manufacturing with Mayne Pharma (ASX). Australian distribution through EBOS/Symbion (ASX), and U.S. commercial partnerships with Shed and Strive.

Funded Near-Term Execution

$19.6M cash and zero debt, supporting near-term U.S. commercial, clinical and regulatory value inflection points.[3]

Footnotes: 1) ~6x refers to median Tmax of ~10 minutes for SPONTAN (5 mg) versus ~60 minutes for oral vardenafil (20 mg), Phase II interim data; ASX announcement 1 May 2026. 2.) As at 17 December 2025 (ASX: 17 Dec 2025) . 3) Appendix 4C for quarter ended 30 June 2026. Cash figures in Australian Dollars.

US Strategy: What FDA approval unlocks

503A enables rapid commercialisation today, while the FDA approval has the potential to materially expand the addressable market and long-term commercial opportunity

ROXUS® - 503A

Rapid commercial launch and market validation

- ✓ **Rapid route to initial US revenues through cash-pay DTC and telehealth channels**
- ✓ **Efficient made-to-order manufacturing model with limited inventory requirements**
- ✓ **Generates commercial experience, physician adoption and real-world data to support broader strategy**
- ✓ **Establishes early physician adoption, prescribing behaviour and commercial proof points ahead of FDA approval**

SPONTAN® - 505(b)(2) approval

Expanded commercial opportunity

1. **Regulatory protection and intellectual property**
   505(b)(2) pathway may provide regulatory exclusivity and strengthen intellectual property protection through potential Orange Book listing
2. **Broader commercial reach**
   FDA-approved labelling supports promotional claims, payer engagement and potential reimbursement, expanding commercial opportunities
3. **Scalable pharmaceutical supply**
   Commercial-scale manufacturing supports broader distribution channels and long-term supply flexibility
4. **Strategic partnering opportunities**
   An FDA-approved product may enhance licensing, partnering and ex-US expansion opportunities via dossier

LTR's phased US strategy is designed to generate near-term commercial momentum while creating the foundation for a significantly larger long-term value opportunity

Illustrative of the potential benefits of FDA approval. Outcomes are not assured and are subject to regulatory and commercial factors.

US Commercialisation: Definitive Agreements Executed for ROXUS®

Two definitive agreements now in place spanning patient demand and pharmacy supply

DEMAND ENGINE

Shed Holdings LLC | Executed 17 Jul 2026

US direct-to-consumer telehealth platform: Mavrox

- First commercial route-to-market for ROXUS® in the United States
- ROXUS live on Mavrox as hero product; patient waitlist established
- Performance-based minimum commercial volume of 150,000 ROXUS® prescription units in the first 12 months from Commercial Launch
- Two-year US DTC telehealth exclusivity from launch, subject to performance

SUPPLY ENGINE

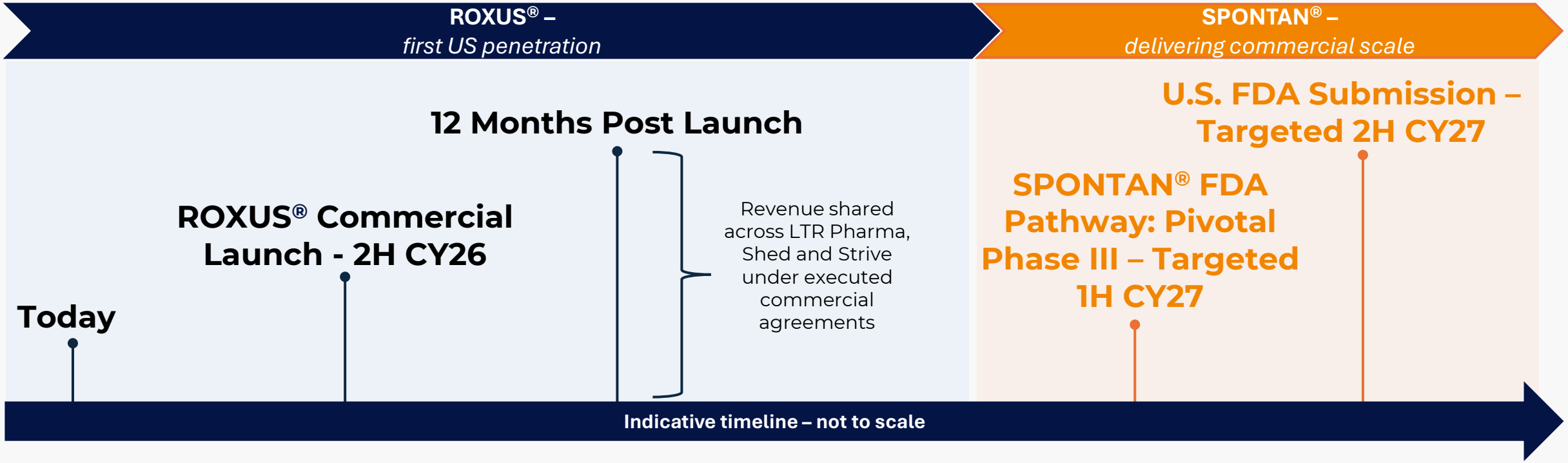
Strive Specialties Inc. | Executed 20 Jul 2026

Exclusive US 503A pharmacy and fulfilment partner

- Five-state 503A platform; nationwide compounding and fulfilment licensure
- Exclusive US pharmacy fulfilment partner with established provider and clinic networks
- Two-year exclusivity from Commercial Launch, subject to ongoing performance
- LTR Pharma remains product owner, intellectual property holder and formulation supplier

Binding commercial framework established across US patient acquisition and pharmacy fulfilment

US Commercialisation: Launch Strategy



ROXUS ®
Key In-Flight Activities:

- Technology transfer
- Commercial inventory planning
- Manufacturing readiness

ROXUS ®
Volume and Pricing:

- Shed commitment to support not less than **150,000 ROXUS® units** during the first 12 months
- LTP anticipates **pricing will be in line with other premium** ED competitors

ROXUS ®
Capital-light US Penetration:

- Capital-light market entry for LTR Pharma
- Shed actively promoting ROXUS® as a differentiated ED product on their platform

SPONTAN ®
FDA Approval for Commercial Scale:

- Unlocks pharma licensing partnerships
- Expands U.S. commercial channels
- Expands the addressable U.S. opportunity
- Supports scalable long-term U.S revenue growth

Why Invest in LTR Pharma

Clinical proof. U.S. launch approaching.

Expanding intranasal portfolio. Funded execution.

Clinical Differentiation

- SPONTAN® / ROXUS® demonstrates ~6x shorter median Tmax versus oral vardenafil, reinforced by Phase II interim data[1] confirming rapid absorption and a favourable safety profile across adult and ≥65-year cohorts.
- Positioned for treatment-experienced and difficult-to-treat populations, including post-prostatectomy patients.

U.S. Commercial Launch

- ROXUS® U.S. commercial launch targeted for H2 CY26; definitive agreements with Shed and Strive establish the route-to-market and launch preparations are underway.
- Shed commitment to support not less than 150,000 ROXUS® prescription units during the first 12 months from Commercial Launch.
- Designed to generate near-term commercial validation ahead of FDA approval.

Clear FDA Value Pathway

- Advancing through the FDA 505(b)(2) pathway following successful Pre-IND engagement, requiring a single pivotal Phase III study.
- FDA approval supports broader commercial reach, scalable pharmaceutical supply, potential payer engagement and strategic partnering opportunities.

Intranasal Portfolio & Capital Position

- SPONTAN® / ROXUS® leads a growing intranasal portfolio; OROFLOW® is an early platform expansion beyond ED into oesophageal motility disorders.
- $19.6M current cash, zero debt[2] and disciplined capital allocation.
- Strategic partnerships across development, manufacturing, distribution and U.S. commercialisation.

Note: (1) Interim data based on preliminary analysis of 27 subjects. Full statistical analysis is ongoing. Refer to the ASX announcement for details. (2) Appendix 4C for quarter ended 30 June 2026. Cash figures in Australian Dollars.

Large ED Market with a Clear Treatment Gap

Oral PDE5 inhibitors remain first-line, but response and persistence limitations leave a sizeable unmet need

~US$5B

estimated annual global ED drug market[1]

~322M

men globally estimated to have ED in 2025[1]

Treatment pathway and gap

1	**Oral PDE5 inhibitors**	First-line therapy; delayed onset and high discontinuation
2	**30–35% inadequate response**	Higher failure rates in difficult-to-treat populations[2]
3	**Invasive second-line options**	Intracavernosal injection utilisation has fallen >55-fold from peak[3]

SPONTAN® / ROXUS®

Rapid-onset, non-invasive PDE5 option

- Positioned across the broad ED market
- Supports patients seeking greater spontaneity
- Provides a non-invasive option for patients inadequately served by oral therapy
- Positioned before invasive treatments

1) Frost & Sullivan, The Erectile Dysfunction Medicines Market, September 2023. 2) McMahon et al., BMJ 2006. 3) Gillman & Chung, ANZ Journal of Surgery 2026 (MBS data 1996–2024; in-office, MBS-billed procedures only).

Phase II Data Reinforce Rapid and Predictable Pharmacokinetic Profile

Interim pharmacokinetic and safety dataset

Key interim findings

- Median Tmax ~10 minutes for SPONTAN® 5 mg
- Comparable PK across adult and ≥65-year cohorts
- No evidence of drug accumulation following 5 days of repeat dosing
- No serious adverse events
- No Grade 3 or 4 treatment-emergent adverse events
- No treatment-related discontinuations

SPONTAN® vs oral comparator

~6x shorter median Tmax

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 Grade 3/4 TEAEs	No serious or severe TEAEs

Study designed in accordance with FDA Pre-IND guidance

Note: Interim data based on preliminary analysis of 27 subjects. Full statistical analysis is ongoing. Lower Cmax relative to oral comparator reflects lower dose. Refer to the ASX announcement dated 1 May 2026 for full details.

Australian Early Access Provides Real-World Clinical Validation

TGA Special Access Scheme | treatment-experienced real-world cohort

1,000+
prescriptions as at 17 Dec 2025[1]

Expanding
prescriber adoption

Established
distribution and fulfilment infrastructure

Improved erectile hardness and/or achieving penetration[2]

Real-world cohort of 147 treatment-experienced men

93% 42 of 45

Seeking greater convenience and spontaneity

64% 56 of 87

Post-prostatectomy subgroup

Context: Only 28% of men report erections firm enough for intercourse five years after radical prostatectomy.[3]

57% 58 of 102

Inadequate response to oral PDE5 therapy

Overall cohort: **68% (100 of 147)**

Non-prostatectomy subgroup: **73% (44 of 60)**

Encouraging real-world outcomes in treatment-experienced and difficult-to-treat populations, including men inadequately served by oral PDE5 therapy and men following prostatectomy.

Source: ASX announcement 11 August 2026 (147-patient real-world cohort). 1) As at 17 December 2025 (ASX announcement 17 December 2025). 2) Composite endpoint: improved erectile hardness and/or achieving penetration; real-world observational data. 3) Penson DF, McLerran D, Feng Z, et al. J Urol 2008;179(5 Suppl):S40-4.

Global Co-Development Agreement Aptar Pharma

Strategic partnership driving regulatory success and market readiness

Combination product expertise

- Co-development agreement with Aptar Pharma (NYSE)
- 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

Portfolio Overview and Development Focus

Validated Platform and Expanding Men's Health Portfolio

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 partners secured (US)

Early Development

OROFLOW – Platform Expansion

Intranasal Spray for Oesophageal Motility Disorders (OMD)

- HREC-approved study; initiation pending hospital contract sign-off
- First platform application beyond ED, in gastrointestinal disease
- Capital prioritised to lead program

Portfolio Expansion

KYZATREX®

Oral Therapy for Testosterone Deficiency

- Exclusive pilot commercialisation agreement with Marius Pharmaceuticals (US)
- FDA-approved oral testosterone therapy; initial Australian patient access via the TGA Special Access Scheme
- Six-month evaluation period, with a right to negotiate an exclusive Australian licence

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

OROFLOW® Expands the Intranasal Platform Beyond ED

First application of the platform in gastrointestinal disease

Significant Unmet Need

OMD can cause impaired swallowing and painful oesophageal contractions, with many patients ultimately requiring invasive interventions including surgery, pneumatic dilation or botulinum toxin injection.

Potential Non-Invasive Treatment

OROFLOW® is designed as a fast-acting intranasal treatment that may improve oesophageal emptying, swallowing function and eating-related chest pain, while avoiding the need to swallow an oral tablet.

Platform Expansion & Market Opportunity

First gastrointestinal application of LTR Pharma's proprietary intranasal platform approved for formal clinical evaluation, addressing an OMD treatment market projected to reach ~US$8.1B by 2034.

HREC-approved investigator-initiated study independently led by Dr Peter Wu, Director of St George Motility Services.

Potential fast-acting, non-invasive treatment for a debilitating condition where many patients ultimately require invasive intervention.

[1] Fact.MR, Ineffective Oesophageal Motility Treatment Market Analysis, 2024. OROFLOW® is an investigator-initiated study, independently led by Dr Wu. ASX announcement: 24 June 2026.

Financial Position

Disciplined capital management supporting clinical and commercial execution

Cash in Bank

$19.6 million

Avg. Quarterly Net Operating Outflow[1]

$2.8 million

Debt Position

Zero debt

Funded Value Inflection Points

1 ROXUS® U.S. Commercial Launch & First Revenues

Targeted H2 CY2026 U.S. commercial launch and commencement of first U.S. commercial revenues via the Section 503A pathway, subject to completion of launch-readiness conditions.

2 SPONTAN® Final Phase II Data & FDA Readiness

Final Phase II PK analysis and submission-enabling activities supporting the FDA 505(b)(2) pathway.

Includes CMC package finalisation, human factors validation and related regulatory workstreams.

3 OROFLOW® Study Initiation

HREC approval received; initiation pending hospital contract sign-off.

Initial clinical results to follow study commencement.

Supporting activities include CMC package finalisation, human factors validation, leachables and non-clinical toxicology.

Funded to deliver near-term U.S. commercial, clinical and regulatory value inflection points

Source: Appendix 4C for the quarter ended 30 June 2026. 1) Average net operating cash outflow per quarter over the twelve months to 30 June 2026. June 2026 quarter net operating outflow: $4.4M. Cash figures in Australian Dollars

Key Milestones

Commercial and clinical catalysts driving key value inflection points

Achieved

- Phase II PK interim data reported
- Pre-IND meeting completed with FDA alignment on development plan
- Extractables study completed
- 1,000+ prescriptions under TGA early access
- Clinical data published in European Journal of Pharmaceutical Sciences
- Definitive U.S. commercial agreements executed with Shed and Strive

Near-Term Catalysts

- **ROXUS® – U.S. Commercial Launch and First Revenues**
  Targeted U.S. commercial launch and commencement of first U.S. commercial revenues via the Section 503A pathway, subject to completion of launch-readiness conditions.
  H2 CY2026
- **SPONTAN® – Final Phase II PK Data**
  Final Phase II PK data and statistical analysis supporting the FDA 505(b)(2) regulatory pathway.
  Q3 CY2026
- **SPONTAN® – Submission-Enabling Activities**
  Completion of submission-enabling activities including CMC package finalisation, human factors validation and related regulatory workstreams.
  H2 CY2026
- **OROFLOW® – Study Initiation**
  HREC approval received; commencement pending hospital contract sign-off.

Development Progression

- **SPONTAN® – Pivotal Phase III**
  Planned commencement of pivotal Phase III study.
- **SPONTAN® – U.S. FDA Submission**
  Planned U.S. FDA submission under the 505(b)(2) pathway.
- **OROFLOW® – Initial Clinical Results**
  Initial clinical results / proof-of-concept assessment following study commencement.

Near-term catalysts spanning first U.S. commercial revenues, late-stage clinical development and platform expansion.

Note: Timings are targets and subject to change

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Authorised for release by the Board of Directors

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Appendix

Supporting information

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+	2003/2010	Yes
Avanafil	Stendra	30 minutes+	2012	Yes

Issues with oral PDE5 inhibitors

- Does not work for 30-35% of patients[1]
- Long response time of 1 hour + affects spontaneity
- Adverse reactions in up to 35% of patients[3]

= High discontinuation rate

And when orals fail, the next options are rarely used

- Injections (ICI): use down >55-fold from peak[2]
  Prosthesis surgery: ~3.6 per 100,000 men[2]

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

1) McMahon et al., BMJ 2006. 2) Gillman & Chung, ANZ Journal of Surgery 2026 (MBS data 1996-2024; in-office, MBS-billed procedures only). 3) Carvalheira et al., J Sex Med 2012.

SPONTAN®

Phase I Pharmacokinetic Study

Rapid absorption, consistent delivery and favourable safety profile

- SPONTAN® nasal spray achieved **rapid absorption** 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.
- **Phase I findings reproduced and extended in the Phase II interim dataset**.

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

Source: SPONTAN Phase I Final Study Report, ASX announcement 14 October 2024; published in the European Journal of Pharmaceutical Sciences (ASX announcement 20 August 2025). Oral comparator: vardenafil 10 mg.

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. 3) Selvin E, Burnett AL, Platz EA. Prevalence and risk factors for erectile dysfunction in the US. Am J Med 2007;120:151-7.

Prevalence in Key Markets

As risk factors become more prevalent, so does ED

Global estimate ~322m men in 2025

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