



SPONTAN

Fast-acting nasal
spray treatment for
erectile dysfunction



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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

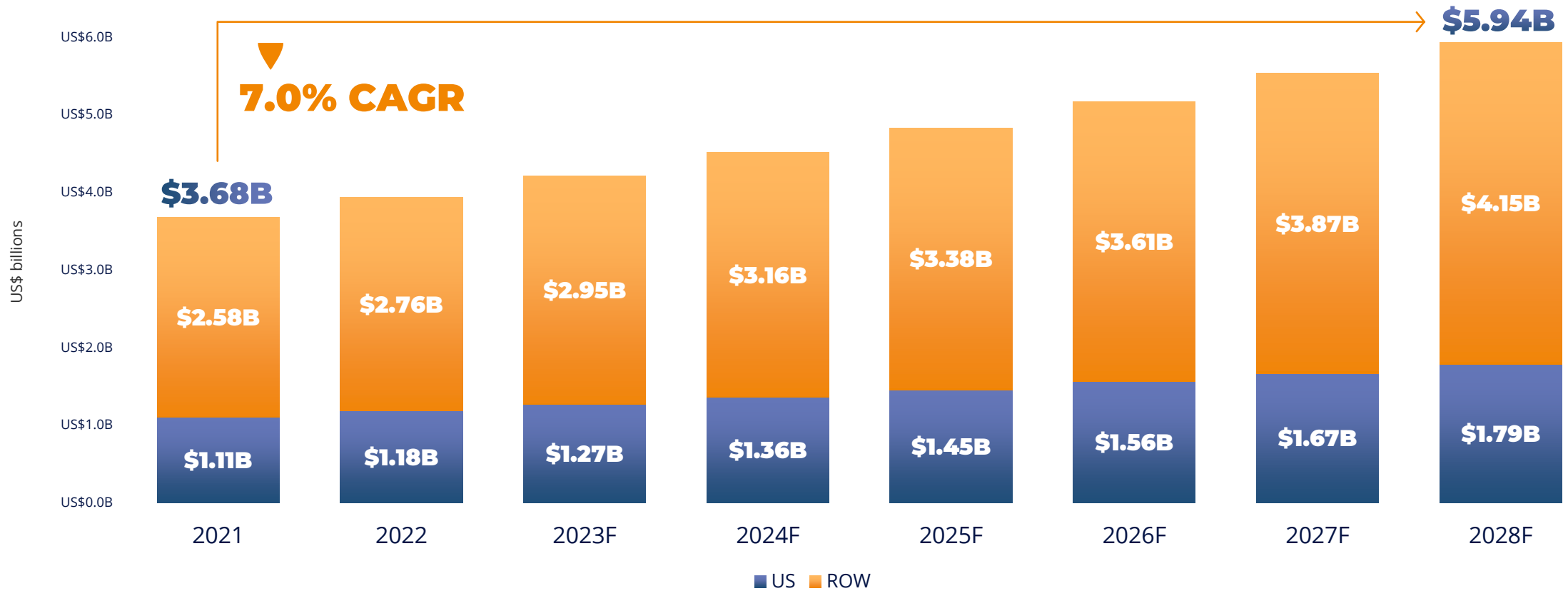


Industry overview*

*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



Company Overview

Nasal Administration

Delivery mechanism can solve many of issues facing PDE5 inhibitors

Advantages vs oral administration



More rapid
onset of action



Less active
pharmaceutical
ingredients required



Higher rate
of absorption



Less drug degradation
due to bypassing the
digestive system



Lower adverse
reactions



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

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



(US)

FDA

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



(AUS)

TGA

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



Key Milestones

Multiple value inflection points for the Company throughout Financial Year 2025

Near Term Execution Pathway	FY25			
	Q1	Q2	Q3	Q4
Full Pivotal Clinical Trial Data	█			
Early Access Use Australia	█	█		
Pre-submission Meeting with FDA & TGA		█	█	
Additional Products to Pipeline			█	
Licensing / Partnering Negotiations			█	█



Offer Overview & Timetable

Capital Raising Overview

Offer Structure

A single tranche placement to sophisticated and institutional investors to raise a minimum of A\$10.5 million (before costs) (Placement) via the issue of up to 14.34m new fully paid ordinary shares (New Shares) utilising the Company's available placement capacity under Listing Rule 7.1.

Offer Price

The Placement conducted at A\$0.7300 per New Share, representing a:

- ▶ 18.9% discount to the last traded price of A\$0.9000 per share on Friday, 19 July 2024
- ▶ 16.0% discount to the 5-day VWAP of A\$0.8693 per share;
- ▶ 14.5% discount to the 10-day VWAP of A\$0.8539 per share; and
- ▶ 13.2% discount to the 30-day VWAP of A\$0.8411 per share.

Ranking

Each New Share issued under the placement will rank equally with existing fully paid ordinary shares on issue

Sole Lead Manager

Alpine Capital Pty Limited (**Alpine Capital**)

Use of Funds & Timetable

Use of Funds	\$10.5m (AUD)
Sales & Marketing Partnering	\$2,000,000
Telemedicine Consumer Website	\$1,000,000
R&D Pipeline Expansion	\$2,000,000
Regulatory Studies	\$1,400,000
Working Capital	\$3,470,000
IR / Cost of the Offer	\$630,000
Total	\$10,500,000

Event	Date
Trading Halt	Monday, 22 July 2024
Trading Halt lifted on announcement to ASX of the Offer	Wednesday, 24 July 2024
Settlement Date of the New Shares issued under the Placement	Tuesday, 30 July 2024
Allotment of New Shares issued under the Placement	Wednesday, 31 July 2024

Corporate Overview

Strong Funding to Commercial Outcomes

(ASX:LTP) Public Market Overview (19 July 2024)

Share Price	A\$0.9000
52-week range	A\$0.24 – A\$1.05
Market Cap	A\$125.48M
Cash equivalents (31 March 2024)	A\$5.28M
Top 20 shareholder percentage	57.94%

1. As at market close Friday, 19 July 2024



LTR Pharma

Appendix

Company History

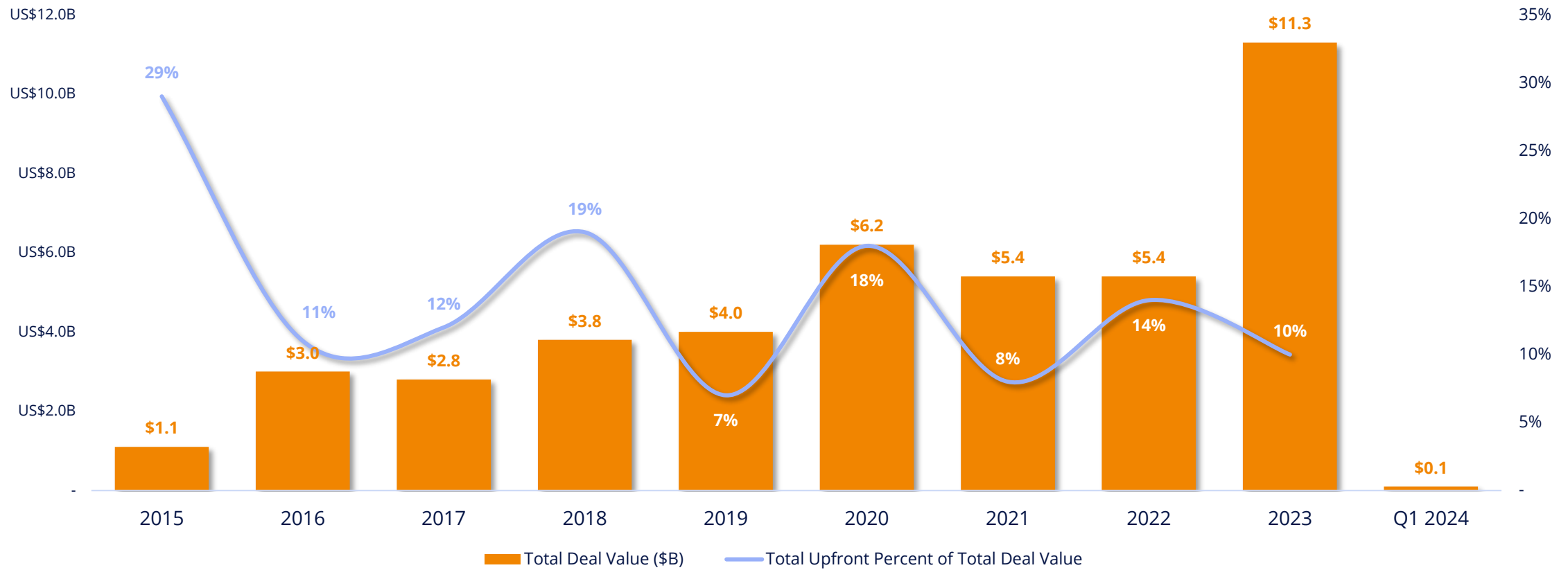
Progressed company substantially derisking the proposition



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 Front¹



ED and its Causes

A major factor in relationship breakdown

Erectile dysfunction (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

Global ~322m men by 2025





Key Risks

Key Risks

Early clinical state of development	LTP's candidate product has proceeded to a pharmacokinetic clinical trial stage. No guarantee can be provided that the proposed clinical work will be successful or result in a product approved for use by a regulatory agency; however, an investigator lead, human proof of concept study completed in February 2020 has already shown positive outcomes in a clinical study and initial results from the pharmacokinetic clinical trial confirmed a faster time to maximum concentration compared to oral PDE5 inhibitors.
Competition	The biotechnology and pharmaceutical industries are highly competitive, and include companies with significantly greater financial, technical, human, research and development, and marketing resources than LTP. There are companies that compete with LTP's efforts to discover, validate and commercialise therapeutic uses for products or product candidates. LTP's competitors may discover and develop products in advance of LTP and/or products that are more effective than those developed by LTP. As a consequence, LTP's current and future products may become obsolete or uncompetitive, resulting in adverse effects on revenue, margins and profitability. LTP anticipates market exclusivity protection in the United States for SPONTAN® for a period of 3 years subject to receiving regulatory approval by the FDA.
Healthcare insurers and reimbursement	In both domestic and foreign markets, a component of LTP's product sales may depend in part upon the availability and amounts of reimbursement from third party health care payer organisations, including government agencies, private health care insurers and other health care payers such as health maintenance organisations and self-insured employee plans. No assurance can be given that reimbursement will be provided by such payers at all or without substantial delay, or, if reimbursement is provided, that the approved reimbursement amounts will be sufficient to enable LTP to sell its products on a profitable basis.
Reliance on key personnel	LTP currently employs a number of key management and scientific personnel and consultants, and its future depends on attracting and retaining suitably qualified personnel. LTP has included, in its terms of employment, provisions aimed at offering competitive remuneration and incentives, assisting in the recruitment and retention of such key personnel. It has also established contractual mechanisms through employment and consultancy contracts to limit the ability of key personnel to join a competitor or compete directly with the Company. Despite these measures, however, there is no guarantee that LTP will be able to attract and retain suitably qualified personnel, and a failure to do so could materially and adversely affect the Company's business, operating results and financial prospects
Regulatory requirements	LTP will need to seek approval from the US FDA and Australia TGA to commercialise and market its product, as well as equivalent regulatory authorities in other foreign jurisdictions to commercialise in those regions. There is a risk that these regulatory authorities may not approve LTP's proposed regulatory approval application or may require LTP to undertake more trials and cause a delay in the LTP's product launch.
Product Liability	As with all new biotechnology products, even after the granting of regulatory approval, there is no assurance that unforeseen adverse events or manufacturing defects will not arise. Adverse events could disrupt the supply chain and expose LTP to product liability claims or litigation, resulting in the removal of the regulatory approval for the relevant products and/or monetary damages being awarded against LTP. In that event, the Company's liability may exceed the Company's insurance coverage.

Key Risks

Intellectual Property	There is no guarantee that LTP's intellectual property, whether owned or licensed from others, comprises all of the rights that LTP may require to freely commercialise its product candidates. Patent applications in significant markets have been lodged in respect of LTP's product candidate. However, there is no assurance that those patent applications will result in granted patents in all desired jurisdictions. If the Company's intellectual property rights are ever challenged it may also not have the funds to oppose the challenge. Lastly, the Company's right to exploit the nasal delivery of Vardenafil is subject to its licensing arrangements. If these licensing arrangements were to be jeopardised, it could have significant detrimental effects on the Company's business.
Trade secrets	LTP relies in-part on trade secrets, which include information relating to the manufacture, development and administration of its products. While LTP has taken protective measures in that regard, they may not provide adequate protection for those trade secrets. This could erode LTP's competitive advantage and materially harm its business. LTP cannot be certain that others will not independently develop the same or similar technologies on their own or gain access to trade secrets or disclose such technology.
Infringements of third-party IP	If a third party accuses the Company of infringing its intellectual property rights or if a third party commences litigation against LTP for the infringement of patent or other intellectual property rights, the Company may incur significant costs in defending that action, whether or not it ultimately prevails. Costs that the Company incurs in defending third party infringement actions would also include diversion of management's and technical personnel's time.
Disruption of business operations	The Company is exposed to a large range of operational risks relating to both current and future operations. Such operational risks include fraud / dishonesty by its employees or service providers, industrial action or disputes and natural disasters. While the Company endeavours to take appropriate action to mitigate these operational risks and, where the Directors consider it practicable, insure against them, the Company cannot remove all risks of disruption to its operations.
Dependence on service providers	The Company intends to operate a significant amount of its key clinical activities through a series of contractual relationships with independent contractors and suppliers. The Company relies on and will continue to rely on a number of its contractors for their expertise in manufacture and clinical development. All of the Company's contracts carry a risk that the third parties do not adequately or fully comply with its or their respective contractual rights and obligations.
Currency risk	Revenue and expenditures in overseas jurisdictions are subject to the risk of fluctuations in foreign exchange markets. Accordingly, payment will be made in those countries' currencies, and may exceed the budgeted expenditure if there are adverse currency fluctuations against the Australian dollar.
Contractual and counterparty risks	The Company will have various contractual rights in the event of non-compliance by a contracting party. However, no assurance can be given that contracts will be fully performed by all contracting parties and that the Company will be successful in securing compliance with each contract by the counterparties to its contracts.



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