



LTR Pharma

# Replacement Prospectus

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LTR Pharma Limited

ACN 644 924 569

For the offer to issue up to 35,000,000 Shares at an issue price of \$0.20 per Share to raise up to \$7 million (with a minimum raising of \$6 million) and other offers

**The Offers are not underwritten.**

Lead Manager:



ALPINE CAPITAL

Australian Legal Advisor:

K&L GATES

**IMPORTANT INFORMATION:**

This is an important document and it should be read in its entirety. If after reading this Prospectus, you do not fully understand it or the rights attaching to the Shares offered by it, you should consult an accountant, solicitor or other professional adviser for assistance. The Shares offered by this Prospectus should be considered highly speculative.

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# 1. Important Notices

## Offers

The Offers contained in this replacement Prospectus are an invitation to acquire fully paid ordinary shares (**Shares**) in LTR Pharma Limited ACN 644 924 569 (**LTP or Company**).

## Lodgement and Listing

This Prospectus is dated 9 November 2023 (**Prospectus Date**) and it replaces the Original Prospectus dated 1 November 2023 relating to the Shares of the Company. A copy of this Prospectus was lodged with the Australian Securities and Investments Commission (**ASIC**) on 9 November 2023.

The Company has applied to ASX Limited (**ASX**) within 7 days after the date of the Original Prospectus for admission of the Company to the official list of ASX and quotation of its Shares on ASX. None of ASIC, ASX or their officers take any responsibility for the content of this Prospectus or for the merits of the investment to which this Prospectus relates.

## Overview of the material changes from the Original Prospectus

This Prospectus has been issued to provide disclosure in relation to the following matters, which are the material changes from the Original Prospectus (and to make consequential amendments):

- further disclosures regarding the Company's statements regarding the expenditure program;
- minor changes to the Indicative Key Dates; and
- minor changes to the description of the interests of experts section of this Prospectus.

## Exposure Period

In accordance with Chapter 6D of the Corporations Act, the Original Prospectus was subject to an exposure period of seven days from the date of lodgement of the Original Prospectus with ASIC. The exposure period was not extended by ASIC.

## Note to Applicants

The information in this Prospectus is not financial product advice and does not take into account your investment objectives, financial situation or particular needs.

It is important that you read this Prospectus carefully and in its entirety before deciding whether to invest in the Company. In particular, you should consider the risk factors that could affect the performance of

the Company. You should carefully consider these risks in light of your personal circumstances (including financial and tax issues) and seek professional guidance from your stockbroker, solicitor, accountant or other independent professional adviser before deciding whether to invest in Shares. Some of the key risk factors that should be considered by prospective investors are set out in section 11. There may be risk factors in addition to these that should be considered in light of your personal circumstances. You should also consider the assumptions underlying the financial information and the risk factors that could affect the Company's business, financial condition and results of operations. No person named in this Prospectus, nor any other person guarantees the performance of the Company or the repayment of capital or any return on investment made pursuant to this Prospectus.

## Specific risks as an early-stage biotechnology company

Applicants should carefully consider the risk factors that affect the Company specifically and generally the biotechnology industry in which it operates. Applicants should note that a company seeking to develop and commercialise a new therapeutic product and obtain regulatory approval and then secure market acceptance / market penetration is a very high-risk endeavour.

## Photographs and diagrams

Photographs used in this Prospectus that do not have descriptions are for illustration only and should not be interpreted to mean that any person endorses this Prospectus or that assets shown in them are owned by the Company.

Diagrams used in this Prospectus are illustrative only and may not be drawn to scale. Unless otherwise stated, all data contained in graphs, charts and tables is based on information available as at the date of this Prospectus.

## No offering where offering would be illegal

This Prospectus does not constitute an offer or invitation in any place in which, or to any person to whom, it would not be lawful to make such an offer or invitation. No action has been taken to register or qualify the Shares or the Offer, or to otherwise permit a public offering of the Shares in any jurisdiction outside Australia. The distribution of this Prospectus outside Australia may be restricted by law and persons who come into possession of this Prospectus outside Australia should seek advice on and observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of applicable securities laws.

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This Prospectus has been prepared for publication in Australia and may not be released or distributed in the United States. This Prospectus does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States. The Shares and Existing Shares have not been, and will not be, registered under the US Securities Act or the securities laws of any state of the United States, and may not be offered or sold in the United States, or to, or for the account or benefit of a US Person, except in a transaction exempt from the registration requirements of the US Securities Act and applicable United States state securities laws. The Offers are not being extended to any investor outside Australia, other than to institutional investors as part of the Offers. This Prospectus does not constitute an offer or invitation to potential investors to whom it would not be lawful to make such an offer or invitation.

#### **Financial information presentation**

Section 8 sets out in detail the financial information referred to in this Prospectus. The basis of preparation of that information is set out in section 8. All financial amounts contained in this Prospectus are expressed in Australian dollars and rounded to the nearest \$1.00 unless otherwise stated. Any discrepancies between totals and sums of components in tables contained in this Prospectus are due to rounding.

#### **Forward looking statements**

Various statements in this Prospectus may be in the nature of forward-looking statements, including statements of current intentions, statements of opinion and predictions as to future events. You should be aware that such statements are not statements of fact and there can be no certainty of outcome in relation to the matters to which the statements relate.

Forward looking statements are subject to various inherent risks and uncertainties (many of which are outside the Company's control) that could cause the Company's actual results to differ materially from the results expressed or anticipated in these statements. As a result, forward looking statements should be read in conjunction with risk factors as set out in section 11 and other information in this Prospectus.

#### **Suitability of investment and general risk factors**

This Prospectus provides information to help investors decide whether they wish to invest in the Company. Before deciding to invest in the Company, potential investors should read this entire Prospectus, and in particular the technical information and the risk factors that could affect the future operations and activities of the Company. The Offers contained in this Prospectus does not take into account the investment objectives, financial situation and particular needs of individual investors. Please read the Application Form carefully. Professional advice should be sought before

deciding to invest in any securities the subject of this Prospectus.

#### **Disclaimer**

No person is authorised to give any information or to make any representation in connection with the Offers described in this Prospectus which is not contained in this Prospectus. Any information not so contained may not be relied upon as having been authorised by the Company, or any other person in connection with the Offers. You should rely only on information in this Prospectus.

It is expected that the Shares will be quoted on ASX. The Company, the Lead Manager and the Share Registry disclaim all liability, whether in negligence or otherwise, to persons who trade Shares before receiving their holding statement.

#### **Obtaining a copy of this Prospectus**

A paper copy of the Prospectus is available free of charge to any person in Australia by calling the LTR Pharma IPO information line on 1300 441 607 (within Australia) or +61 2 7250 6677 (outside Australia) from 9.00 am until 5.00 pm AEDT Monday to Friday during the Offer Period.

This Prospectus is also available to Australian resident investors in electronic form at the Offer website, [LTRPharma.automicipo.com.au](http://LTRPharma.automicipo.com.au). The Offer constituted by this Prospectus in electronic form is available only to Australian residents accessing the website from Australia. It is not available to persons in the United States. Persons who access the electronic version of this Prospectus should ensure that they download and read the entire Prospectus.

Applications for Shares may only be made on the appropriate Application Form attached to, or accompanying, this Prospectus in its paper copy form, or in its electronic form which must be downloaded in its entirety from [LTRPharma.automicipo.com.au](http://LTRPharma.automicipo.com.au). By making an Application, you declare that you were given access to the Prospectus, together with an Application Form. The Corporations Act prohibits any person from passing the Application Form on to another person unless it is attached to, or accompanied by, this Prospectus in its paper copy form or the complete and unaltered electronic version of this Prospectus.

#### **Defined terms and abbreviations**

Defined terms and abbreviations used in this Prospectus are explained in section 14. Unless otherwise stated or implied, references to times in this Prospectus are to AEDT.

#### **Privacy**

By completing an Application Form, you are providing personal information to the Company, and the Share Registry, which is contracted by the

Company to manage Applications. The Company, and the Share Registry on their behalf, collect, hold and use that personal information to process your Application, service your needs as a Shareholder, provide facilities and services that you request and carry out appropriate administration. Your personal information may also be used from time-to-time to inform you about other products and services offered by the Company, which it considers may be of interest to you.

Once you become a Shareholder, the Corporations Act and Australian taxation legislation require information about you (including your name, address and details of the Shares you hold) to be included in the Company's public register. The information must continue to be included in the Company's public register if you cease to be a Shareholder. If you do not provide all the information requested, your Application Form may not be able to be processed. The Company, and the Share Registry may disclose your personal information for purposes related to your investment to third parties including their related companies, agents and service providers and the Company's members, and as disclosed in the Company's Privacy Policy which is available from the Company on request or as otherwise authorised under the *Privacy Act 1988 (Cth)*. Those third parties may be located outside Australia where your personal information may not receive the same level of protection as afforded under Australian law.

You may request access to your personal information held by or on behalf of the Company. You can request access to your personal information or obtain further information about the Company's privacy practices by contacting the Share Registry or the Company. The Company aims to ensure that the personal information it retains about you is accurate, complete and up-to-date. To assist with this, please contact the Company or the Share Registry if any of the details you have provided change. The Company's Privacy Policy contains information about how you may access and seek correction of your personal information, how you may complain about a breach of your privacy, and how the Company will deal with that complaint.

In accordance with the requirements of the Corporations Act, information on the Shareholder register will be accessible by members of the public.

#### **If you have any questions**

If after reading this Prospectus, you do not fully understand it or the rights attaching to the Shares offered by it, you should consult an accountant, solicitor or other professional adviser for assistance. The Company is unable to advise applicants on the suitability or otherwise of an investment in the Company.

**This document is important and should be read in its entirety.**

## 2. Corporate Directory

<p><b>Directors</b></p> <p>Lee Rodne – Executive Chairman</p> <p>Dr. Julian Chick – Non-Executive Director</p> <p>Maja McGuire – Non-Executive Director</p>	<p><b>Australian Legal Adviser</b></p> <p>K&amp;L Gates</p> <p>Level 25, 525 Collins Street</p> <p>Melbourne, Victoria 3000</p>
<p><b>Company Secretary</b></p> <p>Belinda Cleminson</p>	<p><b>Share Registry</b></p> <p>Automic Group</p>
<p><b>Registered Office</b></p> <p>9/204 Alice Street</p> <p>Brisbane, Queensland 4000</p>	<p><b>Patent Attorney</b></p> <p>Griffith Hack</p> <p>10/161 Collins Street</p> <p>Melbourne, Victoria 3000</p> <p>Foley and Lardner LLB</p> <p>3000 K Street N.W.</p> <p>Suite 600, Washington DC</p> <p>DC, 200007-5101</p>
<p><b>Lead Manager</b></p> <p>Alpine Capital Pty Ltd</p> <p>Suite 803, Level 8, 25 Bligh Street</p> <p>Sydney, NSW 2000</p>	<p><b>Investigating Accountant</b></p> <p>William Buck Consultants (WA) Pty Ltd</p> <p>Level 3, 15 Labouchere Road</p> <p>South Perth, Western Australia 6151</p>
<p><b>Auditors</b></p> <p>William Buck Audit (WA) Pty Ltd</p> <p>Level 3, 15 Labouchere Road</p> <p>South Perth, Western Australia 6151</p> <p>HLB Mann Judd (WA Partnership)</p> <p>Level 4, 130 Stirling Street</p> <p>Perth, Western Australia 6000</p> <p>(Resigned effective 31 October 2023.)</p>	<p><b>Industry Expert</b></p> <p>Frost &amp; Sullivan Pty Ltd</p> <p>Suite 1.02, 54 Miller Street</p> <p>North Sydney, NSW 2060</p>



## Key Offer Information

### The Offer

LTR Pharma Limited ACN 644 924 569 (**LTP** or **Company**) (proposed ASX code: LTP) is seeking to raise a minimum of \$6 million (**Minimum Subscription**) and up to a maximum of \$7 million (**Maximum Subscription**) by the issue of up to 35,000,000 Shares at an Offer Price of \$0.20 per Share.

Following the completion of the Offers, the shareholding structure in the Company will be as follows:

Category	Based on the Minimum Subscription	Based on the Maximum Subscription
Existing Shares on issue <sup>1</sup>	104,170,252	104,170,252
Shares offered under this Prospectus under the Investor Offer	30,000,000	35,000,000
Other Shares offered under this Prospectus <sup>2</sup>	250,000	250,000
Total number of Shares on completion of the Offers <sup>3</sup>	134,420,252	139,420,252
Offer Price (A\$) <sup>4</sup>	0.20	0.20
Lead Manager Options	2,393,438	2,792,344
Other Options on issue	2,000,000	2,000,000
Gross proceeds from the Investor Offer	\$6,000,000	\$7,000,000
Indicative market capitalisation at the Offer Price <sup>5</sup>	\$26,884,050.40	\$27,884,050.40

<sup>1</sup> See section 13.2 of this Prospectus for more detail.

<sup>2</sup> Grannus Offer.

<sup>3</sup> The percentage of Shares in the total share capital of the Company available at Listing for investors to freely trade in the public market (i.e. 'free float') is expected to be between approximately 46.69% and 50.52% based on the Minimum Subscription and Maximum Subscription respectively.

<sup>4</sup> Shares may not trade at the Offer Price post listing on ASX.

<sup>5</sup> This represents the Offer Price multiplied by the total number of Shares at Listing.

### Indicative Key Dates\*

Original Prospectus lodged with ASIC	1 November 2023
<b>Replacement Prospectus Lodged with ASIC</b>	9 November 2023
Opening Date	10 November 2023
Closing Date	24 November 2023
Expected date for allocation of Shares	1 December 2023
Holding Statements sent to Shareholders	5 December 2023
Expected date for quotation of the Company's securities on ASX	11 December 2023

\* *The Directors reserve the right to vary the Offer dates and to extend the Issue or to close it at an earlier date. The above dates are indicative only and may change. The Directors reserve the right to amend any and all of the above dates without notice to you including (subject to the ASX Listing Rules and the Corporations Act), to close the Offer early, to extend the Offer, to accept late Applications, either generally or in particular cases, or to withdraw the Offer before settlement. If the Offer is withdrawn before the issue of the Shares, then all Application Monies will be refunded in full (without interest) as soon as practicable in accordance with the requirements of the Corporations Act.*

## Message from the Chairman

Dear Investor

On behalf of the Directors, I have great pleasure in presenting this Prospectus and offering to you the opportunity to become a shareholder in LTR Pharma Limited ACN 644 924 569 (**LTP** or the **Company**).

LTP is a public company, with operations based in Brisbane, Queensland. Our core, immediate focus is on holistically improving men's health, both physically and mentally, through commercialising an innovative nasal spray treatment for erectile dysfunction (**ED**) – a pressing health issue for millions of men that can negatively impact self-esteem and relationships. By addressing ED, we aim to support men's overall mental health, wellbeing, and quality of life, across multiple age brackets.

You are now presented with a compelling opportunity to participate in our Initial Public Offer (**IPO**) as we endeavour to list the Company on the Australian Securities Exchange (**ASX**).

The global market for ED treatments was estimated to be worth US\$3.6 billion in 2021 and is expected to grow to US\$5.9 billion by the end of 2028. Consumer demand warrants new and innovative treatments in this market category.

And we are responding, fast.

Our candidate product, SPONTAN<sup>®</sup>, is set apart from existing therapies by its mechanism of action, a unique intranasal delivery technology which bypasses the digestive system and is designed to overcome certain issues experienced by some patients using other ED therapies, namely oral tablets, by having a significantly faster onset of action, expected within 10 minutes of administration and with an expected lower effective drug dose.

Our proposed delivery technology supports a targeted and efficient delivery of an already proven, effective and regulatory-cleared ED drug, Vardenafil. The key to SPONTAN<sup>®</sup>'s expected success, we believe, is the length of time it takes to potentially work.

Time is something we have carefully considered in the Company's commercial development plan too. Bringing regulated pharmaceutical products to market is typically a long and costly process. However, we believe that SPONTAN<sup>®</sup> will qualify for established and shortened TGA and FDA pathways to commercialisation approval, under the change of route to administration for an already approved drug, and we will work to achieve commercialising SPONTAN<sup>®</sup> in Australia and the United States in the 2024 calendar year.

We have important work ahead of us, with our most imminent priority to execute a bioequivalence trial of SPONTAN<sup>®</sup> to enable LTP to seek these expedited regulatory approvals in order to ultimately sell and market SPONTAN<sup>®</sup> (initially) in the United States and Australia. We have a lean, but highly experienced team of pharmaceutical developers and commercialisation experts driving this program forward.

I encourage you to participate in this exciting and defining chapter of the Company's life cycle by participating in the LTR Pharma Limited IPO.

This Prospectus offers for subscription, Shares in the Company at \$0.20 to raise a maximum of \$7 million along with other offers as detailed in this Prospectus. Alpine Capital Pty Ltd has been appointed as Lead Manager to this IPO.

An investment in the Company is subject to a range of general and specific risks. These risks include risk associated with insufficient funding, innovation and competition risk, risk associated with undertaking clinical trials, regulatory risk, intellectual property and trade secret risk. A summary of the main risk factors associated with an investment pursuant to this Prospectus are highlighted in section 11.

The Closing Date for Application and payment is 5.00pm AEDT on 24 November 2023, unless the Maximum Subscription is reached earlier, or later as determined by the Directors.

In the context of intimacy and ED as a health issue, the desire for greater control over timing, spontaneity, and enjoyment of sexual experiences at the appropriate time is of paramount value. We know the efficacy of action is a key value driver for SPONTAN<sup>®</sup> and in a commercial sense, we hope this opportunity will appeal to the investor market too.

We look forward to your support and participation in our IPO – and hope to welcome you as a valued shareholder soon.

Yours faithfully



**Lee Rodne**  
**Executive Chairman**  
**LTR Pharma Limited**

### 3. Investment Overview

This section is a **summary only** of the information contained in this Prospectus. Investors should read and consider this Prospectus in its entirety before applying for Shares in the Company.

Topic	Details	Where to find more information
<b>A. Company and business model overview</b>		
<b>Who is the issuer of this Prospectus?</b>	The issuer of this Prospectus is LTR Pharma Limited ACN 644 924 569 ( <b>LTP</b> or the <b>Company</b> ).	Section 5
<b>What is the Company's business model?</b>	<p>LTP is a drug development, research and repurposing company, focused on men's health and, currently, commercialising a 'first-in-class' rapid onset, on demand therapeutic nasal spray for the treatment of ED.</p> <p>LTP is currently focused on changing the method of administration of an existing and approved drug that is already on market for the treatment of ED called Vardenafil, also known by the brand names Levitra<sup>®</sup> and Staxyn<sup>®</sup>. LTP is preparing to launch SPONTAN<sup>®</sup>, which is based on an intranasal Vardenafil formulation, SDS-089, by undertaking a bioequivalence trial.</p> <p>The Company plans to meet with, and make applications to, the FDA and TGA post its bioequivalence trial to seek an expedited approval process to sell and market SPONTAN<sup>®</sup> in the United States and in Australia.</p> <p>The Company may also explore alternative avenues to make SPONTAN<sup>®</sup> available to patients where necessary prior to it receiving regulatory approval from the TGA or FDA, for example SPONTAN<sup>®</sup> may be made available to patients via the TGA's special access schemes (<b>SAS</b>) or Authorised Prescriber Scheme (<b>APS</b>) on a needs basis and subject to the relevant regulatory framework.</p>	Sections 5.2, 5.3, 5.5
<b>Our approach - drug repurposing</b>	By strategically focusing on the repurposing of and changing the method of administration of an existing approved drug used for the treatment of ED (Vardenafil), LTP expects to have a reduction in time, cost and risk associated in the regulatory pathway for approvals.	Section 5.3

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Topic	Details	Where to find more information
<p><b>What is the Company's growth strategy?</b></p>	<p>LTP is targeting a large addressable market in ED, developing a faster onset nasal spray product, and seeking to use the shortened TGA and FDA pathways to commercialisation under the change of route to administration for an already approved drug.</p> <p>The Company intends to commercialise and sell SPONTAN<sup>®</sup>, a first in class rapid on demand nasal spray treatment for ED, in global markets, starting in Australia and the United States. The Company's current growth plan for SPONTAN<sup>®</sup> includes commercialising sales in Australia following TGA approval and commercialising sales in the United States following FDA approval, and then globally.</p> <p>In addition, the Company intends to develop a range of new nasal spray products both for the treatment of ED and new indications by investing in product research and development into:</p> <ul style="list-style-type: none"> <li>• Different concentrations/dosages of SPONTAN<sup>®</sup> to address market needs; and</li> <li>• Additional nasal spray products using other approved PDE5 Inhibitors to create a range of nasal spray products for the treatment of ED and non-ED conditions.</li> </ul> <p>Further, the Company will seek entering into sub-licensing arrangements with third parties allowing them to manufacture and/or sell SPONTAN<sup>®</sup> in any jurisdiction in which the Company does not intend to directly operate in.</p>	<p>Section 5.9</p>
<p><b>What are the Company's key strengths/investment highlights?</b></p>	<p>LTP's nasal spray product utilises an already approved drug, Vardenafil, for the treatment of ED which has been approved by the FDA for over 20 years and is also approved for use in Australia by the TGA.</p> <p>LTP's nasal spray product is changing the route of administration of Vardenafil from an oral delivery to an intranasal delivery, offering a significant opportunity given:</p> <ul style="list-style-type: none"> <li>• The large existing market opportunity for ED medications;</li> <li>• The growth in prevalence of ED, primarily caused by growth in aged cohorts, with ED prevalence increasing with age;</li> <li>• Side effects of existing products;</li> <li>• The increased concern of ingesting compounds, with lack of therapeutic benefits for a large cohort of patients; and</li> </ul>	<p>Section 5.8</p>

Topic	Details	Where to find more information
	<ul style="list-style-type: none"> <li>Decreased regulatory burden and costs through the anticipated 505(b)(2) submission pathway for the FDA, and Type F application for the TGA.</li> </ul> <p>As such, LTP anticipates that it will have an expedited pathway to revenue.</p>	
<p><b>How does the Company anticipate it will generate revenue?</b></p>	<p>The Company needs to obtain TGA approval for SPONTAN<sup>®</sup> in Australia and FDA approval for SPONTAN<sup>®</sup> in the United States. The timeframe to meet these milestones and the likelihood of obtaining the approvals are contingent on a number of factors, including clinical trial data derived from a bioequivalence trial, preparation and submission of relevant regulatory applications/documents, and regulatory reviews and meetings with the relevant regulators. The Company intends to commercialise SPONTAN<sup>®</sup> in these jurisdictions upon receipt of the required and relevant regulatory approvals.</p> <p>Subject to the TGA's requirements and applicable laws, LTP may, if there is demand prior to TGA approval, make SPONTAN<sup>®</sup> available to patients in Australia using one or both of the TGA's SAS or APS.</p> <p>Further, the Company will seek entering into sub-licensing arrangements with third parties allowing them to manufacture and sell SPONTAN<sup>®</sup> in any jurisdiction in which the Company does not intend to directly operate in.</p> <p>There is no guarantee that the Company will be able to derive any revenue from SPONTAN<sup>®</sup> or any other product it may develop.</p>	<p>Sections 5.4 and 5.6</p>
<p><b>What are the regulatory requirements the Company will need to satisfy to meet its business objectives?</b></p>	<p>SPONTAN<sup>®</sup> is, for regulatory purposes under the TGA and FDA, an existing drug where the relevant regulatory body will be asked to approve the change to the route of administration (from an oral delivery to an intranasal delivery).</p> <p>In summary, the Company expects that the TGA and FDA will consider the existing safety and efficacy data of the currently approved Vardenafil oral tablets, along with LTP's bioequivalence trial data, Chemistry Manufacturing &amp; Controls (<b>CMC</b>) data, as well as Good Manufacturing Practices (<b>GMP</b>) from LTP's commercial manufacturing, to make a determination with respect to the Company's request for regulatory approval of SPONTAN<sup>®</sup>. However, either of these regulatory agencies may request LTP to complete animal studies to test other characteristics of SPONTAN<sup>®</sup>, such as the toxicology of Vardenafil as an intranasally delivered drug, which may delay its approval.</p>	<p>Sections 5.4 and 5.5</p>

Topic	Details	Where to find more information
	To commence the sale of SPONTAN® in the United States market, LTP intends to apply for approval under the pathway that governs a change of route to the administration of an approved drug which is known as the FDA 505(b)(2) pathway and is described later in this document. For the Australian market, LTP intends to apply for approval under the pathway that governs a change of route to the administration of an approved drug, which is known as a Type F Application and is described later in this document.	
<b>B. Key risks</b>		
<b>Sufficiency of funding</b>	The Company has limited financial resources and will need to raise additional funds from time to time to finance the complete development and commercialisation of its products and achievement of its other longer-term objectives. In certain circumstances, the Company's ability to successfully operate may be subject to its ability to raise funds which will be subject to factors beyond the control of the Company and its Directors (including without limitation cyclical factors affecting the economy and financial and share markets generally).	Section 11.2(a)
<b>Speculative nature of investment</b>	The Shares to be issued pursuant to the Prospectus carry no guarantee with respect to the payment of dividends, returns of capital or the market value of those Shares.	Section 11.1
<b>Expenditure Program</b>	<p>LTP has entered into contracts for a number of the material items anticipated to be covered by the expenditure program set out in the Expenditure Program. The Directors have determined that following the successful close of the Offers, the Company will be well positioned to negotiate the exact terms of all remaining contracts related to its Expenditure Program. It is possible that actual expenditure may be more than estimated by the Company in its anticipated Expenditure Program. This could, depending on the difference in actual costs, require the Company to seek to raise additional funding.</p> <p>The Directors and management have relevant industry experience and have prepared the anticipated Expenditure Program based partly on discussions with, or indicative quotes obtained from, potential suppliers of those services and their own experience of the likely costs for those expenditure items. While the Directors are confident that the Company will be able to source suitable suppliers, there is a risk that the Company may not be able to source those suppliers at the estimated expenditure in the Expenditure Program.</p>	Sections 11.2(f), 11.5



Topic	Details	Where to find more information
<b>Regulatory requirements</b>	<p>The Company and its technology are subject to various laws and regulations including, but not limited to, rigorous regulatory requirements. Even where the Company is approved to proceed with clinical trials, it may ultimately take more time than anticipated to complete them.</p> <p>There is a risk that the TGA and/or the FDA may not approve LTP's proposed new drug application under the relevant regulatory pathways sought by LTP, and this would require LTP to undertake more trials and cause delay in LTP's development program.</p> <p>There is also a material risk that LTP's product candidates may not ultimately satisfy the regulatory requirements nor gain approval, or that the approval process may take much longer than expected.</p> <p>Failure of the Company to obtain regulatory approval and/or remain compliant with these various regulatory requirements could adversely affect the Company's financial performance.</p>	Section 11.2(g)
<b>Intellectual property risk</b>	<p>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 candidate. Patent applications in significant markets have been lodged in respect of SPONTAN<sup>®</sup>. However, there is no assurance that those patent applications will result in granted patents in all desired jurisdictions.</p> <p>Even though these patent applications may be successful, and result in granted patents, a competitor may at any time challenge granted patents and a court may find that although a patent has been granted it is deemed to be invalid or unenforceable or is revoked. It is possible a court may find that the Company's entitlement is subsequently revealed not to have existed, may not have any exclusive patent rights or any patent rights at all and may be prevented from developing and/or commercialising its products. If the Company's intellectual property rights are ever challenged it may also not have the funds to oppose the challenge.</p> <p>Lastly, the Company's right to exploit the nasal delivery of Vardenafil is subject to its licensing arrangements with SDS (refer to the 'Key commercial contracts' section of this application for further details). If this licensing arrangement was jeopardised, it could have significant detrimental effects on the Company's business.</p>	Sections 11.2(i), 11.3, and 13.7(a)
<b>Clinical state of development</b>	<p>The Company's product candidate, SPONTAN<sup>®</sup> is at a clinical stage and substantial further clinical development may be necessary beyond the anticipated bioequivalence trial contemplated by the Company.</p>	11.2(b)

Topic	Details	Where to find more information																																
	If LTP's product candidate, SPONTAN <sup>®</sup> is ultimately shown to be ineffective for therapeutic purposes, the Company's business, the value of its assets and resulting value of its Shares may be materially harmed.																																	
<b>Key personnel</b>	<p>The Company currently employs or engages as consultants, a number of key members of its management and scientific team. The loss of any of these people's services could materially and adversely affect the Company and may impede the achievements of its research, drug development and commercialisation objectives.</p> <p>The successful development of the Company will require the services of additional staff. There can be no assurance that the Company will be able to attract appropriate additional staff and this may adversely affect the Company's prospects for success.</p>	Section 11.2(e)																																
<b>C. Key financial information</b>																																		
<b>What is the key financial information of the Company?</b>	<p>Historical financial performance of the Company:</p> <table border="1" data-bbox="495 846 1682 1328"> <thead> <tr> <th data-bbox="495 846 974 906"></th> <th data-bbox="974 846 1222 906">30 June 2021</th> <th data-bbox="1222 846 1451 906">30 June 2022</th> <th data-bbox="1451 846 1682 906">30 June 2023</th> </tr> </thead> <tbody> <tr> <td data-bbox="495 906 974 966">Revenue</td> <td data-bbox="974 906 1222 966">\$ -</td> <td data-bbox="1222 906 1451 966">\$9,078</td> <td data-bbox="1451 906 1682 966">\$90</td> </tr> <tr> <td data-bbox="495 966 974 1026">General and administrative expenses</td> <td data-bbox="974 966 1222 1026">\$40,803</td> <td data-bbox="1222 966 1451 1026">\$1,303,871</td> <td data-bbox="1451 966 1682 1026">\$637,160</td> </tr> <tr> <td data-bbox="495 1026 974 1086">Research and development expenses</td> <td data-bbox="974 1026 1222 1086">\$ -</td> <td data-bbox="1222 1026 1451 1086">\$348,305</td> <td data-bbox="1451 1026 1682 1086">\$817,835</td> </tr> <tr> <td data-bbox="495 1086 974 1146">Total costs and expenses</td> <td data-bbox="974 1086 1222 1146">\$40,803</td> <td data-bbox="1222 1086 1451 1146">\$1,036,199</td> <td data-bbox="1451 1086 1682 1146">\$1,454,995</td> </tr> <tr> <td data-bbox="495 1146 974 1206">Net loss from operations</td> <td data-bbox="974 1146 1222 1206">\$40,803</td> <td data-bbox="1222 1146 1451 1206">\$1,027,121</td> <td data-bbox="1451 1146 1682 1206">\$1,454,905</td> </tr> <tr> <td data-bbox="495 1206 974 1266">Net assets</td> <td data-bbox="974 1206 1222 1266">\$(40,803)</td> <td data-bbox="1222 1206 1451 1266">\$1,769,466</td> <td data-bbox="1451 1206 1682 1266">\$2,072,484</td> </tr> <tr> <td data-bbox="495 1266 974 1328">Cash balance</td> <td data-bbox="974 1266 1222 1328">\$146,413</td> <td data-bbox="1222 1266 1451 1328">\$1,911,397</td> <td data-bbox="1451 1266 1682 1328">\$1,728,742</td> </tr> </tbody> </table>		30 June 2021	30 June 2022	30 June 2023	Revenue	\$ -	\$9,078	\$90	General and administrative expenses	\$40,803	\$1,303,871	\$637,160	Research and development expenses	\$ -	\$348,305	\$817,835	Total costs and expenses	\$40,803	\$1,036,199	\$1,454,995	Net loss from operations	\$40,803	\$1,027,121	\$1,454,905	Net assets	\$(40,803)	\$1,769,466	\$2,072,484	Cash balance	\$146,413	\$1,911,397	\$1,728,742	Section 6
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Topic	Details	Where to find more information										
	<p>Investors should note that past performance may not be an indicator of future performance. The Company's revenue has historically been derived through R&amp;D tax incentives available through the Australian Tax Office and interest income.</p> <p>The Company's pro forma balance sheet at June 2023 has net assets of \$6,550,704 and \$7,488,466 under the minimum and maximum subscriptions respectively. Please refer to section 8 for further details on the historical and pro forma financial information.</p>											
<p><b>Where can I find financial information in relation to the Company?</b></p>	<p>See section 8 and the Investigating Accountant's Report in section 9.</p>	<p>Sections 8, 9</p>										
<p><b>D. The Company's Directors</b></p>												
<p><b>Who are the directors of the Company?</b></p>	<p>Lee Rodne – Executive Chairman                      Dr Julian Chick – Non-Executive Director                      Maja McGuire – Non-Executive Director</p>	<p>Section 7.1</p>										
<p><b>E. Major Shareholders and related party transactions</b></p>												
<p><b>Who are the major Shareholders and what are their interests in the Company on completion of the Offer?</b></p>	<table border="1"> <thead> <tr> <th data-bbox="495 1114 726 1247">Shareholder Name</th> <th data-bbox="726 1114 957 1247">Shares held as at date of Prospectus</th> <th data-bbox="957 1114 1188 1247">Shares held after completion of Offers</th> <th data-bbox="1188 1114 1465 1247">% of total Shares held after completion of Offers (Minimum Subscription)<sup>2</sup></th> <th data-bbox="1465 1114 1751 1247">% of total Shares held after completion of Offers (Maximum Subscription)<sup>2</sup></th> </tr> </thead> <tbody> <tr> <td data-bbox="495 1247 726 1318">LTR Medical<sup>1</sup></td> <td data-bbox="726 1247 957 1318">46,373,750</td> <td data-bbox="957 1247 1188 1318">46,373,750</td> <td data-bbox="1188 1247 1465 1318">34.50%</td> <td data-bbox="1465 1247 1751 1318">33.26%</td> </tr> </tbody> </table>	Shareholder Name	Shares held as at date of Prospectus	Shares held after completion of Offers	% of total Shares held after completion of Offers (Minimum Subscription) <sup>2</sup>	% of total Shares held after completion of Offers (Maximum Subscription) <sup>2</sup>	LTR Medical <sup>1</sup>	46,373,750	46,373,750	34.50%	33.26%	<p>Section 13.3</p>
Shareholder Name	Shares held as at date of Prospectus	Shares held after completion of Offers	% of total Shares held after completion of Offers (Minimum Subscription) <sup>2</sup>	% of total Shares held after completion of Offers (Maximum Subscription) <sup>2</sup>								
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<p><b>What significant benefits are payable to Directors and other persons connected with the Company or the Offers and what significant interests do they hold?</b></p>	<p><i>Important Notes:</i></p> <p>1. Each of Lee Rodne and Dr Julian Chick have an interest in LTR Medical, representing a 59.10% and 19.70% holding respectively.</p> <p>2. Assumes no participation in the Offers.</p> <p>Directors are entitled to remuneration and fees on commercial terms. Directors and key managers' interests and remuneration are set out in more detail in Sections 7.2 and 7.3.</p> <p>Advisers and other service providers are entitled to fees for services as disclosed in section 13.8.</p> <p>In addition, the following interests in the Company are expected to be held (directly or indirectly) by Directors, key managers and other persons connected with the Company at Listing:</p> <table border="1" data-bbox="495 862 1801 1360"> <thead> <tr> <th data-bbox="495 862 709 1027">Name</th> <th data-bbox="709 862 890 1027">Shares held directly as at date of Prospectus</th> <th data-bbox="890 862 1073 1027">Indirect interest in Shares held as at date of Prospectus</th> <th data-bbox="1073 862 1255 1027">Aggregate interest in Shares after completion of Offers<sup>5</sup></th> <th data-bbox="1255 862 1436 1027">Options held</th> <th data-bbox="1436 862 1619 1027">Aggregate % of total interest in Shares after completion of Offers (Minimum Subscription)<sup>6</sup></th> <th data-bbox="1619 862 1801 1027">Aggregate % of total interest in Shares after completion of Offers (Maximum Subscription)<sup>6</sup></th> </tr> </thead> <tbody> <tr> <td data-bbox="495 1027 709 1092">Lee Rodne</td> <td data-bbox="709 1027 890 1092">1,129,641</td> <td data-bbox="890 1027 1073 1092">51,543,893<sup>1</sup></td> <td data-bbox="1073 1027 1255 1092">52,673,534</td> <td data-bbox="1255 1027 1436 1092">1,000,000</td> <td data-bbox="1436 1027 1619 1092">39.19%</td> <td data-bbox="1619 1027 1801 1092">37.78%</td> </tr> <tr> <td data-bbox="495 1092 709 1141">Dr Julian Chick</td> <td data-bbox="709 1092 890 1141">808,492</td> <td data-bbox="890 1092 1073 1141">-<sup>2</sup></td> <td data-bbox="1073 1092 1255 1141">808,492</td> <td data-bbox="1255 1092 1436 1141">500,000</td> <td data-bbox="1436 1092 1619 1141">0.60%</td> <td data-bbox="1619 1092 1801 1141">0.58%</td> </tr> <tr> <td data-bbox="495 1141 709 1190">Maja McGuire</td> <td data-bbox="709 1141 890 1190">235,492<sup>9</sup></td> <td data-bbox="890 1141 1073 1190">-</td> <td data-bbox="1073 1141 1255 1190">235,492</td> <td data-bbox="1255 1141 1436 1190">500,000<sup>9</sup></td> <td data-bbox="1436 1141 1619 1190">0.18%</td> <td data-bbox="1619 1141 1801 1190">0.17%</td> </tr> <tr> <td data-bbox="495 1190 709 1239">Danny Zanardo</td> <td data-bbox="709 1190 890 1239">1,122,135</td> <td data-bbox="890 1190 1073 1239">-<sup>7</sup></td> <td data-bbox="1073 1190 1255 1239">1,122,135</td> <td data-bbox="1255 1190 1436 1239">-</td> <td data-bbox="1436 1190 1619 1239">0.83%</td> <td data-bbox="1619 1190 1801 1239">0.80%</td> </tr> <tr> <td data-bbox="495 1239 709 1287">Jacques Schipper</td> <td data-bbox="709 1239 890 1287">698,000</td> <td data-bbox="890 1239 1073 1287">-</td> <td data-bbox="1073 1239 1255 1287">698,000</td> <td data-bbox="1255 1239 1436 1287">-</td> <td data-bbox="1436 1239 1619 1287">0.52%</td> <td data-bbox="1619 1239 1801 1287">0.50%</td> </tr> <tr> <td data-bbox="495 1287 709 1336">Kip Vought</td> <td data-bbox="709 1287 890 1336">-</td> <td data-bbox="890 1287 1073 1336">698,000<sup>3</sup></td> <td data-bbox="1073 1287 1255 1336">698,000</td> <td data-bbox="1255 1287 1436 1336">-</td> <td data-bbox="1436 1287 1619 1336">0.52%</td> <td data-bbox="1619 1287 1801 1336">0.50%</td> </tr> <tr> <td data-bbox="495 1336 709 1385">Monil Shah</td> <td data-bbox="709 1336 890 1385">-</td> <td data-bbox="890 1336 1073 1385">1,537,813<sup>4</sup></td> <td data-bbox="1073 1336 1255 1385">1,537,813</td> <td data-bbox="1255 1336 1436 1385">-</td> <td data-bbox="1436 1336 1619 1385">1.14%</td> <td data-bbox="1619 1336 1801 1385">1.10%</td> </tr> <tr> <td data-bbox="495 1385 709 1433">Alpine Capital</td> <td data-bbox="709 1385 890 1433">-</td> <td data-bbox="890 1385 1073 1433">-</td> <td data-bbox="1073 1385 1255 1433">-</td> <td data-bbox="1255 1385 1436 1433">2,792,344<sup>8</sup></td> <td data-bbox="1436 1385 1619 1433">0.00%</td> <td data-bbox="1619 1385 1801 1433">0.00%</td> </tr> </tbody> </table>						Name	Shares held directly as at date of Prospectus	Indirect interest in Shares held as at date of Prospectus	Aggregate interest in Shares after completion of Offers <sup>5</sup>	Options held	Aggregate % of total interest in Shares after completion of Offers (Minimum Subscription) <sup>6</sup>	Aggregate % of total interest in Shares after completion of Offers (Maximum Subscription) <sup>6</sup>	Lee Rodne	1,129,641	51,543,893 <sup>1</sup>	52,673,534	1,000,000	39.19%	37.78%	Dr Julian Chick	808,492	- <sup>2</sup>	808,492	500,000	0.60%	0.58%	Maja McGuire	235,492 <sup>9</sup>	-	235,492	500,000 <sup>9</sup>	0.18%	0.17%	Danny Zanardo	1,122,135	- <sup>7</sup>	1,122,135	-	0.83%	0.80%	Jacques Schipper	698,000	-	698,000	-	0.52%	0.50%	Kip Vought	-	698,000 <sup>3</sup>	698,000	-	0.52%	0.50%	Monil Shah	-	1,537,813 <sup>4</sup>	1,537,813	-	1.14%	1.10%	Alpine Capital	-	-	-	2,792,344 <sup>8</sup>	0.00%	0.00%	<p>Sections 7.2 and 7.3</p>
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Maja McGuire	Non-executive Director	\$40,000	235,492 <sup>6</sup>	-	500,000 <sup>6</sup>	\$56,977																								

Topic	Details	Where to find more information
	<p><i>Important Notes:</i></p> <ol style="list-style-type: none"> <li>1. <i>This represents per annum remuneration after Listing and excludes superannuation and GST (where applicable). The remuneration of each of Dr Julian Chick and Maja McGuire prior to Listing is \$15,000 (excl. superannuation and GST) per annum.</i></li> <li>2. <i>This represents the aggregate interest of Lee Rodne's indirect holdings via associated entities including, LTR Medical (59.10% shareholding), LTR Consulting (100% shareholding) and Trexapharm (49% shareholding).</i></li> <li>3. <i>Dr Julian Chick has a 19.70% shareholding in LTR Medical who holds 46,373,750 shares in LTP which is not shown here.</i></li> <li>4. <i>A summary of the material terms of these options are set out in section 7.2(d) below.</i></li> <li>5. <i>The options were valued using the Black Scholes methodology.</i></li> <li>6. <i>Held by Maja McGuire as trustee for the Scaraf Trust.</i></li> </ol>	
<b>Are there any significant related party transactions?</b>	No.	Section 7.5
<b>No independent valuation</b>	No independent valuation of the Company's intellectual property or generally the Company's Shares has been carried out for the purposes of this Prospectus.	Section 11.6
<b>F. Overview of the Offers</b>		
<b>What are the Offers?</b>	<p>The Offers include:</p> <ol style="list-style-type: none"> <li>1. the Investor Offer – this offer is an initial public offer of between 30,000,000 Shares (at the Minimum Subscription), and 35,000,000 Shares (at the Maximum Subscription), at an Offer Price of \$0.20 per Share. The Maximum Subscription amount to be raised under this Prospectus is \$7 million;</li> <li>2. the Grannus Offer is to satisfy the Company's obligations under its agreement for services provided by Grannus Securities; and</li> </ol>	Section 6.1

Topic	Details	Where to find more information
	<p>3. the Lead Manager Offer is to satisfy the Company's obligations under its agreement for services provided by the Lead Manager.</p> <p>The Company has determined that the Minimum Subscription amount to be raised under this Prospectus is \$6 million (being 30,000,000 Shares). If this Minimum Subscription amount is not raised within 3 months from the date of this Prospectus, all Application Monies will be refunded in full (without interest).</p> <p>All Shares issued under to this Prospectus will be fully paid and will rank equally in all respects with the Shares already on issue.</p>	
<p><b>What is the purpose of the Offers and how will the proceeds of the Investor Offer be used?</b></p>	<p>Following close of the Offers, the Company expects to have raised \$7 million from investors (assuming a Maximum Subscription).</p> <p>The Company intends to use these funds as follows:</p> <ul style="list-style-type: none"> <li>• to support regulatory expenses;</li> <li>• to cover CMC costs (chemistry, manufacturing and control package);</li> <li>• to undertake a bioequivalence trial in relation to SPONTAN®;</li> <li>• to undertake other non-clinical studies;</li> <li>• to support the Company's sales and marketing strategy;</li> <li>• to pay the expenses of the Offers; and</li> <li>• to provide working capital.</li> </ul>	<p>Section 6.4</p>

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Topic	Details	Where to find more information		
<b>Use of funds / Expenditure Program</b>	It is intended that the funds raised under the Investor Offer will be used as follows: If the Minimum Subscription is raised:	Section 6.4		
	<b>Use of Funds / Expenditure Program*</b>		<b>\$</b>	
			<b>Year 1</b>	<b>Year 2</b>
	Regulatory		\$250,000	\$60,000
	CMC (chemistry, manufacturing and control / packaging for sales)		\$320,000	-
	Non-clinical studies		\$50,000	-
	Bioequivalence trial		\$1,350,000	-
	Sales & Marketing		\$200,000	\$240,000
	Payment (SDS Licence Agreement)		\$475,097	-
	Working Capital		\$834,140	\$1,379,797
	Expenses of the Offer		\$749,701	-
	<b>Total</b>		<b>\$4,228,938</b>	<b>\$1,679,797</b>
<p><i>* This table is a statement of current intentions of the Company. Actual use of funds may differ from the budgeted use of funds based on changes in clinical trials budget or formulation development expenses. The Board may alter the way funds are applied in the future. LTP is required to make a US\$300,000 payment pursuant to the SDS Licence Agreement, the expenditure above is estimated using an exchange rate of approximately \$1.00 to US\$0.6314.</i></p>				
	If the Maximum Subscription is raised:			
<b>Use of Funds / Expenditure Program*</b>	<b>\$</b>			
	<b>Year 1</b>	<b>Year 2</b>		
Regulatory	\$250,000	\$100,000		
CMC (chemistry, manufacturing and control / packaging for sales)	\$320,000	-		
Non-clinical studies	\$100,000	\$40,000		
Bioequivalence trial	\$1,350,000	-		
Sales & Marketing	\$350,000	\$460,000		
Payment (SDS Licence Agreement)	\$475,097	-		
Working Capital	\$1,049,140	\$1,586,197		
Expenses of the Offer	\$811,939	-		
<b>Total</b>	<b>\$4,706,176</b>	<b>\$2,186,197</b>		



Topic	Details	Where to find more information
	<p><i>* This table is a statement of current intentions of the Company. Actual use of funds may differ from the budgeted use of funds based on changes in clinical trials budget or formulation development expenses. The Board may alter the way funds are applied in the future. LTP is required to make a US\$300,000 payment pursuant to the SDS Licence Agreement, the expenditure above is estimated using an exchange rate of approximately \$1.00 to US\$0.6314.</i></p> <p>It should also be noted that if the Maximum Subscription is raised, the Company proposes fast-tracking other consumer products that the Company has identified as potential viable future products for the Company - these include additional ED and non-ED opportunities set out in section 5.9. The associated additional expenditure is reflected in the increase in expenses relating to the 'Regulatory', 'Non-clinical studies' and the 'bioequivalence trial' line items with respect to the non-ED pipeline opportunities - i.e. the additional expenses are not with respect to the Company's primary product which remains the focus of the Company.</p>	
<b>Working capital</b>	On completion of the capital raising under this Prospectus, the Company will have sufficient working capital to carry out its stated objectives (as detailed in this Prospectus).	Sections 5.12 and 11.5
<b>Who is eligible to participate in the Investor Offer?</b>	<p><b>Broker Firm Offer</b></p> <p>The Broker Firm Offer is open to persons who have received a firm allocation of Shares from their Broker and who have a registered address in Australia.</p> <p><b>Institutional Offer</b></p> <p>The Institutional Offer is an invitation by the Lead Manager to Australian resident Institutional Investors and other eligible Institutional Investors in eligible jurisdictions outside the United States to bid for Shares, made under this Prospectus.</p> <p><b>General Public Offer</b></p> <p>The General Public Offer is open to investors in eligible jurisdictions to acquire Shares under this Prospectus.</p>	Sections 6.11, 6.12, 6.13
<b>Is the Investor Offer underwritten?</b>	The Investor Offer is not underwritten.	Section 6.10

Topic	Details	Where to find more information
<b>ASX listing application</b>	<p>Not later than 7 days after the date of this Prospectus, an application will be made to the ASX for the Company to be admitted to the Official List of the ASX and for the Official Quotation of the Shares. The fact that the ASX may admit the Company to its Official List is not to be taken in any way as an indication of the value or merits of the Company or of the Shares offered under this Prospectus.</p> <p>Official Quotation, if granted, will commence as soon as practicable after the issue of transaction holding Statements to successful Applicants. If permission for quotation of the Shares is not granted within 3 months after the date of this Prospectus, all Application Monies will be refunded without interest.</p>	Important Notices
<b>How do I apply for Shares?</b>	<p>Depending on your profile as an investor, in accordance with specific instructions in the body of this Prospectus indicated in the next column.</p> <p>Investors applying under the General Public Offer may apply online at <a href="https://apply.automic.com.au/LTRPharma">https://apply.automic.com.au/LTRPharma</a> by completing the online Application Form that forms part of the electronic version of this Prospectus and paying your Application Monies by electronically.</p> <p>Alternatively, investors can submit a paper-based application by completing the Application Form included in or accompanying this Prospectus in accordance with the instructions set out in the Application Form. Cheques must be in Australian currency and made payable to '<b>LTR Pharma Limited - Share Account</b>' and crossed '<b>Not Negotiable</b>'.</p> <p>In respect of the Investor Offer, all Application Monies paid in advance of allotment (excluding those funds to be settled by way of 'delivery versus payment' by the Lead Manager) will be held in a special purpose account until the Shares are issued and allotted under the Investor Offer or the Application Monies are returned to the unsuccessful Applicants.</p> <p>The Offer Price of \$0.20 per Share is payable in full on Application. Applications for Shares under the Broker Firm Offer, and General Public Offer must be for a minimum of 10,000 Shares and thereafter in multiples of 2,500 Shares.</p> <p>Further details in relation to applying for:</p> <ol style="list-style-type: none"> <li>1. The Broker Firm Offer are set out in section 6.11</li> <li>2. The Institutional Offer are set out in section 6.12; and</li> </ol>	Sections 6.11, 6.12, 6.13

Topic	Details	Where to find more information
	3. The General Public Offer are set out in section 6.13.	
<b>Opening and closing of the Offer</b>	Applications may be lodged at any time after the Opening Date until 5.00pm (AEDT) on the Closing Date.	Please see the Key Offer Information section
<b>Allocation policy</b>	<p>The Company reserves the right to authorise the issue of a lesser number of Shares than those for which Application has been made or to reject any Application. Where no issue or allocation is made or the number of Shares issued is less than the number applied for, surplus Application Monies will be refunded without interest.</p> <p>If an Application Form is not completed correctly, or if the accompanying payment is for the wrong amount, it may still be treated as valid. The Company's decision as to whether to treat an Application is valid, and how to construe, amend or complete it, will be final. The Company's decision on the number of Shares to be allocated to an Applicant will also be final.</p>	Section 6.14
<b>Are there any additional costs payable by the Applicant?</b>	No brokerage, commission, stamp duty or any other costs are payable by Applicants on acquisition of the Shares under the Investor Offer.	Section 6.10
<b>Will I be paid dividends?</b>	<p>The Directors do not envisage that the Company will earn any material revenue or be in a position to declare any dividends in the foreseeable future.</p> <p>The financial prospects of the Company are dependent on a number of factors, including without limitation, successful clinical trials, approval of our lead program by relevant regulators, and commercial success once sales are launched.</p>	Section 7.11

Topic	Details	Where to find more information
<b>What are the tax implications of investing in the Shares?</b>	<p>The tax treatment and consequences of the Offers will vary depending on the particular circumstances of the Applicant. The Company accepts no liability or responsibility in relation to any taxation consequences connected to the Offers. Therefore, regarding the appropriate tax treatment that applies to the Offers, it is the responsibility of any Applicant who makes an Application to satisfy themselves by consulting their own professional tax advisers prior to investing in the Company.</p>	Section 12
<b>Where can I find more information about this Prospectus or the Offers?</b>	<p>Further information can be obtained by reading this Prospectus in its entirety. For advice on the Offers you should speak to your stockbroker, accountant or other professional adviser.</p> <p>If you require assistance or additional copies of this Prospectus please contact the LTR Pharma IPO information line on 1300 441 607 (within Australia) or +61 2 7250 6677 (outside Australia) from 9.00 am until 5.00 pm AEDT Monday to Friday during the Offer Period.</p>	Important Notices

# Market Report

## The Erectile Dysfunction Medicines Market

September 2023

This report has been commissioned from Frost & Sullivan by LTR Pharma Limited (hereafter referred to as LTR Pharma or the Company) to support its initial public offering (IPO) process.

### 1. Background, Definitions and Methodology

#### 1.1 Background

LTR Pharma is a biopharmaceutical ('biopharma') company focused on the development and commercialisation of a first-in-class treatment for erectile dysfunction (ED). The Company's lead product (SDS-089, marketed as SPONTAN™) is being developed to be administered via intranasal delivery, offering more rapid onset of effects and optimal dose with a lower amount of active ingredient than existing commercial medications for ED which are taken orally. SPONTAN can be targeted at existing/previous users of ED treatments for whom current approaches are not efficacious or which create adverse effects, as well as individuals suffering from ED who have not sought treatment to date, for example due to concerns about lack of spontaneity in sexual activity due to the slow response time of existing medicines. SPONTAN is likely to be the first nasally administered drug for treatment of ED to receive regulatory approval, and as such has the potential to disrupt the existing market for ED medications.

LTR Pharma has successfully conducted Phase I (human proof-of-concept) trials, and is targeting marketing approval from the US Food and Drug Administration (FDA) via a 505(b)(2) application, an expedited process for a new drug application (NDA) wherein the applicant is able to provide information from earlier studies not conducted by or for the applicant, where the applicant has not obtained a right of reference or use, such as findings by the FDA of safety and/or effectiveness for a listed drug.<sup>1</sup> As the active ingredient in SPONTAN (ildenafil) is already an approved drug for the treatment of ED, the approval route is expedited when compared to new compounds, requiring only a bioequivalence study (a study to determine the rate at which the active pharmaceutical ingredient (API) becomes available) to determine bioequivalence compared to oral administration.

Similarly in Australia, marketing approval can be obtained from the Therapeutic Goods Administration (TGA) through a Category 1 application involving a major variation (new dosage form, change/increase in patient group, change in dosage, new strength, new route of administration [F]).<sup>2</sup>

<sup>1</sup> FDA, accessed from [https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/abbreviated-approval-pathways-drug-product-505b2-or-nda#:~:text=A%20505\(b\)\(2,reference%20or%20use%2C%20including%2C%20for](https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/abbreviated-approval-pathways-drug-product-505b2-or-nda#:~:text=A%20505(b)(2,reference%20or%20use%2C%20including%2C%20for)

<sup>2</sup> TGA, accessed from <https://www.tga.gov.au/resources/resource/forms/prescription-medicine-registration-form>

## 1.2 Methodology

Data provided in this report is based on publicly available data sources, including governmental and trade statistics and reports, peer-reviewed articles in medical journals, company reports and presentations, articles and press reports, and analyst reports. All financial data in the report is in United States dollars (\$) unless otherwise stated.

## 2. Prevalence of ED

This section describes the clinical definition, etiology and risk factors of ED, its current and forecast prevalence (a measure of the frequency of a health condition at a specific point in time) and factors which are driving growth in prevalence.

### 2.1 Clinical Definition, Etiology and Risk Factors

ED is a medical condition wherein an individual is unable to get or keep an erection firm enough for satisfactory sexual intercourse.<sup>3</sup> The severity of ED can differ widely, ranging from failure to always achieve an erection, through episodic failure to the inability to maintain an erection for a long enough period for satisfactory sexual activity. Differing levels of severity, differences by age cohort as well as differences in whether medical care is sought, together with the sensitivity of the topic, have created a wide range of estimations of the prevalence of ED.

The etiology of ED includes both physical and psychological causes. Physical causes include narrowing of the blood vessels leading to the penis (for example, linked to high blood pressure), hormonal issues or injury. Psychological causes can include relationship problems, stress/anxiety and depression. ED can cause a range of co-morbidities, including depression, relationship issues and loss of confidence leading to reduced quality of life. Men with ED have significantly lower quality of life scores than their counterparts without ED. ED has also been found to cause higher work absenteeism and general activity impairment.<sup>4</sup>

Risk factors for ED are varied, and can include obesity, cardiovascular disease, diabetes, excess alcohol consumption and hypertension. Prevalence of ED is significantly higher amongst individuals with cardiovascular risk factors, hypertension and diabetes, where prevalence is reported as high as 50%.<sup>5</sup>

ED is typically diagnosed via a range of psychological and physical examinations, which can include ultrasound imaging, nocturnal erection tests and injection tests. First-line treatments for ED involve lifestyle modifications, management of risk factors and use of oral medications, with

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<sup>3</sup> National Institute of Diabetes and Digestive and Kidney Diseases, accessed from <https://www.niddk.nih.gov/health-information/urologic-diseases/erectile-dysfunction#:~:text=Print%20All%20Sections-.Definition%20%26%20Facts,part%20of%20a%20healthy%20life>.

<sup>4</sup> Rojanasart et al., Quantifying the number of US men with erectile dysfunction who are potential candidates for penile prosthesis implantation, *Sexual Medicine*, 2023, 11, 1–8, <https://doi.org/10.1093/sexmed/>

<sup>5</sup> Selvin et al., Prevalence and Risk Factors for Erectile Dysfunction in the US, *The American Journal of Medicine* (2007) 120, 151-157

second- and third-line treatments involving medical devices (such as vacuum pumps) or other invasive treatments such as penile prosthesis implantation (see Section 3).

## 2.2 Current Prevalence

### 2.2.1 Global

Estimations of the prevalence of ED vary widely, depending on the study population and definition of ED used. Population-based studies have variously reported prevalence ranging from as low as 3.0% to as high as 76.5%.<sup>6</sup> A study across eight countries amongst males aged 40-70 indicated prevalence ranging from 42.1% in Brazil to 52.2% in Italy, with a total self-reported prevalence of 40.5% across all age cohorts.<sup>7</sup>

### 2.2.2 US

As with other markets, there are differing estimations on the prevalence of ED in the US. The prevalence in self-reported studies ranges from 3.0% to 70.2%, with a median of 27.0%. Based on the median prevalence, the number of men with ED in the US is approximately 30 million. However, not all individuals experiencing ED will seek medical diagnosis and treatment. A study based on administrative claims databases identified that 8.0% of men aged 18 years or older in the US had been medically diagnosed with ED, representing approximately 10.3 million individuals.<sup>8</sup> Hence, potentially around one-third of all men with ED currently seek medical treatment.

### 2.2.3 Australia

As with other countries, estimates on the prevalence of ED in Australia vary widely. Data from a longitudinal study of Australian men aged 18-55 indicated an overall prevalence of ED of 13.7%, ranging from 10.8% in younger males (18-24) to 19.9% in those aged 45-55.<sup>9</sup> Studies amongst older age cohorts indicate higher prevalence, with a population-based study of men aged 45 years or older indicating that 16.8% had complete ED, 25.1% had mild ED, 18.8% moderate ED and only 39.3% no ED. The odds of moderate/mild ED increased by 11.3% each year from the age of 45 years, with almost all men aged 75 or older reporting ED.<sup>10</sup>

## 2.3 Forecast Prevalence

The prevalence of ED is likely to increase, driven by ageing populations with a greater number and proportion of individuals in older age cohorts where ED prevalence is higher, together with growing prevalence of risk factors such as diabetes and cardiovascular disease. For example, in the

<sup>6</sup> Kessler et al., The global prevalence of erectile dysfunction: a review, *BJU Int.* 2019 Oct;124(4):587-599. doi: 10.1111/bju.14813. Epub 2019 Jul 2

<sup>7</sup> Goldstein et al., Epidemiology Update of Erectile Dysfunction in Eight Countries with High Burden, *Sex Med Rev* 2020;8:48e58

<sup>8</sup> Rojanasarot et al., Quantifying the number of US men with erectile dysfunction who are potential candidates for penile prosthesis implantation, *Sexual Medicine*, 2023, 11, 1–8, <https://doi.org/10.1093/sexmed/>

<sup>9</sup> Schlichthorst et al., Health and lifestyle factors associated with sexual difficulties in men – results from a study of Australian men aged 18 to 55 years, *BMC Public Health* 2016, 16(Suppl 3):1043

<sup>10</sup> Weber et al., Risk factors for erectile dysfunction in a cohort of 108 477 Australian men, *Med J Aust.* 2013 Jul 22;199(2):107-11. doi: 10.5694/mja12.11548

US prevalence of diagnosed diabetes has increased from approximately 7.5% in 2001-04 to 10.0% by 2017-20.<sup>11</sup>

One study dating from 1999 estimated that in 1995 152 million men globally experienced ED, and this was forecast to increase to 322 million by 2025, a compound annual growth rate (CAGR) of 2.5%.<sup>12</sup> Similarly, in the European Union (EU), the number of men with ED was estimated to have increased 2.5-fold between 2011 and 2019, and 3.5-fold in China between 2007 and 2019.<sup>13</sup> The number of individuals with ED in Europe is estimated at 33 million in 2022, and 150 million in China and SE Asia.<sup>14</sup>

### 3. Treatments for ED

This section describes treatments for ED, including commercially available treatments as well as those in development. Existing first-line treatments primarily include oral phosphodiesterase-5 (PDE5) inhibitors as the gold standard pharmacological products, and lifestyle modifications. However, a significant portion of patients with ED are non-responsive to PDE5 inhibitors or are not able to take oral medications.

Existing second- and third-line treatments include injectable vasodilator agents, vacuum constriction devices (VCDs), intracavernosal injections (ICIs), intraurethral suppository of prostaglandin E1, and penile prosthesis implantation (PPI). Additionally, a topical gel (MED3000, marketed as Eroxon® Stimgel) was commercially launched in the EU in 2022 following approval as a medical device, and US approval is currently ongoing.<sup>15</sup>

#### 3.1 Commercial Medicines

Whilst PDE5 inhibitors are the main medications currently used for treatment of ED, products with other targets are also in development but are still unproven clinically. These are described below in Section 3.1.2.

##### 3.1.1 PDE5 Inhibitors

The mechanism of action (MOA) of PDE5 inhibitors is to cause vasodilation in the penis through blocking the breakdown of cyclic guanosine monophosphate (cGMP) which results in prolongation of the action of mediators of vasodilation including nitric oxide (NO), prolonging penile erection and decreasing pulmonary vascular pressure.<sup>16</sup> Four PDE5 inhibitors are currently approved for ED,

<sup>11</sup> Centers for Disease Control and Prevention (CDC), National and State Diabetes Trends, accessed from <https://www.cdc.gov/diabetes/library/reports/reportcard/national-state-diabetes-trends.html#:~:text=The%20median%20county%2Dlevel%20prevalence,2004%20to%208.4%25%20in%202019.&text=County%2Dlevel%20data%20can%20help,care%20at%20the%20local%20level>.

<sup>12</sup> Ayta et al., The likely worldwide increase in erectile dysfunction between 1995 and 2025 and some possible policy consequences, BJU Int. 1999 Jul;84(1):50-6. doi: 10.1046/j.1464-410x.1999.00142.x

<sup>13</sup> Goldstein et al., Epidemiology Update of Erectile Dysfunction in Eight Countries with High Burden, Sex Med Rev 2020;8:48e58

<sup>14</sup> Futura Medical annual report, 2022

<sup>15</sup> Futura Medical annual report, 2022

<sup>16</sup> National Library of Medicine, Phosphodiesterase Type 5 (PDE5) Inhibitors, accessed from [https://www.ncbi.nlm.nih.gov/books/NBK548192/#:~:text=The%20phosphodiesterase%20type%205%20\(PDE5,includin%20nitric%20oxide%20\(NO\)](https://www.ncbi.nlm.nih.gov/books/NBK548192/#:~:text=The%20phosphodiesterase%20type%205%20(PDE5,includin%20nitric%20oxide%20(NO))



as summarised in Table 1. All are taken orally, recommended 30 minutes to one hour before sexual activity, and no more than once daily. Some additional PDE5 inhibitors, such as fadanafil and udenafil, are also undergoing clinical evaluation. Additionally, alternative administration methods (such as intranasal and sub-lingual), as well as combination therapies involving PDE5 inhibitors in combination with other agents, are in the developmental process.

The first PDE5 inhibitor (sildenafil) was approved for ED in 1998 with tadalafil and varendafil following in 2003, with generic versions for all three of these drugs now available. The most recently available PDE5 inhibitor (avanafil) was approved in 2012 and is still covered by patent exclusivity. In most jurisdictions, PDE5 inhibitors are only available as a prescription (Rx) medicine, although in some markets over the counter (OTC) sales have been legalised. OTC sales of sildenafil were legalised in the UK in 2017 and other markets where sildenafil is available OTC include Poland, Ireland, Norway and New Zealand.

All agents have a similar MOA, but have structural differences, and are cleared from the body at various rates (sildenafil, tadalafil and avanafil at 4-6 hours and tadalafil at up to 36 hours). The median times for maximum concentration are one hour for sildenafil and varendafil and two hours for tadalafil, with avanafil reported at 30-45 minutes, however the time to maximum concentration can range from two hours for sildenafil and up to six hours for tadalafil, significantly reducing the opportunity for spontaneity in sexual activities for many users.<sup>17</sup>

**Table 1: Commercially Available PDE5 Inhibitors for ED, 2023**

Product	Main Brand(s)	Recommended Dose	Approval Date (US)	Generic Availability Date
Sildenafil	Viagra	50mg as a single dose approximately one hour before sexual activity	1998	2017
Tadalafil	Cialis	10mg as a single dose approximately one hour before sexual activity	2003	2018
Varendafil	Levitra (now discontinued), Staxyn	10mg as a single dose approximately one hour before sexual activity	2003	2018
Avanafil	Stendra	100mg as a single dose 30 minutes before sexual activity	2012	N/A

Source: Frost & Sullivan

### 3.1.1.1 Issues and Side-effects

The introduction of PDE5 inhibitors 25 years ago created a significant improvement in treatment of ED, and they have become one of the most widely used medications. Whilst PDE5 inhibitors demonstrate efficacy for most patients, their efficacy can be low for certain patient types, and they can also cause adverse reactions, resulting in a relatively high discontinuation rate. Since the introduction of PDE5 inhibitors, there has been very limited further innovation in commercially

<sup>17</sup> Huang et al., Phosphodiesterase-5 (PDE5) Inhibitors in the Management of Erectile Dysfunction, P T. 2013 Jul; 38(7): 407, 414-419

available treatments for ED, resulting in a significant market opportunity for new therapies targeting individuals for whom PDE5 inhibitors, or their current available delivery mechanism (i.e., oral delivery), are not efficacious or not appropriate.

The percentage of individuals treated with PDE5 inhibitors that fail to respond (non-responders) is reported at 30-35%, resulting from a variety of factors including co-morbidities, complications from treatment for diseases, incorrect administration and psychological factors. This may in some cases be addressed by different dosing regimens.<sup>18</sup> Alternative methods of administration (e.g., intranasal) may also be effective for some non-responders, as well as reducing the response time in responders, as the time required for onset of full effects (which can range up to six hours for tadalafil) can significantly reduce their usefulness for some patients.

The discontinuation rate for oral PDE5 inhibitors, even for individuals where they have been efficacious, is relatively high, with one study estimating a drop-out rate of 49% of users within three years and as high as 70% for users with diabetes. Non-effectiveness (38%), erection recovery (22%) and concerns over cardiovascular safety (16%) are the main reasons for discontinuation, with lack of spontaneity at 9%. The majority of discontinuations occur within three months (55%).<sup>19</sup>

Although oral PDE5 inhibitors are generally well-tolerated, they can also cause adverse reactions including headaches, dyspepsia and nasal congestion.<sup>20</sup> Approximately 35% of individuals report adverse effects.<sup>21</sup> PDE5 inhibitors are contra-indicated for patients taking organic nitrates which can be used to treat conditions such as angina and hypertension.

### 3.1.2 Other Medications

In addition to PDE5 inhibitors, other compounds are at various stages of the clinical development process for treatment of ED, particularly for patients who are non-responders to PDE5 inhibitors (see Table 2).

The most advanced class of compounds in clinical development are monoamine reuptake inhibitors, products that modulate monoamine neurotransmitters in the central nervous system (CNS) e.g., dopamine, noradrenaline, and serotonin. The monoaminergic system plays a key role in various physiological functions, including sexual arousal. Products in development include compounds targeting the dopamine and serotonin systems. Dopaminergic pathways in the central nervous system and potentially in erectile tissue are involved in the erectile function, and modulation of these pathways particularly of D1 and D2 receptors may be effective in the

<sup>18</sup> Cai et al., Practical Approaches to Treat ED in PDE5i Nonresponders, *Aging Dis.* 2020 Oct; 11(5): 1202–1218

<sup>19</sup> Carvalheira et al., Dropout in the Treatment of Erectile Dysfunction with PDE5: A Study on Predictors and a Qualitative Analysis of Reasons for Discontinuation, Article in *Journal of Sexual Medicine* · May 2012

<sup>20</sup> Huang et al., Phosphodiesterase-5 (PDE5) Inhibitors in the Management of Erectile Dysfunction, *P T.* 2013 Jul; 38(7): 407, 414-419

<sup>21</sup> Carvalheira et al., Dropout in the Treatment of Erectile Dysfunction with PDE5: A Study on Predictors and a Qualitative Analysis of Reasons for Discontinuation, Article in *Journal of Sexual Medicine* · May 2012

treatment of ED.<sup>22</sup> The most advanced compounds in this category, IPED2015 and IP2018, are currently at Phase II clinical trials.<sup>23</sup>

A second category of products under clinical development is melanocortin agonists. The melanocortin system regulates several physiological functions and its receptors may be modulated by specific melanocortin agonists. One compound (bremelanotide) has been approved (as Vyleesi®) since 2019 for hypoactive sexual desire disorder in females and is the first approved drug targeting melanocortin receptors. Initial studies have also indicated potential for this treatment in men who are non-responders to PDE5 inhibitors.<sup>24</sup> A Phase II clinical trial of a combination therapy of bremelanotide and a PDE5 inhibitor administered as a single injection is anticipated to commence in the fourth quarter of 2023.<sup>25</sup>

A further category in Phase II clinical development is stem cell therapy, such as the use of bone marrow-derived mesenchymal stem cells (BMSCs) via injection, with a developmental product Cellgram-ED currently undergoing Phase II clinical trials.

Products at an earlier stage of clinical development include libiguins A and B, a class of phragmalin limonoids originating naturally in the root bark of a tree (*Neobegonia mahafalensis*) which have been found to have long-lasting and high-potency effects on sexual activity in animal models.<sup>26</sup> These have been synthesised and a Phase I clinical trial on humans commenced in August 2023.<sup>27</sup> Whilst the MOA is unclear, it differs from that of PDE5 inhibitors, meaning that libiguins represent a new class of compounds for the treatment of ED.

**Table 2: Pharmaceutical Products in Clinical Development for ED, 2023 (excludes PDE5 inhibitors)**

Product	Category	Sponsor	Stage
IP2018	Monoamine reuptake inhibitor targeting the serotonin system	Initiator Pharma A/S	Phase IIa
IPED2015 (pudafensine)	Monoamine reuptake inhibitor targeting the dopamine system	Initiator Pharma A/S	Phase IIb
S1P-205 (Orexa)	Combination of bupropion hydrochloride and trazodone hydrochloride targeting	S1 Pharmaceuticals Inc.	Phase II

<sup>22</sup> Simonsen et al., Modulation of Dopaminergic Pathways to Treat Erectile Dysfunction, *Basic & Clinical Pharmacology & Toxicology*, 2016, 119, 63–74

<sup>23</sup> Initiator Pharma, accessed from <https://www.initiatorpharma.com/en/initiator-pharma-obtains-ip2018-patent-in-europe-for-treatment-of-erectile-dysfunction-and-depression/>

<sup>24</sup> Safarinejad et al., Salvage of sildenafil failures with bremelanotide: a randomized, double-blind, placebo controlled study, *J Urol*. 2008 Mar;179(3):1066-71

<sup>25</sup> Palatin Technologies, accessed from <https://www.prnewswire.com/news-releases/palatin-initiates-clinical-program-for-bremelanotide-co-formulated-with-a-pde5i-for-the-treatment-of-ed-in-patients-non-responsive-to-pde5i-treatment-301897611.html#:~:text=Bremelanotide%20has%20been%20evaluated%20as,improvements%20in%20their%20erectile%20function.>

<sup>26</sup> Razafimahefa et al., Libiguins A and B: novel phragmalin limonoids isolated from *Neobegonia mahafalensis* causing profound enhancement of sexual activity, *Planta Med*. 2014 Mar;80(4):306-14. doi: 10.1055/s-0033-1360390. Epub 2014 Feb 18

<sup>27</sup> Dicot, accessed from <https://www.dicot.se/en/the-pharmaceutical-project/the-drug-candidate-lib-01/>

Product	Category	Sponsor	Stage
	the dopamine and serotonin transporters		
Bremelanotide	Melanocortin receptor 4 (MCR4) agonist	Palatin Technologies Inc.	Phase II
Cellgram-ED	Autologous Mesenchymal Stem Cells (MSC)	Pharmicell	Phase II
LIB-01	Synthesis of libiguins	Dicot AB	Phase I

Source: company websites and reports

### 3.1.3 Other Treatments

For patients for whom oral medications for ED are ineffective, or who are unable to tolerate PDE5 inhibitors, existing alternative treatments include VCDs, intraurethral prostaglandin E1 suppositories, ICIs and PPIs. These are all invasive treatments, which can have adverse effects and barriers to use. Additionally, a topical gel has recently been commercially launched.

VCDs are suction devices which mechanically enhance blood flow into the penis. These devices can cause adverse effects including bruising, pivoting at the base of penis, decreased orgasm, problems such as pain related to the constriction band, and a temporary change to penile sensation.<sup>28</sup>

With intraurethral suppositories, a small intraurethral delivery catheter is used to place prostaglandin E1 (PGE1) within the urethra. However, a significant adverse effect is urethral pain, and the practicality of use is a significant barrier to adoption for many patients.

ICI involves the injection of vaso-active substances directly into the corpora cavernosa (CC) at the lateral base of the penis via a small needle. Whilst initial satisfaction rates with ICI are relatively high, the drop-out rate is also high resulting from issues such as difficulty in injection and desire for a permanent solution.<sup>29</sup>

PPI involves inflatable or malleable implants which are surgically inserted into the penis. Approximately 20,000 PPIs are undertaken each year in the US, indicating that this option is currently utilised by only a small portion of men with ED.<sup>30</sup> PPI can create a range of adverse effects, most significantly infection, as well as having a high cost.

Eroxon® Stimgel was commercially launched in 2022. As it contains no active ingredients it is classed as a medical device rather than a pharmaceutical, with a MOA that involves applying a gel (containing water, ethanol, propylene glycol, glycerine, and carbomer potassium hydroxide) to the

<sup>28</sup> Kim et al., Novel Emerging Therapies for Erectile Dysfunction, World J Mens Health. 2021 Jan;39(1):48-64

<sup>29</sup> Kim et al., Novel Emerging Therapies for Erectile Dysfunction, World J Mens Health. 2021 Jan;39(1):48-64

<sup>30</sup> Duke Health, New Registry Tracks Patient Outcomes From Penile Implant Surgery, accessed from <https://physicians.dukehealth.org/articles/new-registry-tracks-patient-outcomesfrom-penile-implant-surgery#:~:text=According%20to%20Lentz%2C%20industry%20data,20%2C000%20implants%20are%20performed%20annually>

head (glans) of the penis, stimulating blood flow through a cooling and heating mechanism caused by evaporation.<sup>31</sup>

#### 4. Nasal Administration

SPONTAN is being developed to be administered via intranasal delivery. Whilst most drugs (of all types) are administered orally, there is growing interest in intranasal administration, and an increasing number of clinical and non-clinical studies have demonstrated the efficacy and safety of drugs administered nasally. Nasal administration offers advantages over oral administration, including more rapid onset of action, higher rate of absorption, lower adverse reactions and less drug degradation due to bypassing the digestive system. Some commercial drugs and vaccines are already delivered nasally, including corticosteroids (ciclesonide, mometasone furoate, etc.), antihistamines (e.g., azelastine) and live attenuated influenza virus vaccine.<sup>32</sup>

Globally, the pharmaceutical market (excluding Covid vaccines) is estimated at \$1,482 billion in 2022, forecast to grow to \$1,917 billion in 2027 at a CAGR of 5.3%.<sup>33</sup> The intranasal drug market is estimated at \$55.5 billion in 2022 (3.7% of the total pharmaceutical market), but is forecast to grow at 6.6% CAGR, ahead of the broader pharmaceutical market and reflecting growth in the number of commercially-available drugs administered intranasally.<sup>34</sup>

#### 5. Market Size & Growth

This section describes the estimated market size for ED medicines.

Following the commercial launch of Viagra in 1998, the global market for ED medicines grew significantly given the high prevalence of ED and lack of existing treatments, and the market was further stimulated by the introduction of Cialis in 2003. By 2012, global sales of Viagra exceeded \$2 billion,<sup>35</sup> with Cialis sales of \$1.9 billion in the same year.<sup>36</sup> As both products lost exclusivity in 2017 and 2018 respectively, many generic alternatives became available at significantly lower prices, resulting in a decline in market size in value terms. Despite this, by 2021 the global ED medications market size was estimated at approximately \$3.68 billion, and this is forecast to increase to \$5.94 billion by 2028 at a CAGR of 7.1%. The US comprises approximately 30% of the global market.<sup>37</sup>

<sup>31</sup> Eroxon website, accessed from

<https://www.eroxon.co.uk/FrequentlyAskedQuestions#:~:text=It%20works%20by%20suppressing%20an,flow%20and%20normalises%20the%20erection>.

<sup>32</sup> Tai et al., Different Methods and Formulations of Drugs and Vaccines for Nasal Administration, *Pharmaceutics*. 2022 May; 14(5): 1073

<sup>33</sup> IQVIA Institute, *Global use of Medicines*, 2023

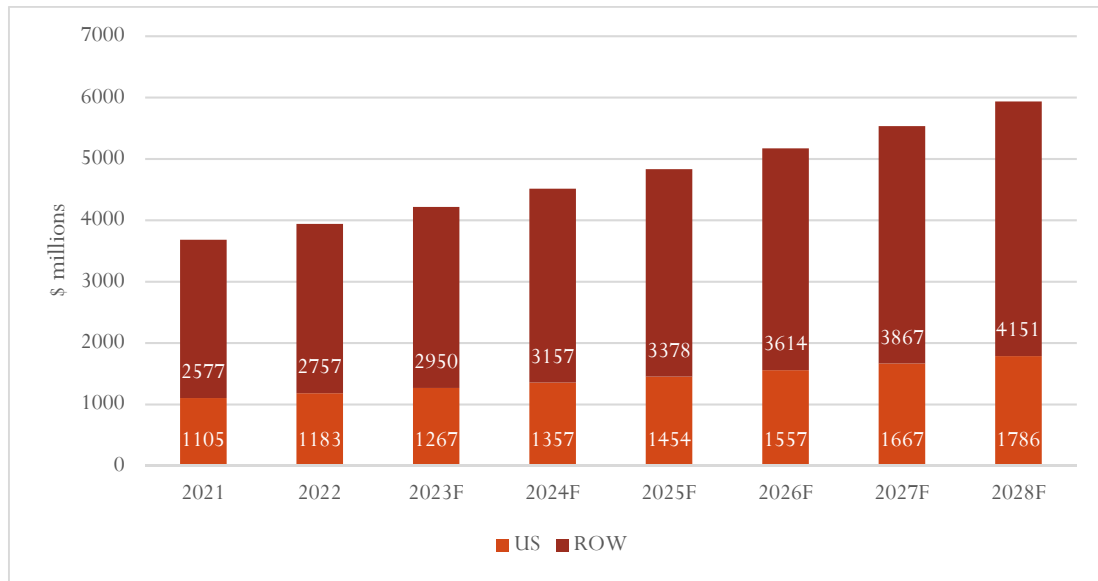
<sup>34</sup> Research and Markets, *Intranasal Drug Delivery: Global Strategic Business Report*, 2023

<sup>35</sup> Pharmaceutical Technology, accessed from <https://www.pharmaceutical-technology.com/comment/viagra-competition-q3-sales/?cf-view>

<sup>36</sup> Eli Lilly, accessed from <https://investor.lilly.com/news-releases/news-release-details/cialisr-tadalafil-marks-10-years-us-approval>

<sup>37</sup> Research and Markets, *The Erectile Dysfunction Treatment Market - Size, Share, Outlook, and Opportunity Analysis, 2021 - 2028*

Figure 1: ED Medicines Market Size, US and Rest of the World (ROW), 2021 to 2028F



Source: Research and Markets; Frost & Sullivan

## 6. Competitive Environment

This section describes companies focused on the development and commercialisation of treatments for ED in addition to LTR Pharma. This excludes biopharma companies with broader product portfolios which include ED medications (such as Pfizer and Eli Lilly).

One company (Futura Medical) has recently launched a new treatment for ED in Europe (as an OTC medical device rather than a medication) and is planning commercial roll-out in other markets. Dicot, Initiator Pharma and S1 Biopharma are focused on the development of new classes of ED treatments. Petros Pharmaceuticals has licensed Stendra (avanafil) which is planning to switch from an Rx to an OTC product in the US, and also markets vacuum erection devices.

Table 3: Companies Focused on ED Treatments, 2023

Company	Status	Market Capitalisation (\$ millions)	Product(s)	Comments
<b>Dicot</b>	Traded on the Spotlight Stock Market	9	LIB-01	Biopharma company developing a modern potency drug that will treat ED and premature ejaculation. Lead candidate LIB-01 has just started Phase I clinical trials.
<b>Futura Medical</b>	Traded on the UK Alternative Investment Market	194	MED3000 (Eroxon® Stimgel)	Company focused on topical formulations and transdermal delivery, targeting sexual health and pain relief. Lead product for ED received EU approval in 2022.

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Company	Status	Market Capitalisation (\$ millions)	Product(s)	Comments
<b>Initiator Pharma</b>	Traded on the Nasdaq First North Growth Market	34	IP2018 IPED2015	Biopharma company developing innovative drugs that target key unmet medical needs within the CNS. Focus is on treatments for ED and Trigeminal Neuralgia.
<b>Petros Pharmaceuticals</b>	Traded on Nasdaq	4	Stendra (avanafil) Vacuum erection devices	Biopharma company focused on men's health therapeutics. Main product is Stendra, licensed from Vivus, which it is aiming to switch to an OTC product. Company also markets vacuum erection devices.
<b>S1 Biopharma</b>	Private	N/A	S1P-205 (Orexa)	Developer of first-in-class drugs to treat sexual dysfunction. Lead compound (Orexa) is targeted at ED.

Source: company websites and reports. Market capitalisation is at 12 September 2023

## 7. Distribution Channels

Following regulatory approval, medicines are commercialised either as prescription-only medicines which require a prescription from an authorised healthcare professional and which are dispensed by a pharmacist, and OTC medicines which are available without a prescription. Currently, most ED medicines are prescription-only, although in some markets PDE5 inhibitors (specifically sildenafil) are available OTC. Non-pharmaceutical products, such as topical gels, are also available OTC.

In the US, medicines require marketing authorisation from the FDA. Similarly in Australia approval from the TGA and registration on the Australian Register of Therapeutic Goods (ARTG) is typically required, although for 'unapproved medicines' an alternative pathway exists through the Special Access Scheme Category B (SAS-B). SAS-B allows a prescriber to prescribe unapproved medicines to a patient under his/her care with appropriate clinical justification provided to the Department of Health. The application may be made online.

Commercialisation of medicines typically involves sales & marketing efforts targeting clinicians and potentially pharmacists, as well as physical distribution to pharmacies which is often undertaken by a distribution partner that supplies pharmacies on a wholesale basis.

## 8. Conclusion

ED is an extremely prevalent condition, affecting over 300 million men globally, with prevalence significantly higher in older age cohorts. A range of factors including population ageing and growing prevalence of risk factors such as diabetes are driving growth in the prevalence of ED.

The introduction of PDE5 inhibitors (initially as Viagra) from 1998 onwards revolutionised the treatment of ED, with a range of medicines now commercially available, including generic versions of drugs such as Viagra and Cialis. Whilst oral PDE5 inhibitors show efficacy for most users, there is a significant cohort of patients (over one-third of ED patients) for whom they are not efficacious (non-responders), and they can also demonstrate adverse effects for some responders and generally have a slow response rate due to needing to pass through the digestive system. Consequently, the discontinuation rate for oral PDE5 inhibitors is relatively high at almost 50%. Existing non-pharmacological treatments which are primarily invasive and can be used as second- and third-line approaches also have adverse effects and barriers to use.

Due to these factors, there is significant interest in the development of new medicines for ED, including alternative methods of administration of PDE5 inhibitors, combination therapies and new classes of compounds. However, the most advanced of these products are still several years from regulatory approval, even assuming that clinical development is successful.

Intranasal delivery of PDE5 inhibitors, such as demonstrated by SPONTAN, offers the opportunity to address some of the limiting factors of oral PDE5 inhibitors, including adverse effects and relatively slow response time. This offers the opportunity to target both existing/previous users of ED medicines as well as ED sufferers who have not sought treatment to date. As SPONTAN is based on an existing approved drug, its regulatory approval is likely to be expedited in comparison to new classes of compounds for treatment of ED. Hence, the product offers the potential to disrupt the existing ED medicines market.

The global ED medicines market is estimated at approximately \$3.94 billion in 2022, and this is forecast to grow to \$5.94 billion by 2028, indicating a large and growing market opportunity.

## 9. Disclosure

This is an independent report prepared by Frost & Sullivan. Save for the preparation of this report and services rendered in connection with this report for which normal professional fees will be received, Frost & Sullivan has no interest in LTR Pharma Limited and no interest in the outcome of the IPO or transaction. Payment of these fees to Frost & Sullivan is not contingent on the outcome of the IPO or transaction. Frost & Sullivan has not and will not receive any other benefits (including any commissions) and there are no factors which may reasonably be assumed to have influenced the contents of this report nor which may be assumed to have provided bias or influence. Frost & Sullivan consents to the inclusion of this report in the Prospectus in the form and context in which it is included. As at the date of this report, this consent has not been withdrawn. Frost & Sullivan does not hold a dealer's license or Financial Services License. This report does not constitute advice in respect of the IPO or transaction.

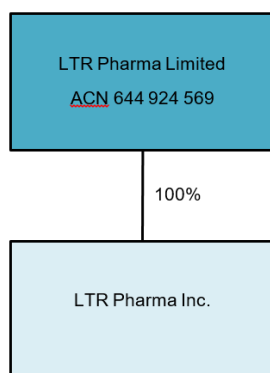


## 5. Company Overview

### 5.1 About the Company

LTP is a drug development, research and repurposing company, focused on men's health and, currently commercialising a 'first-in-class' rapid onset, on-demand therapeutic nasal spray for the treatment of ED.

The corporate structure of the LTP group is as follows:



### 5.2 Company history

LTP was incorporated in October 2020 upon being spun-out of LTR Medical, a successful and profitable medical device and distribution business that works with international and domestic manufacturers on commercialising medical technologies, including medical device nasal spray sales to Australian hospitals.

LTP is currently focused on changing the method of administration of an existing and approved drug that is already on market for the treatment of ED called Vardenafil, also known by the brand names Levitra® and Staxyn®. LTP is preparing to launch SPONTAN®, which is based on an intranasal Vardenafil formulation, SDS-089, by undertaking a bioequivalence trial.

In October 2020, LTP signed a licence agreement with Strategic Drug Solutions Inc (SDS), thereby acquiring specific rights in relation to the SDS-089 formulation developed by SDS (**SDS Licence Agreement**) – please see section 13.7(a) for relevant details. During the subsequent two years, LTP has been working on commercialising SDS-089, the formulation that the Company will market as a product under the name SPONTAN®. The work undertaken by the Company since inception includes:

- assembling a Scientific Advisory Board;
- forming drug development, device and manufacturing arrangements with companies such as Nanopharm Ltd and Mayne Pharma;
- raising capital to finance research and development operations in August 2021, June 2022, and June 2023; and
- optimising the SDS-089 nasal formulation, manufacturing SDS-089 (for bioequivalence trial purposes), producing the protocol for its bioequivalence trial, and obtaining ethics approval to commence the proposed bioequivalence trial.

Since its founding in 2020, LTR Pharma has made significant strides in the development of its flagship product SPONTAN®, including:



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The table below sets out the timeline of the Company's key achievements:

Phase	2024				2025				2026	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
<b>SPONTAN Product Manufacturing</b>	Clinical Manufacturing <sup>6</sup>									
<b>SPONTAN Clinical Development Program</b>	SPONTAN Bioequivalence Trial <sup>7</sup>									
<b>2nd Nasal Spray Product</b>	Pre-clinical Commencement <sup>1</sup>									
<b>Regulatory</b>	FDA Pre IND Guidance Meeting				FDA NDA Application <sup>4</sup>					
	TGA Pre Submission Meeting				TGA Application <sup>3</sup>					
<b>Commercialisation</b>	Licensing discussions <sup>2</sup>				Commencement of US distribution <sup>8</sup>					
	Readiness for SAS/APS Distribution in AUS <sup>5</sup>									

- 1. See development pipeline section 4.9
- 2. See section 4.3 The Company's business model
- 3. See section 4.4 The TGA route to market
- 4. See section 4.5 The FDA 505(b)2 expedited route to market
- 5. See section 4.4 The TGA route to market
- 6. See section 13.7 b vi Mayne Pharma Services
- 7. See section 5.8 Bioequivalence Trial
- 8. Subject to regulatory approval

### 5.3 The Company's business model

LTP's business model focuses on adapting pre-existing pharmaceutical drugs for alternative methods of administration or for alternative indications. This approach can avoid time-consuming and expensive elements of a full clinical trial program including research and development, safety trials and multi-phase clinical trials. LTP instead focuses on bringing repurposed drugs to market in a more expeditious timeframe.

LTP's current focus is on changing the method of administration of an existing and approved drug that has been successful for the treatment of ED. SPONTAN<sup>®</sup> is a Vardenafil-based nasal delivery formulation designed to be a lower dose (i.e. less active ingredient), fast-acting administration that provides a rapid and high availability to a patient's bloodstream compared with the incumbent oral ED treatment products on market (which are first metabolised by the liver before distribution through the patient's bloodstream). This nasal delivery methodology is expected to reduce the health risks to consumers that can be associated with the oral consumption of the current drugs used for the treatment of ED, and is also expected to increase the onset speed and rate of efficacy of the treatment.

Vardenafil has been approved by the FDA as an oral therapy for the treatment of ED after completing extensive safety and efficacy human trials. Vardenafil was launched on the global markets in 2003. In June 2003, the National Drugs and Poisons Committee (NDPSC, the predecessor to TGA until 2005) approved Vardenafil as a new medicine in Australia. In 2012, Vardenafil went 'off-patent' with the first generic product available in global markets. Since 2018, Vardenafil has been available from multiple generic manufacturers in its oral formulation in Australia and abroad.

The market for LTP's proposed nasal delivery product is large given the potential benefit to the patients. It is estimated that around 46% of people using existing oral medications for the treatment of ED stop or discontinue their use because of the inconvenience of the delayed onset of action or no effect at all during the desired timeframe. As such, LTP's new nasal delivery product is seeking to offer an ED treatment to patients looking for a more rapid onset of effect than existing ED treatments, taking advantage of the growing market opportunity being driven by a number of factors, including;

- (a) The growing prevalence of ED;
- (b) Delayed onset of existing oral ED medications; and
- (c) Increased concerns of ingesting compounds.

The Company needs to obtain TGA approval for SPONTAN<sup>®</sup> in Australia, and FDA approval for SPONTAN<sup>®</sup> in the United States, in order to market and sell the product in those jurisdictions as detailed below. LTR Inc is LTP's fully owned subsidiary in the United States. LTR Inc is currently inactive. Once LTP is in a position to sell / distribute SPONTAN<sup>®</sup> in the United States, it will use LTR Inc as its operating vehicle for its operations in the United States.

Subject to achieving successful launch of SPONTAN<sup>®</sup> in the United States and Australia, LTP intends to commercialise SPONTAN<sup>®</sup> in the United States and Australia through direct sales and indirect distribution partnerships with specialist men's health distributors and specialist ED pharmaceutical wholesalers.

The Company also currently intends to expand its operations into the United Kingdom, Europe and Asia, subject to obtaining relevant regulatory approvals in those jurisdictions - under the international harmonisation of regulatory standards/approvals of pharmaceuticals. Finally, the Company will also seek entering into sub-licensing arrangements with reputable healthcare companies for the manufacture, marketing, sale, and/or distribution third parties allowing them to manufacture and/or sell of SPONTAN<sup>®</sup> in any jurisdiction in which the Company does not intend to directly operate in from time to time based on its then operations and intentions for commercialisation.

After SPONTAN<sup>®</sup> is successfully commercialised, LTP plans to investigate additional applications in ED and the broader healthcare landscape. The Company believes that it has the capability to redefine treatment paradigms for ED and in a number of other therapeutic fields. LTP plans to engage in research initiatives that may result in innovative solutions to other pressing healthcare issues and plans to commence further research and development into its development pipeline as further outlined in Section 5.14 of this Prospectus.

#### **5.4 The TGA route to market**

In Australia, LTP intends to seek approval from the TGA via a Category 1 application involving a significant change (new dosage form, change/increase in patient group, change in dosage, new strength, and new route of administration – Type F Application). The Category 1 – Type F Application process offers potential advantages over new drug applications such as an expedited approval process as companies can often leverage existing safety and efficacy data from the original registration of the approved drug. If LTP receives approval from the TGA, this can lead to significant cost and time savings for the Company. LTP plans to hold a meeting with the TGA to review its

clinical and quality data, including GMP manufacturing data, after completing its bioequivalence clinical trial which is expected to finalise by the middle of the 2024 calendar year.

Given the existing safety profile of Vardenafil, the regulatory pathways for repurposed drugs, such as the Category 1 – Type F Application process is expected to be available to the Company. However, even if SPONTAN<sup>®</sup> meets the requirements for a Category 1 – Type F Application process, the TGA may require additional studies be undertaken by the Company. These studies could include further safety evaluations in response to TGA's concerns or adverse events, more robust efficacy data, and quality control validations considering changes to the manufacturing process. The TGA may also request research be conducted on potential drug interactions, particularly if the drug is to be used in conjunction with other therapeutic agents. Finally, post-marketing surveillance could be mandated to continuously monitor the drug's performance once it is on the market.

The Company may also explore alternative avenues to make SPONTAN<sup>®</sup> available to patients where necessary prior to it being approved by the TGA subject to relevant regulatory considerations - for example, SPONTAN<sup>®</sup> 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. These schemes provide the ability for health practitioners to prescribe drugs/therapeutic products that can have a clinical benefit to their patients but are not yet included on the Australian Register of Therapeutic Goods (**ARTG**). The application process for these pathways do not require a detailed dossier from the Company, instead, the prescribing physician must be convinced of the necessity of the relevant product and be willing to assume full responsibility for its use. These schemes are generally more expedient and are utilised when patients have exhausted all other acceptable treatment options available to them.

## 5.5 The FDA 505(b)2 expedited route to market

The FDA regulates, among other things, the research, manufacture, promotion, and distribution of drugs in the United States under the Federal Food, Drug, and Cosmetic Act (**FDCA**) and other statutes and implementing regulations. The process required by the FDA before prescription drug product candidates may be marketed in the United States generally involves the following:

- (a) Completion of extensive nonclinical laboratory tests, animal studies and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice regulations;
- (b) Submission to the FDA of an Investigational New Drug application (an **IND**), which must become effective before human clinical trials may begin;
- (c) For some products, performance of adequate and well-controlled human clinical trials in accordance with the FDA's regulations, including Good Clinical Practices, to establish the safety and efficacy of the product candidate for each proposed indication;
- (d) Submission to the FDA of a New Drug Application (an **NDA**);
- (e) Satisfactory completion of an FDA preapproval inspection of the manufacturing facilities at which the product is produced to assess compliance with the Current Good Manufacturing Practice (**cGMP**) regulations; and

- (f) FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

There are three pathways that the FDA may grant an NDA:

505(b)(1) NDA	505(b)(2) NDA	505(j) ANDA
Full application – data predominantly obtained from studies conducted by and for the sponsor	Hybrid between an ANDA (505(j)) and full NDA (505(b)(1))	Appropriate for drug products that are the same as approved products

Under the 505(b)(2) NDA pathway, the process is significantly truncated based on the following:

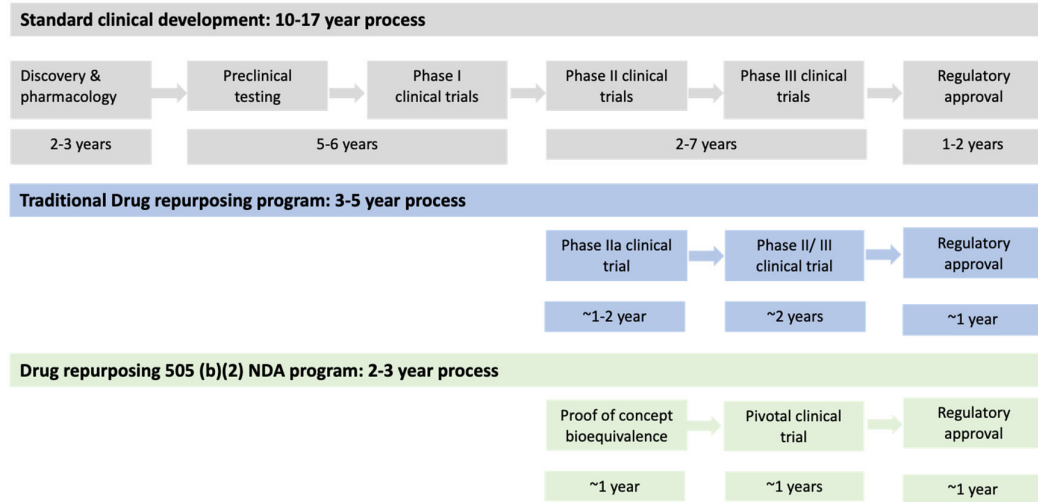
- (a) The 505(b)(2) process begins with formulation development, proof of concept studies, bioequivalence studies, then a pre-IND meeting with the FDA, then moves to completion of development (and studies, if necessary) and then to the NDA filing.
- (b) The goals of the pre-IND meeting: In proposing a 505(b)(2) development strategy in a pre-IND meeting, the objective is to gain FDA input and concurrence with the studies, with the chemistry, manufacturing and controls (CMC) strategy and with clinical research plans in a way that minimises the number of studies required.
- (c) The number and type of studies required: Since the 505(b)(2) pathway allows the use of public data or the FDA’s previous findings of the referenced drugs safety and efficacy data, ‘change in route of administration’ development programs may conduct bridging studies that can negate the need for nonclinical or clinical studies, or both.
- (d) Timing of CMC work: For a 505(b)(2) product, the clinical trial materials for bioequivalence ‘bridging’ studies (often demonstrations of clinical bioequivalence) must be representative of the commercial manufacturing process. In general, the stability batches that will be used for shelf-life determinations are also prepared at this time.
- (e) Timing of studies: Because 505(b)(2) development plans rely largely on pre-existing safety and efficacy data, studies can often be started simultaneously and developed in parallel, significantly shortening the overall time to market.

LTP is targeting a United States NDA filing with the FDA for market approval of SPONTAN® to be completed by the end of the first quarter of 2025 under the 505(b)(2) approval pathway regulatory strategy. LTP expects that this regulatory approval pathway is available to it on the basis that it is ‘repurposing’ or there is a ‘change in route of administration’ of an existing approved drug. That is, LTP anticipates the previous approval of oral and oral dispersible tablet Vardenafil by global regulators including the FDA would allow LTP to use the existing safety and efficacy clinical and nonclinical data as LTP is only changing the route of administration to improve the therapeutic effect and drug efficacy onset.

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LTP expects that on approval, SPONTAN<sup>®</sup> will also receive a 3-year market exclusivity in the United States, awarded to SPONTAN<sup>®</sup> by the FDA, which typically is reserved for drugs approved under the full 505(b)(1) and 505(b)(2) NDA pathways.

The benefit of LTP's business model is a significantly reduced time to approval and lower cost, even when compared with traditional drug repurposing strategies as shown below:



## 5.6 Product Development

The SDS-089 formulation, to be marketed as SPONTAN<sup>®</sup> has been developed to be a fast acting, on-demand treatment solution for the ED market. This intranasal formulation has been optimised by LTP's drug development contractor Nanopharm Ltd. The formulation is now capable of being manufactured for commercial purposes by the commercial contract manufacturing organisation Mayne Pharma, and Mayne Pharma has completed manufacturing and packaging studies ahead of LTP's proposed bioequivalence trial.

Please refer to section 5.2 for additional information of LTP's operations.

## 5.7 Compelling proof of concept data

LTP has completed an investigator lead, human proof of concept study titled '*A Randomized, Single-Dose, Cross-over, Bioavailability Study to Evaluate SDS-089 Solution as Nasal Spray in Comparison to Levitra Oral Tablet 10 mg in Healthy Volunteers*' for SDS-089. The study was completed in February 2020. This study, completed by Western University of Health Sciences, California, United States and was designed to compare the plasma concentration levels of Vardenafil in healthy male subjects.

The study undertaken was a randomised, single dose cross-over study of males aged between 24 to 45 with 12 healthy participants. The delivery of the SDS-089 nasal spray solution used a 100 ul per dose nasal spray device manufactured by AptarGroup Inc.. The study assessed the plasma concentration levels of Vardenafil HC1 in healthy male subjects comparing Vardenafil HC1 as SDS-089 nasal spray (4 mg) and an oral Vardenafil tablet (10 mg).

The study was published in May 2023 with The Journal of Sexual Medicine and confirmed the rapid onset of effect for SDS-089 is approximately 10 to 15 minutes compared to up to 60 minutes which is typical of existing oral ED drugs. Based on the pharmacokinetic data, this study showed positive characteristics / attributes for SDS-089, including:

- » SDS-089 showed faster Tmax (the amount of time a drug is present at maximum concentration in a patient's serum) suggesting rapid onset via nasal spray delivery ( $\leq 10$  minutes);
- » SDS-089 shows a Cmax (the peak concentration of a drug in a patient's serum) within 10 minutes suggesting patient will respond shortly after administration;
- » no severe adverse events being detected; and
- » an acceptable safety profile for SDS-089.

### 5.8 Bioequivalence Trial

LTP is now progressing to a human bioequivalence trial comparing the proposed change in delivery of Vardenafil in a nasal spray to oral tablets. As such, the trial will compare the pharmacokinetics or the movement of drug into, through, and out of the human body between LTP's candidate nasal spray and the selected Reference Listed Drug, in this case Levitra<sup>®</sup>. LTP expects that this clinical strategy will expedite the NDA filing, ARTG registration and product market launch in the United States and Australia.

The trial is titled '*A Phase 1, Randomized, Open-label, Single-dose, Two-period, Two-treatment, Cross-over Study Comparing the Pharmacokinetics of Vardenafil Following Administration of SDS-089 Nasal Spray and Levitra Tablet in Healthy Male Adult Subjects*'.

The primary objective is to assess the relative bioavailability of Vardenafil following administration of the SPONTAN<sup>®</sup> nasal spray compared to Levitra<sup>®</sup> tablets.

The design of the trial is a single-dose, randomised, open-label, 2-treatment, 2-period crossover study of SPONTAN<sup>®</sup> nasal spray (5 mg Vardenafil consisting of a single 2.5 mg spray in each nostril) compared to Levitra<sup>®</sup> tablet (10 mg Vardenafil) in healthy adult male subjects under fasting conditions. The duration of trial for each participant is approximately 4 weeks (including screening).

The bioequivalence trial has been scientifically and ethically reviewed and approved by the Bellberry Limited Human Research Ethics Committee. The period of approval is 21 March 2023 - 21 March 2024. However, an annual extension may be granted upon successful completion and noting of a progress report required to be submitted at least 30 days prior to 31 March 2024. The Bellberry Limited Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research.

Pending the successful completion of the bioequivalence trial that is in accordance with the trial's protocols including where all relevant expected data has been obtained, the Company will be able to use the trial data in its new drug applications (i.e. an NDA) with the FDA, and the TGA for relevant regulatory approvals.

While LTP is optimistic about SPONTAN<sup>®</sup>'s path to regulatory approval, there is a risk



that the FDA or the TGA may require additional studies, which may delay approval and therefore commercialisation timelines. LTP is prepared to undertake any additional clinical and non-clinical work that may be necessary to meet regulatory requirements, but generally expects that it will be able to secure regulatory approvals and drive the successful commercial adoption of SPONTAN<sup>®</sup> on a global scale in due course.

### **5.9 How will SPONTAN<sup>®</sup> be manufactured and sold, if approved?**

SPONTAN<sup>®</sup> is to be produced by third-party commercial manufacturers under contract. Currently, LTP has contracted with ASX-listed Mayne Pharma, a manufacturer based in Adelaide, South Australia for this purpose. Section 13.7(b)(vi) of this Prospectus provides an overview of the service agreement entered with Mayne Pharma in relation to their services.

If LTP is able to secure regulatory approval from the FDA and TGA, LTP intends to manufacture its product using Mayne Pharma's services and bring SPONTAN<sup>®</sup> to market in the United States and Australia through direct sales and distribution partnerships with specialist men's health distributors and specialist ED pharmaceutical wholesalers.

The Board and management team of LTP have extensive experience launching and commercialising new medical products in Australia and abroad. In Section 7 of this Prospectus, the profiles of the Directors and management team outline these qualifications in more detail.

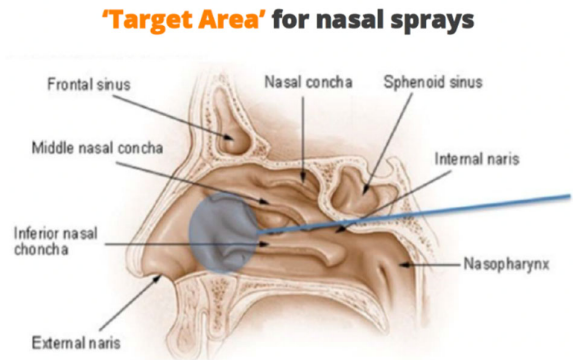
### **5.10 Competitive advantages of SPONTAN<sup>®</sup>**

Given the success of oral delivery of phosphodiesterase type 5 inhibitors (**PDE5 Inhibitors**), in the treatment of ED, LTP believes these compounds are good candidates for successful reformulation into a nasal delivery system generally speaking. The result is a product, that is a combination of intranasal medical device technology and a reformulation of an ED drug (Vardenafil) designed to address two major concerns in the market:

- » dosing issues with existing ED oral drugs (and the corresponding side effect profile); and
- » rapid onset of action desired by patients.

With certain commercial concerns relating to the incumbent orally delivered ED products, LTP is pursuing nasal delivery given a number of advantages including:

- (a) the drug degradation that is observed in the gastrointestinal tract is absent;
- (b) hepatic first pass metabolism is absent;
- (c) rapid drug absorption and quick onset of action can be achieved;
- (d) bioavailability of larger drug molecules can be improved by means of absorption enhancer or other approach; and
- (e) the nasal bioavailability for smaller drug molecules is good.



LTP believes SPONTAN<sup>®</sup> will have numerous competitive advantages compared to existing oral tablet ED treatments currently on the market, including:

- (a) Faster onset of action allowing it to be used at the time of need over being planned ahead.
- (b) Increased safety profile due to use less active drug than some oral tablets.
- (c) Reduced need to have unwanted drug concentration circulating in the body.
- (d) Easier delivery method for those patients that are unable to take oral tablets due to medical conditions such as dysphagia (difficulty swallowing).

Sildenafil, Vardenafil, Tadalafil and Avanafil are all classed as PDE5 Inhibitors and are approved by the FDA and TGA for the treatment of ED. PDE5 Inhibitors are 'first-line' treatments, meaning they are most commonly recommended as the first treatments prescribed for the treatment of ED. LTP's product SPONTAN<sup>®</sup> contains the PDE5 Inhibitor drug Vardenafil and has been designed to be a fast acting, on demand treatment for ED. A comparative table showing the expected timing advantage of SPONTAN<sup>®</sup> is shown in the table below:

Generic (Brand)	EFFECT	MEDIAN tmax (minutes)
<b>Sildenafil</b> (Viagra®)	Taken on an empty stomach <b>one hour before sex</b>	60
<b>Vardenafil</b> (Levitra®, Staxyn®)	<b>Taken one hour</b> before sex with or without food	60
<b>Tadalafil</b> (Cialis®)	<b>Taken one to two hours</b> before sex with or without food	120
<b>Avanafil</b> (Stendra®)	<b>Taken 30 – 45 minutes</b> before sex with or without food	30 to 45
<b>SDS-089</b> (SPONTAN®™)  LTR Pharma	Proof of Concept Study showed faster T max <b>within 6 – 15minutes</b>	<b>10</b>

LTP does not consider other existing treatments or those that are in various stages of research and development as major competitors to SPONTAN® or, with respect to those under development, relevant yet as they're still unproven technologies in LTP's view and not considered first-line treatments for ED.

### 5.11 Other potentially competitive companies

The biotechnology and pharmaceutical industries are highly competitive. As detailed in the Frost & Sullivan Report (see section 4), there are a number of potential treatments for ED currently available on the market.

LTP is not aware of any other company that has produced or is currently developing a nasal spray technology for the treatment of ED which would directly compete with SPONTAN®. LTP however, expects that it will need to compete with existing and emerging pharmaceutical companies producing oral tablets for the treatment of ED, some of which have established current market for ED treatments, including the oral PDE5 Inhibitor brand names such as Viagra, Levitra, Staxyn, Cialis and Stendra. These oral PDE5 Inhibitor treatments are known to cause side effects in some patients including headaches, diarrhoea, aches and muscle pains, dizziness, flushing, sneezing, stuffy or runny nose, indigestion as well as numerous other side effects. LTP believes that SPONTAN® may have a better safety profile (with reduced side effects), due to SPONTAN® administering a lower dose of the PDE5 Inhibitor to patients (but this remains subject to further testing on SPONTAN®).

LTP is also aware of other groups researching and developing other technologies for the treatment of ED including oral sprays, gels and topical solutions. Whilst there is currently a very large market for new treatments in ED, LTP believes that these technologies are still unproven for the treatment of ED and PDE5 Inhibitor are still the first line of treatment for ED.

For personal use only

## 5.12 Overview of the Company's Expenditure Program and anticipated use of funds from the proceeds of the Investor Offer

The purpose of the Investor Offer is to raise funds to:

- (a) achieve a listing on the ASX to broaden the Company's investor base;
- (b) perform a bioequivalence trial on the lead product, SPONTAN®;
- (c) engagement with regulators (TGA and FDA) to confirm regulatory enabling studies;
- (d) completion of the trials/studies required to enable regulatory approval; and
- (e) meet the Company's ongoing administration and corporate overhead expenses, including costs of the capital raising.

The Directors are satisfied that following the successful close of the Offers and from the application of existing funds, the Company will have sufficient working capital to meet its stated objectives.

The following tables show the application of funds over two years:

If the Minimum Subscription is raised:

Use of Funds / Expenditure Program	\$6,000,000	
	Year 1	Year 2
Regulatory	\$250,000	\$60,000
CMC (chemistry, manufacturing and control / packaging for sales)	\$320,000	-
Non-clinical studies	\$50,000	-
Bioequivalence trial	\$1,350,000	-
Sales & Marketing	\$200,000	\$240,000
Payment (SDS Licence Agreement)	\$475,097	-
Working Capital	\$834,140	\$1,379,797
Expenses of the Offer	\$749,701	-
<b>Total</b>	<b>\$4,228,938</b>	<b>\$1,679,797</b>

*\* This table is a statement of current intentions of the Company. Actual use of funds may differ from the budgeted use of funds based on changes in clinical trials budget or formulation development expenses. The Board may alter the way funds are applied in the future. LTP is required to make a US\$300,000 payment pursuant to the SDS Licence Agreement, the expenditure above is estimated using an exchange rate of approximately \$1.00 to US\$0.6314.*

If the Maximum Subscription is raised:

Use of Funds / Expenditure Program	\$7,000,000	
	Year 1	Year 2
Regulatory	\$250,000	\$100,000

CMC (chemistry, manufacturing and control package) / Commercial Packaging	\$320,000	-
Non-clinical studies	\$100,000	\$40,000
Bioequivalence trial	\$1,350,000	-
Sales & Marketing	\$350,000	\$460,000
Payment (SDS Licence Agreement)	\$475,097	-
Working Capital	\$1,049,140	\$1,586,197
Expenses of the Offer	\$811,939	-
<b>Total</b>	<b>\$4,706,176</b>	<b>\$2,186,197</b>

*\* This table is a statement of current intentions of the Company. Actual use of funds may differ from the budgeted use of funds based on changes in clinical trials budget or formulation development expenses. The Board may alter the way funds are applied in the future. LTP is required to make a US\$300,000 payment pursuant to the SDS Licence Agreement, the expenditure above is estimated using an exchange rate of approximately \$1.00 to US\$0.6314.*

The tables above are a statement of current intentions as at the date of this Prospectus. Actual use of funds may differ from the budgeted use of funds based on changes in clinical trials budget or possible formulation development expenses. The Board may alter the way funds are applied in the future. This table does not include any benefit from R&D tax incentives available through the Australian Tax Office.

### 5.13 Company's intellectual property

LTP's is currently focused on developing new and improved formulations for intranasal delivery of PDE5 Inhibitors that have the potential to improve therapeutic treatment of ED.

The mark 'SPONTAN' received its early trade mark acceptance from IP Australia on 27 April 2022, and was officially registered on 7 November 2022. The relevant details of the trade mark are as follows:

Trade Mark No.	Trade Mark	Class / Specification	Status	Owner(s)	Address for Service	Lodgement Date	Renewal Date
2259335	"SPONTAN"	<b>Class 5: Pharmaceutical products for treating erectile dysfunction</b>	Registered	LTR Pharma Pty Ltd*	Griffith Hack  Griffith Hack Lawyers, Level 15, 376-390 Collin St, Melbourne, VIC, 3000, AUSTRALIA	29 March 2022	29 March 2032

*Important Note: \* See section 5 of the Patent Report.*

Trade mark registrations remain valid for 10 years from the filing date and may be renewed every 10 years upon payment of applicable fees.

The relevant formulation which underpins LTP's product SPONTAN® has been licensed to LTP by Strategic Drug Solutions, Inc (SDS). SDS, as the licensor of the relevant intellectual property, is the owner/applicant on the patent applications

identified in the Patent Report in section 10. LTP has certain rights under its agreement with SDS for the assignment of these patents (please section 13.7(a) for additional details).

Please also see the Patent Report set out in section 10 for further details about LTP's licenced patents.

## 5.14 Development Pipeline

LTP intends to ultimately develop and commercialise additional products for both ED and non-ED uses, which objectives include;

### (a) Additional ED Products

In addition to the current formulation for SPONTAN<sup>®</sup>, LTP intends to develop a range of nasal spray products by investing in product research and development into:

- (i) Different concentrations/dosages of SPONTAN<sup>®</sup> to address market needs.
- (ii) Additional nasal spray products using other approved PDE5 Inhibitors to create a range of nasal spray products for the treatment of ED, increasing LTP's portfolio and competitive advantage.

### (b) Non-ED uses

LTP has identified an unmet need for an easy to administer dosage form of PDE5 Inhibitors (explained further below), for use in the following indications, which are currently treated using oral PDE5 Inhibitor administration:

- (i) **Pulmonary Arterial Hypertension (PAH):** is a rare, progressive disorder characterised by high blood pressure (hypertension) in the arteries of the lungs (pulmonary artery) for no apparent reason. The pulmonary arteries are the blood vessels that carry blood from the right side of the heart through the lungs. Symptoms of PAH include shortness of breath (dyspnea) especially during exercise, chest pain, and fainting episodes.

Sildenafil (the active ingredient in Viagra<sup>®</sup>) was approved by the FDA for the treatment of PAH in 2005 under the brand name Revatio (as Sildenafil 20-mg tablets and 10-mg/12.5-mL single-use vial injections). Tadalafil is also being used to treat PAH under the trade name Adcirca (Tadalafil 20-mg tablets). Like Vardenafil, Sildenafil and Tadalafil decrease the activity of PDE5, a substance produced in the lungs and other parts of the body that breaks down another substance called cyclic guanosine monophosphate (**Cyclic GMP**). Cyclic GMP causes the blood vessels (arteries) to relax and widen so that more Cyclic GMP is available for the blood vessels inside the lungs. This leads to relaxation or widening, of those vessels. Relaxing and widening of the blood vessels in the lungs decreases the pulmonary blood pressure to the heart and improves its function. This reduces blood pressure in the lungs which generally results in the ability to be more active. Research studies have verified this improvement. LTP plans to seek a repurposing of the SPONTAN<sup>®</sup> formulation for this indication.

- (ii) **Scleroderma or systemic sclerosis:** is a chronic connective tissue disease caused by the immune system mistakenly attacking healthy tissues, triggering vasoconstriction, or the narrowing of blood vessels. Complications include Raynaud's phenomenon, a condition resulting in discoloration of the fingers and/or the toes, which results from reduced blood flow to the fingers or toes, leading to digital ulcers, or sores on the extremities that often become infected. A chronic connective tissue disease that causes very poor circulation in the extremities like fingers and toes, similar to frost bite.

PDE5 Inhibitors such as Vardenafil and Sildenafil have found to be effective against this indication when given orally. LTP plans to pursue the benefits of SPONTAN<sup>®</sup> for this indication.

- (iii) **Osteoporosis:** is a condition where bones become thin, weak and fragile and can lead to fractures for elderly patients. Vardenafil has been found in animal studies to act on bone cells, resulting in the formation of new bone and reduced removal of old bone. LTP aims to explore the use of SPONTAN<sup>®</sup> for this indication to potentially co-treat ED and osteoporosis in ageing men, and osteoporosis in postmenopausal women.

## 6. Details of the Offers

### 6.1 The Offers

The Offers under this Prospectus comprise of:

- (a) the Investor Offer of up to 35,000,000 Shares at \$0.20 per Share to raise a minimum of \$6 million and up to \$7 million before costs. If the Minimum Subscription is not achieved, the Offers will not proceed. The Shares issued under the Investor Offer will represent approximately between 22.32% (Minimum Subscription), and 25.10% (Maximum Subscription), of Shares on issue at Listing;
- (b) the Grannus Offer - see section 6.6; and
- (c) the Lead Manager Offer - see section 6.7.

The Offers are made subject to the terms and conditions set out in this Prospectus. All Shares will rank equally with each other.

Please refer to the 'Key Offer Information' section for the Opening Date and Closing Dates for the Offers, and refer to the remainder of this section 6 for details on how to apply for Shares under the Investor Offer.

### 6.2 Structure of the Investor Offer

This Investor Offer comprises the:

- (a) **Broker Firm Offer** - open to Australian resident retail clients of Brokers who have received a firm allocation for their Broker;
- (b) **Institutional Offer** - an invitation to bid for Shares made to Institutional Investors in Australia and in certain other eligible jurisdictions; and
- (c) **General Public Offer** - open to the investors in eligible jurisdictions to acquire Shares under this Prospectus.

Details of Broker Firm Offer and the allocation policy under it are described in section 6.11.

Details of the Institutional Offer and the allocation policy under it are described in section 6.12.

Details of the General Public Offer are described in section 6.13.

The allocation of Shares between the Broker Firm Offer, Institutional Offer, and General Public Offer will be determined by the Lead Manager in agreement with the Company having regard to the allocation policies described below.

### 6.3 Important dates

The key dates, including details of the Offer Period, are set out in the 'Key Offer Information' section of this Prospectus.



The Company reserves the right to close any of the Investor Offers early, extend the Offer Closing Date for any Investor Offer or accept late Applications without notifying any recipients of this Prospectus or any Applicants. Any change to the Offer Closing Date (including if closed early or extended) will have a consequential effect on the date for the issue of the Shares.

No Shares will be issued or transferred on the basis of this Prospectus later than 13 months after the date of this Prospectus.

#### 6.4 Purpose of the Offers and use of funds

The purpose of the Investor Offer is to raise funds to:

- (a) achieve a listing on the ASX, broadening the Company's investor base and future access to capital; and
- (b) invest in the Group's core business model and undertake product development.

The purpose of the Grannus Offer is to satisfy the Company's obligations under its agreement for services provided by Grannus Securities, and the purpose behind the Lead Manager Offer is to satisfy the Company's obligations under its agreement for services provided by the Lead Manager.

Subject to the qualifications noted in section 11 (Risks) of this Prospectus, the Directors are satisfied that following the successful close of the Investor Offer, and from the application of existing funds, the Company will have sufficient working capital to meet its stated objectives.

The following tables show the proposed application of funds raised as part of the Investor Offer:

If the Minimum Subscription is raised:

Use of Funds / Expenditure Program	\$6,000,000	
	Year 1	Year 2
Regulatory	\$250,000	\$60,000
CMC (chemistry, manufacturing and control / packaging for sales)	\$320,000	-
Non-clinical studies	\$50,000	-
Bioequivalence trial	\$1,350,000	-
Sales & Marketing	\$200,000	\$240,000
Payment (SDS Licence Agreement)	\$475,097	-
Working Capital	\$834,140	\$1,379,797
Expenses of the Offer	\$749,701	-
<b>Total</b>	<b>\$4,228,938</b>	<b>\$1,679,797</b>

*\* This table is a statement of current intentions of the Company. Actual use of funds may differ from the budgeted use of funds based on changes in clinical trials budget or formulation development expenses. The Board may alter the way funds are applied in the future. LTP is required to make a US\$300,000 payment pursuant to the SDS Licence Agreement, the expenditure above is estimated using an exchange rate of approximately \$1.00 to US\$0.6314.*

If the Maximum Subscription is raised:

Use of Funds / Expenditure Program	\$7,000,000	
	Year 1	Year 2
Regulatory	\$250,000	\$100,000
CMC (chemistry, manufacturing and control package) / Commercial Packaging	\$320,000	-
Non-clinical studies	\$100,000	\$40,000
Bioequivalence trial	\$1,350,000	-
Sales & Marketing	\$350,000	\$460,000
Payment (SDS Licence Agreement)	\$475,097	-
Working Capital	\$1,049,140	\$1,586,197
Expenses of the Offer	\$811,939	-
<b>Total</b>	<b>\$4,706,176</b>	<b>\$2,186,197</b>

*\* This table is a statement of current intentions of the Company. Actual use of funds may differ from the budgeted use of funds based on changes in clinical trials budget or formulation development expenses. The Board may alter the way funds are applied in the future. LTP is required to make a US\$300,000 payment pursuant to the SDS Licence Agreement, the expenditure above is estimated using an exchange rate of approximately \$1.00 to US\$0.6314.*

It should also be noted that if the Maximum Subscription is raised, the Company proposes fast-tracking other consumer products that the Company has identified as potential viable future products for the Company.

The Company expects to principally fund its future operations through its existing cash reserves, any cash flow generated by the business and through the funds raised under the Investor Offer. The Directors have made enquiries and believe that the Company will have sufficient cash flow from the Company's operations to meet its business needs during the 24-month period following Listing.

On Listing, as at the date of this Prospectus, the Company does not propose to enter into any material debt financing arrangements.

## 6.5 Equity Incentive Plan

As at the date of Listing, the Company will not have any options or securities on issue under its Equity Incentive Plan other than the options issued to the Directors as set out in section 7.2.

The maximum number of securities which may be issued under the Equity Incentive Plan is 20,913,037 securities.

## 6.6 Grannus Offer

The Company has entered into a Services Agreement with Grannus Securities for the provision of advisory services related to the Company's Listing. A summary of this agreement is set out in section 13.7(b)(vii).

The Grannus Offer is made solely to the Grannus Securities and is not available to the public.

## 6.7 Lead Manager Offer

As part of the Offers, the Company proposes to issue to the Lead Manager (or nominated entity) up to 2,792,344 options. If exercised, the Lead Manager Options will equate to approximately 1.72% (under the Minimum Subscription) to 1.92% (under the Maximum Subscription) of the total fully diluted equity on issue in the capital of the Company at the time of Listing.

These options will be unlisted but transferable and will have an exercise price that is at a 30% premium to the Offer Price (that is, \$0.26 per Option) and have an expiry date of three years from Listing.

The Lead Manager Offer is made solely to the Lead Manager and is not available to the public.

A further summary of the mandate agreement between the Company and the Lead Manager is set out in section 13.7(c).

## 6.8 Pro forma historical and balance sheet

The Company's pro forma balance sheet following completion of the Investor Offer, including details of the pro forma adjustments, is set out in section 8 of this Prospectus.

## 6.9 Control

The Directors do not expect any Shareholder to control the Company (within the meaning of Section 50AA of the Corporations Act) on completion of the Offers.

## 6.10 Terms and conditions of the Investor Offer

Topic	Summary
What is the type of security being offered?	Ordinary, fully paid Shares in the Company.
What are the rights and liabilities attached to the securities being offered?	A description of the Shares, including the rights and liabilities attaching to them, is set out in section 6.1 and 13.4.
What is the consideration payable for the Shares?	The Offer Price is \$0.20 per Share.
What are the cash proceeds to be raised?	A minimum of \$6 million up to a maximum of \$7 million (before costs and expenses).

<b>Is the offer for the issue of new securities or existing securities?</b>	New Shares.
<b>What is the minimum and maximum Application size under the Broker Firm Offer, and the General Public Offer?</b>	<p><b>Broker Firm Offer</b> Applications for Shares under the Broker Firm Offer must be for a minimum of 10,000 Shares and thereafter in multiples of 2,500 Shares and payment for the Shares must be made in full at the issue price of \$0.20 per Share. There is no maximum number of value of Shares that may be applied for under the Broker Firm Offer.</p> <p><b>General Public Offer</b> Applications for Shares under the General Public Offer must be for a minimum of 10,000 Shares and thereafter in multiples of 2,500 Shares and payment for the Shares must be made in full at the issue price of \$0.20 per Share. There is no maximum number of value of Shares that may be applied for under the General Public Offer.</p>
<b>Is the Investor Offer underwritten?</b>	No.
<b>What is the allocation policy?</b>	The allocation of Shares between the Broker Firm Offer, the Institutional Offer, and the General Public Offer will be determined by agreement between the Company and the Lead Manager, having regard to the policies described in section 6.14.
<b>When will I receive confirmation whether my Application has been successful?</b>	It is expected that initial holding statements are expected to be mailed by standard post on or about the 'Expected date for allocation of Shares' as set out in the Indicative Key Dates section of this Prospectus.
<b>Will the Shares be quoted?</b>	<p>The Company will apply for admission to the Official List of the ASX and quotation of Shares on ASX is expected under the code 'LTP'. Completion of the Offers are conditional on the ASX approving this application. If approval is not given within three months after such application is made (or any longer period permitted by law), the Offers will be withdrawn, and all Application Monies received will be refunded without interest as soon as practicable.</p> <p>The Company will be required to comply with the ASX Listing Rules, subject to any waivers obtained by the Company from time to time. ASX takes no responsibility for this Prospectus or the investment to which it relates. The fact that ASX may admit the Company to the Official List is not to be taken as an indication of the merits of the Company or the Shares offered for subscription.</p>
<b>When are the Shares expected to commence trading?</b>	<p>It is expected that trading of the Shares on the ASX will commence on the 'Expected date for quotation of the Company's securities on ASX' as set out in the Indicative Key Dates section of this Prospectus.</p> <p>It is the responsibility of each Applicant to confirm their holding before trading in Shares.</p> <p>Applicants who sell Shares before they receive an initial statement of holding do so at their own risk.</p> <p>The Company, the Share Registry and the Lead Manager disclaim all liability, whether in negligence or otherwise, to persons who sell Shares before receiving their initial statement of holding, even if such person received confirmation of allocation from the Share Registry, by a Broker or otherwise.</p>
<b>Are there any escrow arrangements?</b>	Yes. Details are provided in section 6.17 below.

<b>Are there any taxation considerations?</b>	Yes. Please refer to section 12 and note it is recommended that all potential investors consult their own independent tax advisers regarding the income tax (including capital gains tax), stamp duty and GST consequences of acquiring, owning and disposing of Shares, having regard to their specific circumstances.
<b>Has any ASIC relief or ASX waiver or confirmation been sought, obtained or relied on?</b>	No.
<b>Are there any brokerage, commission or stamp duty considerations?</b>	No brokerage, commission or stamp duty is payable by Applicants on acquisition of Shares under the Investor Offer.
<b>What should I do with any enquiries?</b>	Enquiries in relation to this Prospectus may be directed to the LTR Pharma IPO information line on 1300 441 607 (within Australia) or +61 2 7250 6677 (outside Australia) from 9.00 am until 5.00 pm AEDT Monday to Friday during the Offer Period. Enquiries in relation to the Broker Firm Offer should be directed to your Broker. If you are unclear in relation to any matter or are uncertain as to whether the Company is a suitable investment for you, you should seek professional guidance from your stockbroker, solicitor, accountant, financial adviser or other independent professional adviser before deciding whether to invest.

## 6.11 Broker Firm Offer

### (a) Who may apply?

The Broker Firm Offer is open to persons who have received a firm allocation of Shares from their Broker and who have a registered address in Australia. If you have received a firm allocation of Shares from your Broker, you will be treated as an Applicant in respect of that allocation. You should contact your Broker to determine whether you can receive an allocation of Shares from them under the Broker Firm Offer.

The Broker Firm Offer is not open to persons in the United States.

### (b) How to apply

Applications for Shares under the Broker Firm Offer must be made using the appropriate Application Form. If you are an investor applying under the Broker Firm Offer, you should complete and lodge your Application Form and Application Monies with the Broker from whom you received your firm allocation of Shares. Applicants under the Broker Firm Offer must not be sent to the Share Registry.

Applications for Shares under the Broker Firm Offer must be for a minimum of 10,000 Shares and thereafter in multiples of 2,500 Shares and payment for the Shares must be made in full at the issue price of \$0.20 per Share. The Company and Lead Manager reserve the right to aggregate any Applications which they believe are multiple applications from the same person, or to reject or scale back any Applications.

There is no maximum number of value of Shares that may be applied for under the Broker Firm Offer. However, the Company and the Lead Manager reserve the right to close the Broker Firm Offer early or extend the Broker Firm Offer, and may amend or waive the Offer Application procedures at their discretion (subject to the applicable laws).

By submitting an Application, you declare that you were given access to this Prospectus, together with an Application Form.

Under the Corporations Act, a person must not pass an Application Form to another person unless it is attached to, or accompanied by, a hard copy of this Prospectus or the complete and unaltered electronic version of this Prospectus.

Neither the Company, the Lead Manager, nor the Share Registry takes any responsibility for any acts or omissions of your Broker in connection with an Application.

**(c) How to pay**

Applicants under the Broker Firm Offer must pay their Application Monies in accordance with instructions received from their Broker.

**(d) Broker Firm allocation policy**

The allocation of firm stock to Brokers will be determined by agreement between the Company and the Lead Manager. Shares which have been allocated to Brokers for allocation to their Australian resident retail clients will be issued to the Applicants who have received a valid allocation of Shares from those Brokers (subject to the right of the Company and the Lead Manager to reject or scale back Applications). It will be a matter for those Brokers how they allocate Shares among their retail clients and they (and not the Company or the Lead Manager) will be responsible for ensuring that retail clients, who have received an allocation of Shares from them, receive the relevant Shares.

**(e) Application Monies**

Application Monies received under the Broker Firm Offer will be held in a special purpose account until Shares are issued and allotted or transferred to successful Applicants. Applicants under the Broker Firm Offer whose Applications are not accepted, or who are allocated a lesser dollar amount of Shares than the amount applied for, will be mailed (or otherwise in the Company's discretion provided with) a refund (without interest) of all or part of their Application Monies, as applicable. No refunds pursuant solely to rounding will be provided. Interest will not be paid on any Application Monies refunded and any interest earned on Application Monies pending the allocation or refund will be retained by the Company.

**(f) Announcement of final allocations in Broker Firm Offer**

Applicants in the Broker Firm Offer will be able to confirm their allocation through the Broker from whom they received their allocation.

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## 6.12 Institutional Offer

### (a) Invitation to bid

The Institutional Offer is an invitation by the Lead Manager to Australian resident Institutional Investors and other eligible Institutional Investors in jurisdictions outside the United States to bid for Shares, made under this Prospectus. The Lead Manager separately advised Institutional Investors of the Application procedures for the Institutional Offer.

### (b) Institutional Offer allocation policy

The allocation of Shares under the Institutional Offer will be determined by agreement between the Company and the Lead Manager. The Lead Manager, in consultation with the Company, will determine the basis of allocation of Shares among Institutional Investors. Participants in the Institutional Offer will be advised of their allocation of Shares, if any, by the Lead Manager.

If you sell Shares before receiving a holding statement, you do so at your own risk, even if you obtained details of your holding from the LTR Pharma IPO information line.

## 6.13 General Public Offer

### (a) Who may apply?

The General Public Offer is open to investors in eligible jurisdictions to acquire Shares under this Prospectus.

### (b) How to apply

Applicants should read this Prospectus carefully and in their entirety before deciding whether to apply under the General Public Offer. If you are unclear in relation to any matter or are uncertain as to whether Shares are a suitable investment for you, you should seek professional guidance from your accountant, financial adviser, stockbroker, lawyer or other professional adviser before deciding whether to invest.

Applications for Shares under the General Public Offer must be made by using the relevant Application Form as follows:

- (i) using an online Application Form at <https://apply.automic.com.au/LTRPharma> and paying the Application Monies electronically; or
- (ii) completing a paper-based application using the relevant Application Form attached to, or accompanying, this Prospectus or a printed copy of the relevant Application Form attached to the electronic version of this Prospectus.

By completing an Application Form, each Applicant under the General Public Offer will be taken to have declared that all details and statements made by them are complete and accurate and that they have personally received the Application Form together with a complete and unaltered copy of the Prospectus.

By making an Application, you also declare that you were given access to this Prospectus together with an Application Form.

Under the Corporations Act, a person must not pass an Application Form to another person unless it is attached to, or accompanied by, a hard copy of this Prospectus or the complete and unaltered electronic version of this Prospectus.

Applications must be received by no later than 5.00 pm on the Closing Date and it is your responsibility to ensure that this occurs.

**(c) Is there a minimum or maximum Application size?**

Applications must be for a minimum of 10,000 Shares. Applications in excess of the minimum number of Shares must be in multiples of 2,500 Shares and payment for the Shares must be made in full at the issue price of \$0.20 per Share.

There is no maximum amount that may be applied for under the General Public Offer. However, there is no assurance that any Applicant will be allocated any Shares, or the number of Shares for which the Applicant applied.

**(d) How to pay**

If paying by BPAY<sup>®</sup> or EFT, please follow the instructions on the Application Form. A unique reference number will be quoted upon completion of the online application. Your BPAY<sup>®</sup> reference number will process your payment to your application electronically and you will be deemed to have applied for such Shares for which you have paid. Applicants using BPAY<sup>®</sup> or EFT should be aware of their financial institution's cut-off time (the time payment must be made to be processed overnight) and ensure payment is processed by their financial institution on or before the day prior to the Closing Date of the Offer. Application Monies must be received by 5pm (AEDT) on the Closing Date. You do not need to return any documents if you have made payment via BPAY<sup>®</sup> or EFT.

Cheques must be in Australian currency and made payable to '**LTR Pharma Limited – Share Account**' and crossed '**Not Negotiable**', must be mailed or delivered to the address set out on the Application Form by no later than the Closing Date. The Company and the Lead Manager may elect to extend the Offer or any part of it, or to accept late applications in particular cases or generally. The Offers, or any part of it, may be closed at an earlier date or time without notice. Applicants are therefore encouraged to submit their Application Forms as soon as possible.

Payment may also be made in Australian dollars and via BPAY<sup>®</sup> by applying online following instruction at <https://apply.automic.com.au/LTRPharma>. If the payment is not made via EFT or BPAY<sup>®</sup>, the Application will be incomplete and will not be accepted. When completing the BPAY payment, Applicants should ensure that they use the specific Biller Code and your unique CRN provided on the online Application Form. If Applicants do not use the correct CRN their Application will not be recognised as valid.

Completed paper-based Application Forms must be received by the Share Registry or the Company no later than 5.00 pm (AEDT) on the Closing Date. An Application constitutes an offer to subscribe for Shares under the terms and

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conditions set out in this Prospectus. The Company reserves the right to vary the Closing Date without notice.

The online Application Form and Application Monies must be received by the Share Registry by 5:00 pm (AEDT) on the Closing Date. It is your responsibility to ensure that your EFT or BPAY<sup>®</sup> payment is received by the Share Registry by no later than 5:00 pm (AEDT) on the Closing Date. You should be aware that physical delivery of cheques may take some time or your financial institution may implement earlier cut-off times with regard to payments by BPAY<sup>®</sup>, and you should therefore take this into consideration when making payment.

*Payment will only be accepted in Australian currency.*

**(e) Application Monies**

Application Monies received under the General Public Offer will be held in a special purpose account until Shares are issued and allotted to successful Applicants. Applicants under the General Public Offer whose Applications are not accepted, or who are allocated a lesser dollar amount of Shares than the amount applied for, will be mailed (or otherwise in the Company's discretion provided with) a refund (without interest) of all or part of their Application Monies, as applicable. No refunds pursuant solely to rounding will be provided. Interest will not be paid on any Application Monies refunded and any interest earned on Application Monies pending the allocation or refund will be retained by the Company.

**(f) How do I confirm my allocation?**

Applicants in the General Public Offer will be able to call the LTR Pharma IPO information line on 1300 441 607 (within Australia) or +61 2 7250 6677 (outside Australia) from 9.00 am until 5.00 pm AEDT Monday to Friday to confirm their allocation from the date of allotment.

If you sell Shares before receiving a holding statement, you do so at your own risk, even if you obtained details of your holding from the LTR Pharma IPO information line.

#### **6.14 Allocation policy under the Investor Offer**

The allocation of Shares under the Investor Offer and the various Offers it comprises will be determined by agreement between the Company and the Lead Manager.

The allocation policy is influenced by the following factors:

- (a) the number of Shares applied for by particular Applicants;
- (b) the timeliness of the Applications;
- (c) the Company's desire for an informed and active trading market following Listing on ASX;
- (d) the Company's desire to establish a wide spread of Shareholders;
- (e) overall levels of demand under the Investor Offer;

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- (f) the likelihood that particular Applicants will be long term Shareholders; and
  - (g) any other factors that the Company and the Lead Manager considered appropriate.

The Company, in conjunction with the Lead Manager, reserves the right to reject any Application or to allocate any Applicant fewer Shares than the number applied for under the Investor Offer. Where the number of Shares issued to an Applicant is less than the number applied for, or where no issue is made, surplus Application Monies will be refunded without any interest to the Applicant as soon as practicable after the Closing Date.

#### **6.15 Restrictions on distribution**

Each Applicant in the Offers will be taken to have represented, warranted and agreed as follows:

- (a) it understands that the Shares have not been, and will not be, registered under the US Securities Act or the securities laws of any state of the United States and may not be offered, sold or resold in the United States;
- (b) it is not in the United States;
- (c) it has not and will not send the Prospectus or any other material relating to the Offers to any person in the United States; and
- (d) it will not offer or sell the Shares in the United States or in any other jurisdiction outside Australia.

#### **6.16 Acknowledgements**

Each Applicant under each Offer will be required to make certain representations, warranties and covenants set out in the confirmation of allocation letter distributed to it.

Additionally, each Applicant under the Offers will be deemed to have:

- (a) agreed to become a member of the Company and to be bound by the terms of the Constitution and the terms and conditions of the Offers;
- (b) acknowledged having personally received a printed or electronic copy of the Prospectus (and any supplementary or replacement prospectus) accompanying the Application Form and having read them all in full;
- (c) declared that all details and statements in their Application Form are complete and accurate;
- (d) declared that the Applicant(s), if a natural person, is/are over 18 years of age;
- (e) acknowledged that once the Company receives an Application Form it may not be withdrawn;
- (f) applied for the number of Shares at the Australian dollar amount shown on the front of the Application Form;

- (g) agreed to being allocated and issued the number of Shares applied for (or a lower number allocated in a way described in this Prospectus), or no Shares at all;
- (h) authorised the Company and the Lead Manager and their respective Officers or agents, to do anything on behalf of the Applicant(s) necessary for Shares to be allocated to the Applicant(s), including to act on instructions received by the Share Registry upon using the contact details in the Application Form;
- (i) acknowledged that, in some circumstances, the Company may not pay dividends;
- (j) acknowledged that any dividends paid by the Company may be unfranked or only partially franked and that the unfranked portion of any such dividends may not attach conduit foreign income;
- (k) acknowledged that the information contained in this Prospectus (or any supplementary prospectus) is not investment advice or taxation advice or a recommendation that Shares are suitable for the Applicant(s), given the investment objectives, financial situation or particular needs of the Applicant(s); and
- (l) declared that the Applicant(s) is/are a resident of Australia and are not acting for the account or benefit of any person in the United States or any other foreign person (except as applicable to the Institutional Offer, or if they are an overseas Applicant, they are in full compliance with all laws of any country relevant to their Application).

#### **6.17 Restricted securities**

Subject to the Company being admitted to the Official List, certain securities on issue in the Company following completion of the Listing will be classified by ASX as restricted securities and will be required to be held in escrow for up to 24 months from the date of Listing.

No Shares issued under the Investor Offer are subject to escrow. However, certain Shares and any other securities held by related parties of the Company and promoters may be subject to ASX imposed escrow for a period of up to 24 months following Listing. The Company anticipates that a portion of the shares held by certain Shareholders, who are unrelated third-party investors may be subject to ASX imposed escrow of up to 12 months from the date on which they initially invested in the Company.

During the period in which these securities are prohibited from being transferred, trading in Shares may be less liquid which may impact on the ability of a Shareholder to dispose of his or her Shares in a timely manner.

The Company will announce to the ASX full details (quantity and duration) of the Securities required to be held in escrow prior to the Shares commencing trading on ASX.

## 7. Board, Management and Corporate Governance

### 7.1 Board of directors

The Board comprises an Executive Chairman and two Non-executive Directors.

(a) Lee Rodne – Executive Chairman

Lee holds over 25 years' experience in the healthcare and technology sectors and has been in executive leadership roles in both public and private enterprises. He previously worked in Fortescue Metals Group and led a healthcare technology spin out (Allied Medical) as its CEO and Managing Director that resulted in increasing its valuation from \$800k to a peak of \$250 million (ASX:AHZ, AVR). Lee led AHZ when it was recognised as Australia's Emerging Company of the Year in 2013 during Ausbiotech's Johnson & Johnson industry life science awards. He was also the Senior Executive of Sirius Minerals Plc that led to its lead acquisition project and reached a peak market capitalisation of over \$1 billion on the London exchange. Lee holds an MBA from the University of St Thomas, Minnesota and B.A. degree in Business Management from St John's University.

Lee is not considered an independent Director as he is a company co-founder and retains equity as outlined in section 7.2(c) of this Prospectus.

(b) Dr Julian Chick, Non-executive Director

Julian is an experienced healthcare executive with over 20 years' experience in senior management and board positions including in ASX listed companies Avexa (ASX:AVX) and Admedus (ASX: AHZ, AVR), and is the Chairman of Cann Group Limited (ASX:CAN). He has eight years' investment banking experience and has also held a role as an analyst reviewing healthcare and biotechnology investment opportunities for private equity investors and venture capitalists. Julian has a PhD in Physiology.

Julian is a director of LTR Medical and has a 19.7% shareholding in LTR Medical. Despite his direct and indirect interest in the capital of the Company, the other members of the Board are satisfied that Julian has and will continue to bring independent judgement to bear on all issues and act in the best interests of LTP. Accordingly, the Board considers that Julian will be an independent director.

(c) Maja McGuire, 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.

Maja commenced her career at Clayton Utz, gaining experience in a broad range of corporate, commercial and banking and finance matters. Subsequently joining the Canadian Bankers Association (Toronto), Maja advocated on behalf of Canadian banks on issues pertaining to developments in domestic and international banking regulation related primarily to capital adequacy and funding.

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Between 2014 and 2018, Maja was General Counsel and Company Secretary of previously named Admedus Limited (now Anteris Technologies ASX: AVR), a global healthcare company focused on developing, commercialising, manufacturing, and distributing next generation medical technologies and devices. Between 2018 and 2020, Maja undertook the role of General Counsel and Company Secretary at US based Alexium International Group Limited (ASX: AJC), a company which holds proprietary patent applications for novel technologies developed to provide thermal regulation and flame retardancy.

Maja continues her career as a consulting lawyer and board director, bringing experience in strategy formulation, governance, compliance, capital markets, stakeholder engagement, risk management, general commercial contracts and dispute resolution.

Maja is currently the non-executive chair of ASX listed TechGen Metals Limited (ASX: TG1), non-executive director of Kuniko Limited (ASX: KNI), non-executive director of Indiana Resources Limited (ASX: IDA), and non-executive director of LTP. She holds BComm and LLB qualifications from The University of Western Australia.

The Board considers that Maja is an independent director.

## **7.2 Directors' shareholding qualifications, remuneration and interests**

Except as disclosed in the Prospectus, no Director or proposed Director of the Company, or firm in which a Director or proposed Director is a partner, has any interest, nor has had any interest for registration, or has received or is entitled to receive any sum for services rendered by either him or the firm to induce him to become or qualify him as a Director, or otherwise in connection with the promotion or formation of the Company or in the property proposed to be acquired by the Company in connection with its promotion or formation.

### **(a) Shareholding qualifications and remuneration**

The Directors are not required under the Constitution of the Company to hold any Shares in order to qualify as Directors.

Under the Constitution, the Company's Non-Executive Directors are entitled to be paid for their services as Directors, including annual fees, provided the annual fees do not exceed in aggregate the maximum sum that is from time to time approved by the Shareholders in a general meeting. This sum does not include remuneration in the form of share, option or other equity plans separately approved by the Shareholders in a general meeting. The Company's Shareholders have previously resolved to set a cap of \$350,000 in respect of remuneration of Non-Executive Directors.

### **(b) Directors' interests in securities and remuneration**

Set out below are details of the interests of the Directors in the Shares and other securities of the Company immediately prior to lodgement of the Prospectus with the ASIC for registration. Interests include those held directly and indirectly.

Name	Position	Annual Remuneration <sup>1</sup>	Shares directly held	Shares held indirectly	Options held <sup>4</sup>	Option valuation <sup>5</sup>
Lee Rodne	Executive Chairman	\$250,000	1,129,641	51,543,893 <sup>2</sup>	1,000,000	\$113,954
Dr Julian Chick	Non-Executive Director	\$40,000	808,492	- <sup>3</sup>	500,000	\$56,977
Maja McGuire	Non-executive Director	\$40,000	235,492 <sup>6</sup>	-	500,000 <sup>6</sup>	\$56,977

*Important Notes:*

1. *This represents per annum remuneration after Listing and excludes superannuation and GST (where applicable). The remuneration of each of Dr Julian Chick and Maja McGuire prior to listing is \$15,000 (excl. superannuation and GST) per annum.*
2. *This represents the aggregate interest of Lee Rodne's indirect holdings via associated entities including, LTR Medical (59.10% shareholding), LTR Consulting (100% shareholding) and Trexapharm (49% shareholding).*
3. *Dr Julian Chick has a 19.70% shareholding in LTR Medical who holds 46,373,750 shares in LTP which is not shown here.*
4. *A summary of the material terms of these options are set out in section 7.2(c) below.*
5. *The options were valued using the Black Scholes methodology.*
6. *Held by Maja McGuire as trustee for the Scaraf Trust.*

(c) Other interests of Directors

Indirect holdings

(i) Lee Rodne

- (A) Lee holds a 59.10% interest in LTR Medical which holds 46,373,750 Shares (pre-Offers, 44.89% of the Company); and
- (B) Lee holds a 49% interest in Trexapharm Inc. which holds 4,188,000 Shares (pre-Offers, 4.05% of the Company); and
- (C) Lee holds an 100% interest in LTR Consulting which holds 982,143 shares (pre-Offers, 0.95% of the Company).

(ii) Dr Julian Chick

Julian has an indirect holding in 19.70% of LTR Medical which holds 46,373,750 shares (pre-Offers, 44.89% of the Company).

(iii) Maja McGuire

Maja holds 235,492 Shares for the Scaraf Trust (pre-Offers, 0.18% of the Company). Maja is a beneficiary under the Scaraf Trust.

(d) Director Options

The Company has issued 2,000,000 options to the Directors, pursuant to the EIP, in the proportions set out in the table in section 7.2(b) above, on the following material terms:

- (i) The options vest immediately if the Company is admitted to the Official List of ASX.
- (ii) If not exercised, the options automatically expire 5 years after the grant date.
- (iii) The exercise price of an option is equal to \$0.22, being a 10% premium to the subscription price of a share under the Prospectus.

(e) Appointment terms

The Company has entered into appointment letters with each Non-Executive Director and the Executive Chairman on the following key terms:

- (i) The remuneration for each Director is set out in the table at section 7.2(b);
- (ii) For Non-Executive Directors, the appointment shall cease if the Non-Executive Director:
  - (A) is terminated at any time in accordance with the provisions of the Constitution or any applicable law;
  - (B) resigns; or
  - (C) is removed from office for any reason;
- (iii) For the Executive Chairman, the appointment shall cease if it is terminated by the Executive Chairman (Lee Rodne) or the Company;
- (iv) Each of the Non-Executive Directors and the Executive Chairman and CEO:
  - (A) will apply the highest standards of confidentiality during their appointment;
  - (B) will be expected to exercise duties of care and diligence, good faith, proper use of position and proper use of information as well as the fiduciary duties imposed by applicable law;
  - (C) will attend Board meetings and may also serve as a member of the Audit and Risk Committee, Nomination Committee, Remuneration Committee, or any other committee established by the Board; and
  - (D) will be entitled to be reimbursed reasonable expenses incurred in performing their duties, including the cost of attending Board meetings, travel, accommodation and entertainment as agreed to by the Board.

The Company has also entered into an employment agreement with Lee Rodne, the principle terms of which includes the following:

- (i) confirmation that the remuneration for Lee Rodne is as set out in the table at section 7.2(b);
- (ii) provisions protecting confidential information and intellectual property; and
- (iii) a non-competition undertaking in relation to the same field of treatments for ED in which the Company operates.

The agreement may be terminated by Lee Rodne or the Company by giving 9 months' written notice. The agreement may also be terminated by the Company without notice on appropriate grounds for summary dismissal.

### **7.3 Key managers background, remuneration and interests**

#### **(a) Background**

##### **(i) Danny Zanardo**

Danny has over 25 years of commercial experience in the Australian and global healthcare sectors across pharmaceuticals and medical devices. He has held executive positions in both private and ASX listed entities including Admedus Ltd, Roche and Actelion and has a track record of successfully commercialising new medical technologies across Europe, North America, Asia Pacific and MENA. Danny holds a degree in health science and several postgraduate qualifications in marketing, global business management and biotechnology.

Danny is the Vice President of Commercial.

##### **(ii) Jacques Schipper**

Jacques brings over 14 years of experience in Finance, Commercial Management and 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.

He has built a strong track record of delivering growth and a passion for continuous improvement. He brings a broad multi-sector experience from high growth start-up, scale-up to large corporations across a range of industries including Med Tech, Resources, Manufacturing, Agriculture and Food and Professional Services. He drives excellence in operational (P&L) leadership, innovation leadership with a focus on new market entry and commercialisation and definition of novel value propositions. Jacques previously lived and worked extensively in Europe with financial management and business improvement responsibilities across operations in Great Britain, Netherlands, Belgium, Germany, France, Spain and Switzerland. Jacques received his Bachelor of Science in Business from the Breda University of Applied Science and is currently an Executive MBA candidate at Maastricht University.



Jacques is the Chief Financial Officer.

(iii) Mike Sweeting

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 focused on commercialisation preparedness. Most recently, Mike built all functions related to Market Access for Scilex Pharmaceuticals, a San Diego-based startup. Mike was responsible for hiring and managing the Corporate Account Director team, and for developing and implementing all Payer/PBM strategies, the value proposition story, and all aspects of commercial and government contracting (including creating and chairing the U.S. Pricing Committee, Government Price Reporting and GTN calculations). Mike also created all policy and procedures governing the Market Access team. Prior to his work at Scilex, he built the Corporate Account Team for Questcor Pharmaceuticals before it was acquired by Mallinckrodt Pharmaceuticals. Mike spent 23 years with Sanofi-Aventis, establishing a track record of success using his strong leadership skills to manage teams of up to 250 employees, including Regional Directors, District Sales Managers, Managed Care Account Executives, Access & Reimbursement Managers and Sales Representatives, while guiding a \$265 million sales effort that spanned the metabolism, cardiovascular and internal medicine business units. In addition, he has also held leadership positions in oncology, autoimmune and rare disease business units. Mike received his Bachelor of Science in Business from the University of Arizona.

Mike is Vice President, US Sales and Marketing.

(iv) Kip Vought

Kip is a senior pharmaceutical R&D and regulatory executive with over 25 years of industry experience across major global markets. Highly experienced in determining and executing efficient and cost-effective global development program. Successful leadership in preparation and conduct of Agency meetings (PIND and equivalent, EOP1, EOP2, and PNDA/MAA and regional equivalents) obtaining agreement on data requirements for introducing pharmaceutical products to the clinic, progressing through development, and preparation/submission of market applications. Regulatory strategy development includes pediatric programs, obtaining orphan drug status, Fast Track status (and global equivalents), and accelerated approval for orphan indications and/or breakthrough therapies. Kip has successfully led the execution of development programs through preclinical development to market approvals, and supporting commercial products (i.e., post-approval studies to support label changes, promotional materials, and CMC changes). Indications include oncology, analgesia, dermatology, gastrointestinal, cardiovascular, anti-infectives, and pulmonary / respiratory. Kip's experience extends to NCE/NMEs, repurposed drugs (505(b)(2)/10(c) and equivalents), siRNAs, monoclonal antibodies, oligonucleotides, biologics, high-value generics, and over the counter (OTC) products (including novel OTC dosage forms). Dosage forms include solid oral (including modified release), topical/transdermal

(patches, creams, ointments, gels, etc.), sprays (oral and topical), inhalation, nasal, and parenteral. Kip has a Chemistry (pre-Med) degree from the University of Miami, Florida with Minors in History and Philosophy.

Kip is Vice President Global Regulatory Affairs.

(v) Dr. Monil Shah

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 was Chief Development Officer at WindMIL Therapeutics, responsible for the MILs cell therapy platform. He was the Chief Operating Officer of IRX Therapeutics / Brooklyn ImmunoTherapeutics leading cytokine drug development for oncology patients. Prior to that, he was the Medical Affairs Lead for Immuno-Oncology at Bristol Myers Squibb responsible for checkpoint inhibitor development programs.

Monil also was the Founder and Head of Clinical Development and Operations at Ventrus Biosciences prior to its merger with Assembly Biosciences. Prior to Ventrus, Monil led the Solid Tumor Development Programs and the Clinical Portfolio and Strategic Planning function at Celgene, as well as the Oncology Development and Operations activities at Fibrogen and Novacea. He began his career at Novartis in the Oncology Early Development Group prior to joining the Medical Sciences Group at Amgen. Monil received his Bachelor of Science in Pharmacy and Doctorate of Pharmacy degrees from Rutgers University in New Jersey.

Monil is Vice President Operations and Clinical Development.

(vi) Professor Geoffrey Strange

Geoffrey is a senior executive and medical researcher with over 20 years' experience in the biopharmaceutical and medical industries. He's actively involved in a range of scientific and professional activities on a national and international basis including as a Fellow of both the Cardiac Society and Pulmonary Hypertension (PAH) Society of ANZ and a representative on the Department of Health's Medicine review committee. He has led the effort for translational outcomes of funding for combination therapy for PAH in Australia. He is also the founder, principal investigator and director of the largest Echocardiography study linked to mortality worldwide. He has been an expert scientific advisor for numerous global pharmaceutical companies including Pfizer, Novartis, Bayer Pharmaceuticals Australia, Glaxo Smith & Kline (GSK) Australia and Edwards LifeSciences. He holds the position of Professor within the Faculty of Medicine and Health at The University of Sydney and the School of Medicine, University of Notre Dame Australia. Geoffrey is widely published and has a wealth of scientific and corporate experience in advising and leading global medical strategies. Geoffrey specialises in taking scientific and clinical data / concepts, through to commercial success. Geoff received his Bachelor of Health Science degree from the University of Western Sydney, his Graduate Diploma –

Clinical Cardiology from NSW College of Nursing and his Doctor of Philosophy from the School of Epidemiology, Monash University.

Geoffrey is a Medical Affairs Executive.

(b) Key Manager remuneration and interests

(i) Jacques Schipper (Chief Financial Officer (**CFO**))

The Company has engaged Jacques Schipper of Theshepherdfinance Pty Ltd to provide CFO services.

Theshepherdfinance Pty Ltd has confidentiality obligations with the Company during its engagement and thereafter to hold in confidence any confidential information that it possesses and not to disclose it unless it receives the Company's prior written consent.

Theshepherdfinance Pty Ltd's engagement is renewable on an annual basis.

(ii) Jay Rodne (Director – LTR Inc.)

The Company has entered into an appointment letter with Jay Rodne in relation to his directorship of LTR Inc. on the following key terms:

- (A) The remuneration is US\$3,000 per month.
- (B) The appointment shall cease on 60 days' written notice by either party with or without cause or due to a material breach of the agreement.

The agreement also contains confidentiality provisions, indemnification of the director by LTR Inc. and is renewable on an annual basis. This agreement is governed by the laws of Washington, United States.

(iii) Key Managers' interests

Set out below are details of the interests of the Key Managers in the Shares of the Company immediately prior to lodgement of the Prospectus with the ASIC for registration. Interests include those held directly and indirectly.

Name	Position	Shares directly held	Shares held indirectly
Danny Zanardo	Vice President of Commercial	1,122,135	<sup>-1</sup>
Jacques Schipper	CFO	698,000	-
Kip Vought	Vice President Global Regulatory Affairs	-	698,000 <sup>2</sup>
Monil Shah	Vice President Operations and Clinical Development	-	1,537,813 <sup>3</sup>

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Jay Rodne	Director of LTR Inc.	-	-
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*Important Notes:*

1. *Danny Zanardo has a 4.93% shareholding in LTR Medical who holds 46,373,750 shares in LTP which is not shown here.*
2. *This represents Kip Vought's indirect interest via the holdings of IAA Consulting Inc.*
3. *This represents Monil Shah's Indirect interest via the holdings of IAA Consulting Inc and Early Asset Investment Partnership LLC.*

## **7.4 Scientific Advisory Board**

The Company has established a Scientific Advisory Board to provide expert guidance and insights on scientific and technical matters in relation to the Company's programs. The advisors bring valuable expertise and credibility, helping the Company stay at the forefront of innovation.

The Scientific Advisory Board comprises of the following members:

(a) **Professor Eric Chung**

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.

(b) **Professor Russ Chess-Williams**

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.

## **7.5 Related party transactions**

Other than relevant agreements with the directors as noted in this Prospectus, LTP is not a party to any agreements or arrangements involving a related party. Jay Rodne is the director for LTP Inc. and is Lee Rodne's sibling.

## **7.6 Employee Incentive Plan**

(a) **Background**

The EIP was adopted by the Company and approved by shareholders to permit the Board of the Company to promote the long-term success of the Company and provide ongoing incentives to ESS Participants (as defined below) from time to time.

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**(b) Key terms**

(i) Awards

Under the EIP, the Company may offer or issue to ESS Participants, the following Awards:

- (A) **performance rights:** a right to be issued or provided with a Share at nil issue price on specific vesting conditions being achieved;
- (B) **options:** a right to be issued or provided with a Share on payment of an exercise price and which can only be exercised if specific vesting conditions are achieved;
- (C) **loan shares:** Shares issued subject to a limited recourse loan and at nil interest rate, subject to specific vesting conditions;
- (D) **deferred share awards:** Shares issued to Eligible Participants:
  - » who elect to receive Shares in lieu of any wages, salary, director's fees, or other remuneration; or
  - » by the Company in its discretion, in addition to their wages, salary and remuneration, or in lieu of any discretionary cash bonus or other incentive payment;
- (E) **exempt share awards:** Shares issued for no consideration or at an issue price which is a discount to the market price with the intention that up to \$1,000 (or such other amount which is exempted from tax under the *Income Tax Assessment Act 1936* (Cth) or the *Income Tax Assessment Act 1997* (Cth) from time to time) of the total value or discount received by each employee will be exempt from tax; and
- (F) any other ESS Interest as defined under section 1100E of the Corporations Act.

(ii) ESS Participants

Awards may be granted at the discretion of the Board to any person who is an ESS Participant, who in relation to the EIP includes:

- (A) a Primary Participant; or
- (B) a Related Person.

(iii) Price

The Board has discretion to determine the issue price and/or exercise price for the ESS Participant.

(iv) Vesting and exercise of Employee Awards

The Awards held by a participant will vest in and become exercisable by that participant upon the satisfaction of any vesting conditions specified

in the offer and in accordance with the rules of the EIP. Vesting conditions may be waived at the discretion of the Board.

(v) Change of control

In the event a takeover bid is made to acquire all of the Shares on issue, or a scheme of arrangement, selective capital reduction or other transaction is initiated which has an effect similar to a full takeover bid, the Board may waive unsatisfied vesting conditions in relation to some or all Employee Rights. Further, if a takeover bid is made to acquire all of the Shares on issue, participants may accept the takeover bid in respect of any Employee Rights (other than exempt share awards) which they hold notwithstanding the restriction period in respect of those Employee Rights has not expired. The Board may, in its discretion, waive unsatisfied vesting conditions in relation to some or all Awards in the event of such a takeover or other transaction.

(vi) Claw Back

If any vesting conditions of an Award are mistakenly waived or deemed satisfied when in fact they were not satisfied, then in accordance with the terms of the EIP, the Board may determine that the relevant Awards expire (if not yet exercised), or it may otherwise recover from the participant some or all Shares issued upon exercise of the Award or any proceeds received from the sale of those shares.

(vii) Variation of Share capital

If prior to the exercise of an Employee Right, the Company undergoes a reorganisation of capital or bonus issue, the terms of the Employee Rights will be changed to the extent necessary to comply with the Listing Rules.

## 7.7 Automatic Share Registry

The Company has entered into an agreement with Automic whereby share registry and company secretarial services will be provided in return for fees.

The Company has retained the services of Automic since the middle of the 2021 calendar year, and appointed Belinda Cleminson of Automic as Company Secretary on 15 September 2023.

## 7.8 Legal or disciplinary action

No Director (or company that the Director was a director of at the relevant time) has, in the 10 year period ending on the date of this Prospectus, had any legal or disciplinary action against the Director that is relevant to the Director's role in the Company and a potential investor's decision to apply for Shares.

## 7.9 Insolvent companies

No Director has been an officer of a company that entered into a form of external administration because of insolvency while the Director was an officer of the company or within 12 months of the Director ceasing to be an officer of the company.

## 7.10 Corporate governance

The Directors are responsible for the strategic direction of the Company, the identification and implementation of corporate policies and goals, and monitoring of the business and affairs of LTP on behalf of its members.

The Company is cognisant of the Corporate Governance Principles and Recommendations (4th edition) as published by ASX Corporate Governance Council and acknowledges that the eight principles set out in that document are fundamental to good corporate governance.

The Board believes that the structure of the Company, its management and business practices provide a basis of governance which meets the essential corporate governance principles articulated by ASX in that publication.

One of the key objectives of the Board is to ensure timely, transparent and accurate communication with all members and compliance with all regulatory requirements (including its ASX continuous disclosure requirements once Listed). To this effect the Board has established a number of committees.

The Board has formally adopted a Corporate Governance Policy for the Company. Under this Corporate Governance Policy, the Board has established:

- (a) an Audit and Risk Committee whose primary function is to provide additional assurance regarding the quality and reliability of financial information used by the Board and financial information provided by the Company pursuant to its statutory reporting requirements.
- (b) a Nomination Remuneration and a Remuneration Committee:
  - (i) to review the composition of the Board to ensure that the Board has an appropriate mix of expertise and experience and to assess and review the performance of the Directors of the Company; and
  - (ii) to review and report to the Board on matters concerning executives' and Directors' remuneration.

The Company's Corporate Governance Policy can be found on the Company's website at <https://www.ltrpharma.com/investor-centre/>.

While the ASX Corporate Governance Principles and Recommendations are not compulsory, the Company will and in accordance with Listing Rule 4.10, advise the market whether it meets the ASX Corporate Governance Principles and Recommendations and if not, state why not. Please find below a summary of the Company's compliance with the ASX Corporate Governance Principles and Recommendations:

Principle / Recommendation	Requirement of	Comply	Explanation of compliance / non-compliance									
<i>Principle 1</i>	<i>Lay solid foundations for management and oversight:</i>											
Recommendation 1.1	A listed entity should have and disclose a board charter setting out: (a) the respective roles and responsibilities of its board and management; and (b) those matters expressly reserved to the board and those delegated to management.	Yes	The Company's Board Charter outlines the respective roles and responsibilities of its Board and management (and those expressly reserved to the Board or delegated to management). A copy of the Company's Board Charter will be disclosed on its website at listing.									
Recommendation 1.2	A listed entity should: (a) undertake appropriate checks before appointing a director or senior executive or putting someone forward for election as a director; and (b) provide security holders with all material information in its possession relevant to a decision on whether or not to elect or re-elect a director.	Yes	The Company's Nomination Committee will ensure that appropriate checks (including those of the person's character, experience, education, criminal record and bankruptcy history) will be undertaken before appointing or nominating a new candidate as a director. In order to provide greater transparency around the appointment process, the Company will provide shareholders with all material information in its possession relevant to a decision on whether or not to elect a director.									
Recommendation 1.3	A listed entity should have a written agreement with each director and senior executive setting out the terms of their appointment.	Yes	The Company has written agreements with each of its directors and senior executives setting out the terms of their appointment.									
Recommendation 1.4	The Company Secretary of a listed entity should be accountable directly to the board, through the chair, on all matters to do with the proper functioning of the board.	Yes	The Board Charter outlines the roles, responsibility and accountability of the Company Secretary. The Company Secretary is accountable directly to the Board through the chairperson on all matters relating to the proper functioning of the Board.									
Recommendation 1.5	A listed entity should: (a) have and disclose a diversity policy; (b) through its board or a committee of the board set measurable objectives for achieving gender diversity in the composition of its board, senior executives and workforce generally; and (c) disclose in relation to each reporting period: 1. the measurable objectives set for that period to achieve gender diversity; 2. the entity's progress towards achieving those objectives; and 3. either: A. the respective proportions of men and women on the board, in senior executive positions and across the whole workforce (including how the entity has defined "senior executive" for these purposes); or B. if the entity is a "relevant employer" under the Workplace Gender Equality Act, the entity's most recent "Gender Equality Indicators", as defined in and published under that Act.  If the entity was in the S&P/ASX 300 Index at the commencement of	No	The Board has adopted a Diversity Policy which provides a framework for the Company to establish measurable diversity objectives that are annually reviewed. The Board considers that, due to the size, nature and stage of development of the Company, setting measurable objectives for the Diversity Policy at this time is not appropriate. The Board will consider setting measurable objectives as the Company increases in size and complexity. The Company currently has one female director (Maja McGuire) and no female senior executives <table border="1" data-bbox="1291 1117 1883 1203"> <thead> <tr> <th></th> <th>Number</th> <th>Percentage</th> </tr> </thead> <tbody> <tr> <td><b>Board</b></td> <td>1/3</td> <td>33%</td> </tr> <tr> <td><b>Senior Executives</b></td> <td>0/6</td> <td>0%</td> </tr> </tbody> </table> A copy of the Company's Diversity Policy is disclosed on its website.		Number	Percentage	<b>Board</b>	1/3	33%	<b>Senior Executives</b>	0/6	0%
	Number	Percentage										
<b>Board</b>	1/3	33%										
<b>Senior Executives</b>	0/6	0%										



Principle / Recommendation	Requirement of	Comply	Explanation of compliance / non-compliance
	the reporting period, the measurable objective for achieving gender diversity in the composition of its board should be to have not less than 30% of its directors of each gender within a specified period.		
Recommendation 1.6	<p>A listed entity should:</p> <p>(a) have and disclose a process for periodically evaluating the performance of the board, its committees and individual directors; and</p> <p>(b) disclose for each reporting period whether a performance evaluation has been undertaken in accordance with that process during or in respect of that period.</p>	Yes	<p>The Board Charter and the Performance Evaluation Policy set out that the Nomination Committee of the Company will conduct an annual performance review of the board that:</p> <ul style="list-style-type: none"> <li>• compares the performance of the Board with the requirements of its charter;</li> <li>• examines of the Board's interaction with management;</li> <li>• reviews the nature of information provided to the Board by management;</li> <li>• reviews management's performance in assisting the Board to meet its objectives;</li> <li>• undertakes an analysis of whether there is a need for existing Directors to undertake professional development;</li> <li>• critically reviews the mix of the Board to ensure it covers the skills needed to address existing and emerging business and governance issues relevant to the Company and to ensure the currency of each Director's knowledge and skills and whether the Director's performance has been impacted by other commitments; and</li> <li>• suggests any amendments to this charter as are deemed necessary or appropriate.</li> </ul> <p>As outlined in the Performance Evaluation Policy, the Company will disclose, in relation to each financial year, whether or not the relevant annual performance evaluations have been conducted in accordance with the above processes.</p>
Recommendation 1.7	<p>A listed entity should:</p> <p>(a) have and disclose a process for evaluating the performance of its senior executives at least once every reporting period; and</p> <p>(b) disclose for each reporting period whether a performance evaluation has been undertaken in accordance with that process during or in respect of that period.</p>	Yes	<p>The Performance Evaluation Policy sets out requirements for senior management performance evaluation.</p> <p>The nomination committee will annually review the performance of its senior executives and address any issues that may emerge from that review. The Board has authority to develop key performance indicators for management to assess the performance of each senior executive.</p> <p>As outlined in the Performance Evaluation Policy, the Company will disclose, in relation to each financial year, whether or not the relevant annual performance evaluations have been conducted in accordance with the above processes.</p>

Principle / Recommendation	Requirement of	Comply	Explanation of compliance / non-compliance
<i>Principle 2</i>	<i>Structure the board to add value:</i>		
Recommendation 2.1	<p>The board of a listed entity should:</p> <p>(a) have a nomination committee which:</p> <ol style="list-style-type: none"> <li>1. has at least three members, a majority of whom are independent directors; and</li> <li>2. is chaired by an independent director, and disclose:</li> <li>3. the charter of the committee;</li> <li>4. the members of the committee; and</li> <li>5. as at the end of each reporting period, the number of times the committee met throughout the period and the individual attendances of the members at those meetings;</li> </ol> <p>or</p> <p>(b) if it does not have a nomination committee, disclose that fact and the processes it employs to address board succession issues and to ensure that the board has the appropriate balance of skills, knowledge, experience, independence and diversity to enable it to discharge its duties and responsibilities effectively.</p>	No	<p>The Company's Nomination Charter outlines the structure of its Nomination Committee, including the composition, general scope and authority of the sub-committee, the frequency of meetings and the sub-committee's duties and responsibilities.</p> <p>The Company's Nomination Charter will be comprised of Maja McGuire and Julian Chick acting as Chair. Each member of the Nomination Committee is considered by the Board to be an independent director.</p> <p>At the end of the Company's reporting period, the number of times the Nomination Committee met through the period and the individual attendances of the members of the Nomination Committee will be included in the "Corporate Governance" section of the Company's annual report and / or on the Company's website. Pursuant to the Nomination Charter, the Nomination Committee will meet at least twice a year.</p> <p>Key features of the Nomination Committee's terms of reference will be included in the "Corporate Governance" section of the Company's annual report and/or on the Company's website.</p> <p>The proposed composition of this committee is deemed appropriate given the size of the Company, the Board, and the Company's circumstances. However, the nomination committee structure is proposed to be reviewed over time and as the composition of the Company's Board develops.</p>
Recommendation 2.2	A listed entity should have and disclose a board skills matrix setting out the mix of skills that the board currently has or is looking to achieve in its membership.	No	<p>The Nomination Committee will advise the Board in relation to the appointment of Board members by assessing the extent to which the required knowledge, experience and skills of prospective board members are represented on the board by updating and disclosing a skills matrix.</p> <p>The Company will include in the "Corporate Governance" section in the annual report and/or on its website an account of the mix of skills and diversity it seeks to achieve in the membership of its Board.</p>
Recommendation 2.3	<p>A listed entity should disclose:</p> <p>(a) the names of the directors considered by the board to be independent directors;</p> <p>(b) if a director has an interest, position or relationship of the type described in Box 2.3 of the Recommendations but the board is of the opinion that it does not compromise the independence of the director, the nature of the interest, position or relationship in</p>	Yes	<p>This Prospectus discloses (in section 7.1) the names of directors considered to be independent and any interests, positions or relationships of the type described in Box 2.3 of the ASX Recommendations and the length of service (where applicable).</p> <p>In addition, in accordance with the Board Charter, Directors considered by the Board to be independent will be identified as such, along with their length of service in that capacity, in the</p>

Principle / Recommendation	Requirement of	Comply	Explanation of compliance / non-compliance
	question and an explanation of why the board is of that opinion; and (c) the length of service of each director.		"Corporate Governance" section in the Company's annual report and / or on the Company's website. The Board will assess at least annually whether each director is considered to be independent. Information relevant to this assessment must be provided to the Board by each director. Should a director's independent status change, this will be disclosed and explained in a timely manner to the market.
Recommendation 2.4	A majority of the board of a listed entity should be independent directors.	Yes	As at Listing, the Board will comprise of two independent directors and one non-independent director. It is noted however that the Chairman is not considered to be an independent director. The composition of this Board is deemed as appropriate given the size of the Company, and its size, and the Board's independence will be reviewed over time and as the Company and its composition grows.
Recommendation 2.5	The chair of the board of a listed entity should be an independent director and, in particular, should not be the same person as the CEO of the entity.	No	The Chair of the Board will be Lee Rodne who is not considered to be an independent director. The Company currently does not have a CEO.
Recommendation 2.6	A listed entity should have a program for inducting new directors and for periodically reviewing whether there is a need for existing directors to undertake professional development opportunities to maintain the skills and knowledge needed to perform their role as directors effectively.	Yes	The Company Secretary is responsible for facilitating the induction and professional development of directors. The nomination committee is responsible for ensuring an effective induction process is in place for new directors and regularly reviewing whether the directors as a group have the skills, knowledge and familiarity with the Company and its operating environment required to fulfil their role on the Board and on Board committees effectively and, where any gaps are identified, consider what training or development could be undertaken to fill those gaps.
<b>Principle 3</b>	<b>Act ethically and responsibly:</b>		
Recommendation 3.1	A listed entity should articulate and disclose its values.	Yes	The Company's values are set out in section 2 of the Corporate Code of Conduct. A copy of the Company's a statement of values in the "Corporate Governance" section of the Company's website.
Recommendation 3.2	A listed entity should: (a) have and disclose a code of conduct for its directors, senior executives and employees; and (b) ensure that the board or a committee of the board is informed of any material breaches of that code.	Yes	The Company has adopted the Corporate Code of Conduct which sets out the responsibility of its directors, senior executives and employees to report any breaches of the Code of Conduct to the Board. The Code of Conduct will be disclosed in the "Corporate Governance" section of the Company's website.
Recommendation 3.3	A listed entity should: (a) have and disclose a whistleblower policy; and (b) ensure that the board or a committee of the board is informed of any material incidents reported under that policy.	Yes	The Company has adopted a Whistleblower Policy for its directors, senior executives, contractors, suppliers, associates and employees, and will disclose the Whistleblower Protection Policy on its website. The Company will ensure that the Board is informed

Principle / Recommendation	Requirement of	Comply	Explanation of compliance / non-compliance
			of any material incidents reported under the Whistleblower Policy.
Recommendation 3.4	A listed entity should: <ul style="list-style-type: none"> <li>(a) have and disclose an anti-bribery and corruption policy; and</li> <li>(b) ensure that the board or a committee of the board is informed of any material breaches of that policy.</li> </ul>	Yes	The Company's Code of Conduct contains information about anti-bribery and corruption. Moreover, the Company has adopted the Anti-bribery and anti-corruption policy (ABC Policy). The Company will disclose this policy by making it available on its website. The Company will ensure that the board is informed of any material breaches of the anti-bribery and corruption provisions of the ABC Policy.
<b>Principle 4 - Safeguard integrity in corporate reporting:</b>			
Recommendation 4.1	The board of a listed entity should: <ul style="list-style-type: none"> <li>(a) have an audit committee which: <ol style="list-style-type: none"> <li>1. has at least three members, all of whom are non-executive directors and a majority of whom are independent directors; and</li> <li>2. is chaired by an independent director, who is not the chair of the board,</li> </ol> and disclose: <ol style="list-style-type: none"> <li>3. the charter of the committee;</li> <li>4. the relevant qualifications and experience of the members of the committee; and</li> <li>5. in relation to each reporting period, the number of times the committee met throughout the period and the individual attendances of the members at those meetings;</li> </ol> or <ul style="list-style-type: none"> <li>(b) if it does not have an audit committee, disclose that fact and the processes it employs that independently verify and safeguard the integrity of its corporate reporting, including the processes for the appointment and removal of the external auditor and the rotation of the audit engagement partner.</li> </ul> </li> </ul>	No	The Company's Audit and Risk Committee will comprise of Julian Chick and Maja McGuire, and each are considered by the Board to be independent directors. The Audit and Risk Committee will be chaired by Maja McGuire who is considered to be an independent director and is not the Chair of the Board. The Audit and Risk Committee Charter will be made available on the Company's website. The relevant qualifications and experience of the members of the committee is disclosed in section 7.1 of this Prospectus and also be disclosed on the Company's website. At the end of the Company's reporting period, the number of times the audit and risk committee met through the period and the individual attendances of the members of the audit and risk committee will be included in the "Corporate Governance" section of the Company's annual report and / or on the Company's website. The proposed composition of this committee is deemed appropriate given the size of the Company, the Board, and the Company's circumstances. However, the committee structure is proposed to be reviewed over time and as the composition of the Company's Board develops.
Recommendation 4.2	The board of a listed entity should, before it approves the entity's financial statements for a financial period, receive from its CEO and CFO a declaration that, in their opinion, the financial records of the entity have been properly maintained and that the financial statements comply with the appropriate accounting standards and give a true and fair view of the financial position and performance of the entity and that the opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.	Yes	The Company's Audit and Risk Charter requires the CEO and the Chief Financial Officer to provide a declaration that the financial records of the Company have been properly maintained and that the financial statements comply with the appropriate accounting standards and give a true and fair view of the financial position and performance of the Company and that the opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively. The declaration must be given before the Board approves the financial statements for the financial year.

<b>Principle / Recommendation</b>	<b>Requirement of</b>	<b>Comply</b>	<b>Explanation of compliance / non-compliance</b>
Recommendation 4.3	A listed entity should disclose its process to verify the integrity of any periodic corporate report it releases to the market that is not audited or reviewed by an external auditor.	Yes	The Audit and Risk Committee will be responsible for establishing procedures for verifying the integrity of any periodic corporate report it releases to the market that is not audited or reviewed by an external auditor. These risk management procedures will be disclosed on the Company's website.
<i>Principle 5 - Make timely and balanced disclosure:</i>			
Recommendation 5.1	A listed entity should have and disclose a written policy for complying with its continuous disclosure obligations under listing rule 3.1.	Yes	The Company has adopted a Continuous Disclosure Policy which it will disclose on its website.
Recommendation 5.2	A listed entity should ensure that its board receives copies of all material market announcements promptly after they have been made.	Yes	In accordance with its Continuous Disclosure Policy, the Company will ensure that the Board is provided with all copies of all material market announcements promptly after they have been made.
Recommendation 5.3	A listed entity that gives a new and substantive investor or analyst presentation should release a copy of the presentation materials on the ASX Market Announcements Platform ahead of the presentation.	Yes	In accordance with its Continuous Disclosure Policy, where the Company gives a new and substantive investor or analysis presentation, the Company will ensure the presentation is released on the ASX Market Announcements Platform ahead of that presentation.
<i>Principle 6 - Respect the rights of security holders:</i>			
Recommendation 6.1	A listed entity should provide information about itself and its governance to investors via its website.	Yes	Information about the Company and its governance will be available on the Company's website. In particular, the Company will upload the following documents to its website: a) Board Charter; b) Code of Conduct; c) Audit and Risk Charter; d) Nomination Charter; e) Remuneration Committee Charter; f) Performance Evaluation Policy; g) Continuous Disclosure Policy; h) Trading Policy; i) Diversity Policy; j) Whistleblower Policy; k) Anti-Bribery and Anti-Corruption Policy; and l) Shareholder Communication Policy.
Recommendation 6.2	A listed entity should have an investor relations program that facilitates effective two-way communication with investors.	Yes	The Company has adopted a Shareholder Communication Policy to facilitate effective two-way communication with investors.
Recommendation 6.3	A listed entity should disclose how it facilitates and encourages participation at meetings of security holders.	Yes	The Shareholder Communication Policy outlines a strategy to encourage shareholder participation at meetings and the policy will be disclosed on the Company's website.
Recommendation 6.4	A listed entity should ensure that all substantive resolutions at a meeting of security holders are decided by a poll rather than by a show of hands.	Yes	The Company intends that when calling a vote at a meeting of shareholders, all substantive resolutions will be decided by a poll rather than a show of hands.

Principle / Recommendation	Requirement of	Comply	Explanation of compliance / non-compliance
Recommendation 6.5	A listed entity should give security holders the option to receive communications from, and send communications to, the entity and its security registry electronically.	Yes	The Company will, and will ensure that the share registry will, give shareholders an option to receive notices electronically rather than by post, to the extent that is permitted by the ASX Listing Rules and the <i>Corporations Act 2001 (Cth)</i> .
<b>PRINCIPLE 7 - Recognise and manage risk:</b>			
Recommendation 7.1	The board of a listed entity should: <ul style="list-style-type: none"> <li>(a) have a committee or committees to oversee risk, each of which:               <ul style="list-style-type: none"> <li>1. has at least three members, a majority of whom are independent directors;</li> <li>2. is chaired by an independent director</li> </ul>               and disclose:               <ul style="list-style-type: none"> <li>3. the charter of the committee;</li> <li>4. the members of the committee; and</li> <li>5. as at the end of each reporting period, the number of times the committee met throughout the period and the individual attendances of the members at those meetings;</li> </ul>               or             </li> <li>(b) if it does not have a risk committee or committees that satisfy the requirements above, disclose that fact and the processes it employs for overseeing the entity's risk management framework.</li> </ul>	No	The Audit and Risk Committee will be comprised of Maja McGuire and Julian Chick, and each are considered by the Board to be independent directors. The Audit and Risk Committee will be chaired by Maja McGuire who is an independent director and not the Chair of the Board. The Audit and Risk Committee Charter, which includes the members of the committee, will be made available on the Company's website. At the end of the Company's reporting period, the number of times the Audit and Risk Committee met in that period, and the individual attendances of the members of the Audit and Risk Committee, will be included in the "Corporate Governance" section of the Company's annual report and / or on the Company's website. The proposed composition of this committee is deemed appropriate given the size of the Company, the Board, and the Company's circumstances. However, the committee structure is proposed to be reviewed over time and as the composition of the Company's Board develops.
Recommendation 7.2	The board or a committee of the board should: <ul style="list-style-type: none"> <li>(a) review the entity's risk management framework at least annually to satisfy itself that it continues to be sound and that the entity is operating with due regard to the risk appetite set by the board; and</li> <li>(b) disclose, in relation to each reporting period, whether such a review has taken place.</li> </ul>	Yes	The Audit and Risk Committee Charter sets out that the risk management framework must be reviewed at least annually. At the end of the Company's reporting period, details of whether such a review has taken place will be included in the "Corporate Governance" section of the Company's annual report and / or on the Company's website.
Recommendation 7.3	A listed entity should disclose: <ul style="list-style-type: none"> <li>(a) if it has an internal audit function, how the function is structured and what role it performs; or</li> <li>(b) if it does not have an internal audit function, that fact and the processes it employs for evaluating and continually improving the effectiveness of its governance, risk management and internal control processes.</li> </ul>	Yes	Due to the nature and size of its business, at this stage, the Company does not have an internal audit function. The Company's Audit and Risk Committee will be responsible for evaluating and continually improving the effectiveness of the Company's governance, risk management and internal control processes, cognizant of the size, stage, and scope of the Company's activities. The Audit and Risk Committee will consider annually whether there is a need for an internal audit function and make a recommendation to the Board if and when appropriate.

Principle / Recommendation	Requirement of	Comply	Explanation of compliance / non-compliance
Recommendation 7.4	An entity should disclose whether it has any material exposure to environmental or social risks and, if it does, how it manages or intends to manage those risks.	Yes	The Audit and Risk Committee is responsible for monitoring and reviewing the effectiveness of the Company's control framework in the area of operational risk (among other areas). Due to the nature of the Company's business within the video technology industry, no environmental or social risks are currently expected and none have been disclosed. Should any such risks arise in the future, the Company intends to disclose them on its website or in its annual report and set out how it intends to manage those risks.
<b>PRINCIPLE 8 - Remunerate fairly and responsibly:</b>			
Recommendation 8.1	<p>The board of a listed entity should:</p> <p>(a) have a remuneration committee which:</p> <ol style="list-style-type: none"> <li>1. has at least three members, a majority of whom are independent directors;</li> <li>2. is chaired by an independent director, and disclose:</li> <li>3. the charter of the committee;</li> <li>4. the members of the committee; and</li> <li>5. as at the end of each reporting period, the number of times the committee met throughout the period and the individual attendances of the members at those meetings; or</li> </ol> <p>(b) if it does not have a remuneration committee, disclose that fact and the processes it employs for setting the level and composition of remuneration for directors and senior executives and ensuring that such remuneration is appropriate and not excessive.</p>	No	<p>The Company's Remuneration Committee Charter outlines the structure of its Remuneration Committee, including the composition, general scope and authority of the sub-committee, the frequency of meetings and the sub-committee's duties and responsibilities.</p> <p>The Company's Remuneration Committee will be comprised of Maja McGuire and Julian Chick (acting as Chair), and each are considered by the Board to be independent directors.</p> <p>At the end of the Company's reporting period, the number of times the Remuneration Committee met through the period and the individual attendances of the members of the Remuneration Committee will be included in the "Corporate Governance" section of the Company's annual report and / or on the Company's website. Pursuant to the Remuneration Committee Charter, the Remuneration Committee will meet at least twice a year.</p> <p>Key features of the Remuneration Committee's terms of reference will be included in the "Corporate Governance" section of the Company's annual report and/or on the Company's website.</p> <p>The proposed composition of this committee is deemed appropriate given the size of the Company, the Board, and the Company's circumstances. However, the committee structure is proposed to be reviewed over time and as the composition of the Company's Board develops.</p>
Recommendation 8.2	A listed entity should separately disclose its policies and practices regarding the remuneration of non-executive directors and the remuneration of executive directors and other senior executives.	Yes	The Company's Remuneration Committee Charter outlines its policies and practices regarding the remuneration of non-executive directors and the remuneration of executive directors and other senior executives. A copy of the Company's Remuneration Committee Charter will be disclosed on its website.
Recommendation 8.3	<p>A listed entity which has an equity-based remuneration scheme should:</p> <p>(a) have a policy on whether participants are permitted to enter into</p>	Yes	The Company has adopted a Trading Policy and will disclose the policy on its website.

Principle / Recommendation	Requirement of	Comply	Explanation of compliance / non-compliance
	<p>transactions (whether through the use of derivatives or otherwise) which limit the economic risk of participating in the scheme; and</p> <p>(b) disclose that policy or a summary of it.</p>		
<i>PRINCIPLE 9 - Additional Recommendations that apply only in certain cases:</i>			
Recommendation 9.1	A listed entity with a director who does not speak the language in which board or security holder meetings are held or key corporate documents are written should disclose the processes it has in place to ensure the director understands and can contribute to the discussions at those meetings and understands and can discharge their obligations in relation to those documents.	N/A	All directors speak fluent English.
Recommendation 9.2	A listed entity established outside Australia should ensure that meetings of security holders are held at a reasonable place and time.	N/A	N/A.
Recommendation 9.3	A listed entity established outside Australia, and an externally managed listed entity that has an AGM, should ensure that its external auditor attends its AGM and is available to answer questions from security holders relevant to the audit.	N/A	N/A.

The Company intends to keep its Shareholders up to date on all material information through its website (<https://www.ltrpharma.com/investor-centre/>) and/or the ASX platform under its expected ASX ticker code 'LTP'.



## 7.11 Dividends

The Directors do not envisage that the Company will declare, or be able to declare, any dividends in the foreseeable future.

The financial prospects of the Company are dependent on a number of factors, and any surplus funds will be used to fund the Company's operations rather than distributing the funds as dividends.

In light of these factors and having regard to ASIC Regulatory Guide 170, the Directors consider at this stage the Company is unable to provide potential investors with reliable revenue, profit or cash flow projections or forecasts. An investment in the Company is a long term investment, with long development time frames and no dividends should be expected in the short term.

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## 8. Financial Information

### 8.1 Introduction

The financial information in this Section 8 consists of:

The historical financial information, which comprises the:

- historical consolidated statements of financial position as at 30 June 2023, 30 June 2022 and 30 June 2021;
- historical consolidated statements of profit or loss and other comprehensive income and historical consolidated statements of cash flows for the years ended 30 June 2023, 30 June 2022 and the period ended 30 June 2021; and
- notes to the financial statements,

(together referred to as the “**Historical Financial Information**”); and

- the pro forma historical financial information, which comprises the pro forma historical consolidated statement of financial position as at 30 June 2023 (“**Pro Forma Historical Financial Information**”),

(collectively referred to as the “**Financial Information**”).

The Pro Forma Historical Financial Information has been prepared based on the audited statutory Historical Financial Information as at 30 June 2023, adjusted for the pro forma transactions as detailed in Section 8.3, as if they had occurred as at 30 June 2023.

The Directors are responsible for the inclusion of the Financial Information in the Prospectus.

The purpose of the inclusion of the Financial Information is to illustrate the effects of the Offers (as defined in Section 8.3) and the relevant pro forma transactions.

William Buck Consulting (WA) Pty Ltd has prepared an Independent Limited Assurance Report in respect to the Financial Information. A copy of this report, which includes an explanation of the scope and limitations of the Independent Limited Assurance Report contained in Section 9.

The information presented in this Section 8 should be read in conjunction with the Independent Limited Assurance Report contained in Section 9, the risk factors as detailed in Section 11, other information included in this Prospectus and the latest audited financial statements.

### 8.2 Basis of preparation

The Historical Financial Information has been prepared in accordance with the recognition and measurement requirements of Australian Accounting Standards (including Australian Accounting Interpretations) as adopted by the Company.

The Pro Forma Historical Financial Information has been derived from the Historical Financial Information, and assumes the completion of the pro forma adjustments, as detailed in Section 8.3 as if those adjustments had occurred as at 30 June 2023. The Pro Forma Historical Financial Information has been prepared in accordance with and should be read in conjunction with the accounting policies detailed in the Company’s Annual Report for the year ended 30 June 2023.

The Financial Information contained in this Section 8 is presented in an abbreviated form and does not contain all the disclosures that are provided in a financial report prepared in accordance with the Corporations Act and Australian Accounting Standards. In this section, “\$” denotes Australian Dollars and “US\$” denotes United States Dollars

The Historical Financial Information of the Group has been extracted from the financial reports of the Group for the years ended 30 June 2023, 30 June 2022 and the period ended 30 June 2021, which were audited by HLB Mann Judd Services (WA Partnership), who issued unmodified audit opinions on the respective financial reports.

### 8.3 Pro Forma Historical Financial Information adjustments

The Pro Forma Historical Financial Information has been compiled by adjusting the Consolidated Statement of Financial Position of the Group as at 30 June 2023 and reflecting the impact of the following items and pro forma transactions which are yet to occur, but all of which are proposed to occur immediately before or following completion of the Offers.

The following adjustments have been made:

- (a) The issue of 30,000,000 ordinary fully paid shares issued at \$0.20 per Share raising \$6,000,000 in a minimum raise, with a maximum raise of 35,000,000 shares raising \$7,000,000 at an issue price of A\$0.20 per Share, before costs (**Investor Offer**);
- (b) the issue of 250,000 shares to Grannus to satisfy the Company's obligations under its agreement for services provided by Grannus Securities (Grannus Offer).
- (c) the cash payment of A\$360,000 and issue of 2,393,438 options at the Minimum Subscription, the cash payment of \$420,000 and issue of 2,792,344 options at the Maximum Subscription. (**Lead Manager Offer**);
- (d) transaction costs of \$389,701 of which A\$64,429 and A\$325,272 have been allocated to equity and profit or loss respectively in the Minimum Subscription, transaction costs of A\$391,939 relating to Offers of which A\$72,389 and A\$319,553 have been allocated to equity and profit or loss respectively (**Transaction Costs**);
- (e) the issue of 2,000,000 Options to Directors (2,000,000 unlisted options exercisable at A\$0.22 each, the options vest immediately if the Company is admitted to the Official List of ASX (**Board Options**); and
- (f) Payment of US\$500,000 equivalent to \$792,079 to SDS under the SDS Licence Agreement (Section 13.7(a)).

The pro forma cash and cash equivalents in the Pro Forma Financial Information takes into account the transactions above, but, does not include the impact of net operating costs of the Group since 30 June 2023 to the date of this Prospectus (excluding costs of the Offers as noted above).

## 8.4 Historical Consolidated Statements of Profit or Loss and Other Comprehensive Income

	Audited 30 June 2023	Audited 30 June 2022	Audited 30 June 2021
	\$	\$	\$
<b>Continuing operations</b>			
Other Income	-	9,078	-
Interest income	90	238	11
<b>Expenses</b>			
Employee benefits expense	(445,994)	(390,496)	-
Consultancy and legal fees	(129,315)	(279,933)	(19,056)
Office and administrative costs	(16,089)	(4,615)	-
Research and development expense	(817,835)	(348,305)	-
Finance costs	(20)	(27)	(9,383)
Other expenses	(26,450)	(2,014)	(9,514)
Currency gains/(losses)	(19,292)	(11,047)	(2,861)
<b>Loss before tax</b>	<b>(1,454,905)</b>	<b>(1,027,121)</b>	<b>(40,803)</b>
Income tax expense	-	-	-
<b>Loss after income tax</b>	<b>(1,454,905)</b>	<b>(1,027,121)</b>	<b>(40,803)</b>
Other comprehensive income	23,507	44,827	-
<b>Total comprehensive income (loss)</b>	<b>(1,431,398)</b>	<b>(982,294)</b>	<b>(40,803)</b>

The above historical of Profit or Loss and Other Comprehensive Income are to be read in conjunction with Sections 8.2 and 8.8

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## 8.5 Historical Consolidated Statements of Cash Flows

	Audited 30 June 2023	Audited 30 June 2022	Audited 30 June 2021
	\$	\$	\$
<b>Cash flows from operating activities</b>			
Interest income	90	238	11
Payments to suppliers and employees	(1,535,587)	(577,468)	(29,077)
Interest paid	(20)	(27)	-
R&D tax incentives received	-	9,078	-
<b>Net cash (outflow) by operating activities</b>	<b>(1,535,517)</b>	<b>(568,179)</b>	<b>(29,066)</b>
<b>Cash flows from investing activities</b>			
Payment for Computer Equipment	(1,987)	-	
<b>Net cash (outflow) from investing activities</b>	<b>(1,987)</b>	<b>-</b>	
<b>Cash flows from financing activities</b>			
Proceeds from issue of Shares	1,447,510	2,344,210	-
Equity raising funds in advance	-	-	103,000
Share issue costs	(69,055)	-	-
Proceeds from borrowings	-	-	350,120
Loans advanced	-	-	(274,780)
<b>Net cash inflow by financing activities</b>	<b>1,378,455</b>	<b>2,344,210</b>	<b>178,340</b>
<b>Cash and cash equivalents at beginning of year</b>	<b>1,911,397</b>	<b>146,413</b>	<b>-</b>
Net increase/(decrease) in cash held	(159,049)	1,776,031	149,274
Effects of exchange rate changes on cash	(23,606)	(11,047)	(2,861)
<b>Cash and cash equivalents at end of year</b>	<b>1,728,742</b>	<b>1,911,397</b>	<b>146,413</b>

The above historical consolidated statements of cash flows are to be read in conjunction with Sections 8.2 and 8.8

## 8.6 Historical Consolidated Statement of Financial Position

	Audited 30 June 2023	Audited 30 June 2022	Audited 30 June 2021
	\$	\$	\$
<b>ASSETS</b>			
<b>CURRENT ASSETS</b>			
Cash and cash equivalents	1,728,742	1,911,397	146,143
Other assets	64,821	43,295	-
<b>TOTAL CURRENT ASSETS</b>	<b>1,793,563</b>	<b>1,954,692</b>	<b>146,143</b>
<b>NON-CURRENT ASSETS</b>			
Trade and other receivables	300,180	290,680	276,287
<b>TOTAL NON-CURRENT ASSETS</b>	<b>300,180</b>	<b>290,680</b>	<b>276,287</b>
<b>TOTAL ASSETS</b>	<b>2,093,743</b>	<b>2,245,372</b>	<b>422,700</b>
<b>LIABILITIES</b>			
<b>CURRENT LIABILITIES</b>			
Trade and other payables	(11,259)	(465,906)	(1,000)
Borrowings	-	-	(359,503)
Other liabilities	(10,000)	(10,000)	(103,000)
<b>TOTAL CURRENT LIABILITIES</b>	<b>(21,259)</b>	<b>(475,906)</b>	<b>(463,503)</b>
<b>TOTAL LIABILITIES</b>	<b>(21,259)</b>	<b>(475,906)</b>	<b>(463,503)</b>
<b>NET ASSETS</b>	<b>2,072,484</b>	<b>1,769,466</b>	<b>(40,803)</b>
<b>EQUITY</b>			
Issued capital	4,526,979	2,792,563	-
Accumulated losses	(2,522,829)	(1,067,924)	(40,803)
Reserves	68,334	44,827	-
<b>TOTAL EQUITY</b>	<b>2,072,484</b>	<b>1,769,466</b>	<b>(40,803)</b>

The above historical consolidated statements of financial position are to be read in conjunction with Sections 8.2 and 8.8

## 8.7 Pro Forma Historical Consolidated Statement of Financial Position

	Note	Audited 30 June 2023	Pro forma adjustment Minimum Subscription	Pro forma Adjustment Maximum Subscription	Pro forma Minimum Subscription	Pro forma Maximum Subscription
		\$	\$	\$	\$	\$
<b>ASSETS</b>						
<b>CURRENT ASSETS</b>						
Cash and cash equivalents	2	1,728,742	4,478,220	5,415,982	6,206,962	7,144,724
Other assets		64,821	-	-	64,821	64,821
<b>TOTAL CURRENT ASSETS</b>		<b>1,793,563</b>	<b>4,478,220</b>	<b>5,415,982</b>	<b>6,271,783</b>	<b>7,209,545</b>
<b>NON-CURRENT ASSETS</b>						
Trade and other receivables		300,180	-	-	300,180	300,180
<b>TOTAL NON-CURRENT ASSETS</b>		<b>300,180</b>	<b>-</b>	<b>-</b>	<b>300,180</b>	<b>300,180</b>
<b>TOTAL ASSETS</b>		<b>2,093,743</b>	<b>4,478,220</b>	<b>5,415,982</b>	<b>6,571,963</b>	<b>7,509,725</b>
<b>LIABILITIES</b>						
<b>CURRENT LIABILITIES</b>						
Trade and other payables		(11,259)	-	-	(11,259)	(11,259)
Borrowings		-	-	-	-	-
Other liabilities		(10,000)	-	-	(10,000)	(10,000)
<b>TOTAL CURRENT LIABILITIES</b>		<b>(21,259)</b>	<b>-</b>	<b>-</b>	<b>(21,259)</b>	<b>(21,259)</b>
<b>TOTAL LIABILITIES</b>		<b>(21,259)</b>	<b>-</b>	<b>-</b>	<b>(21,259)</b>	<b>(21,259)</b>
<b>NET ASSETS</b>		<b>2,072,484</b>	<b>4,478,220</b>	<b>5,415,982</b>	<b>6,550,704</b>	<b>7,488,466</b>
<b>EQUITY</b>						
Issued capital	3	4,526,979	6,020,000	7,020,000	10,546,979	11,546,979
Capital raising cost		-	(664,429)	(772,386)	(664,429)	(772,386)
Accumulated losses	4	(2,522,829)	(1,345,259)	(1,339,540)	(3,868,088)	(3,862,369)
Reserves	5	68,334	467,908	507,908	536,242	576,242
<b>TOTAL EQUITY</b>		<b>2,072,484</b>	<b>4,478,220</b>	<b>5,415,982</b>	<b>6,550,704</b>	<b>7,488,466</b>

The above pro forma historical consolidated statement of financial position is derived from the historical consolidated statement of financial position adjusted for the pro forma transactions noted in Section 8.3 and is to be read in conjunction with Sections 8.2 and 8.8.

## 8.8 Notes to and forming part of the Historical and Pro Forma Historical Financial Information

### Summary of significant accounting policies

This Prospectus does not include all the notes of the type normally included in an annual financial report. Accordingly, this Prospectus should be read in conjunction with the annual report of the Group for the year ended 30 June 2023. The significant accounting policies which have been adopted in the preparation of the historical and pro forma historical financial information are set out below. These policies have been consistently applied to all periods presented unless otherwise stated.

#### (a) Reporting framework

The historical and pro forma historical financial information has been prepared in accordance with the recognition and measurement, but not all the disclosure requirements specified by all the Australian Accounting Standards, Australian Accounting Interpretations, other authoritative pronouncements of the Australian Accounting Standards Board (AASB) and the Corporations Act. The historical and pro forma historical financial information has been prepared on an actuals basis and is based on historical costs, modified, where applicable, by the measurement at fair value of selected non-current assets, financial assets and financial liabilities based on 'the Directors' estimates of Net Realisable Value. The pro forma historical financial information is presented in Australian dollars.

#### (b) New and amended standards adopted by the Group

Any standards and interpretations that have been issued but are not yet effective, and that are available for early application, have not been applied by the Company in these financial statements. There would be no material impact of those issued but not yet effective standards on the financial statements. Australian Accounting Standards that have recently been issued or amended but are not yet effective have not been adopted for the reporting year ended 30 June 2023.

#### (c) Cash and Cash Equivalents

Cash and cash equivalents include cash on hand, deposits held at call with banks, other short-term highly liquid investments with original maturities of 3 months or less, and bank overdrafts. Bank overdrafts are shown within short-term borrowings in current liabilities on the statement of financial position.

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(d) Critical accounting estimates

The preparation of the financial statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the company's accounting policies. Management bases its judgements, estimates and assumptions on historical experience and on other various factors, including expectations of future events that management believes to be reasonable under the circumstances. The resulting accounting judgements and estimates will seldom equal the related actual results.

(e) Fair Value Estimation

The fair value of financial assets and financial liabilities must be estimated for recognition and measurement or for disclosure purposes.

When an asset or liability, financial or non-financial, is measured at fair value for recognition or disclosure purposes, the fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date; and assumes that the transaction will take place either: in the principal market; or in the absence of a principal market, in the most advantageous market.

(f) Issued Capital

Shares are classified as equity. Issued and paid up capital is recognised at the fair value of the consideration received by the Group. Incremental costs directly attributable to the issue of new Shares or Options are shown in equity as a deduction, net of tax, from the proceeds.

(g) Share-Based Payments

Equity-settled share-based payments are provided to officers, consultants and other advisors. These share-based payments are measured at the fair value of the equity instrument at the grant date. The fair value of Options is determined using an appropriate pricing model. The fair value determined at the grant date is expensed on a straight-line basis over the vesting period, based on the Group's estimate of equity instruments that will eventually vest where they are subject to non-market vesting conditions. At each reporting date, the Group revises its estimate of the number of equity instruments expected to vest. The impact of the revision of the original estimates, if any, is recognised in profit or loss over the remaining vesting period, with a corresponding adjustment to the share based payments reserve. Equity-settled share-based payments may also be provided as consideration for the acquisition of assets and/or extinguishment of liabilities. Where Shares are issued and vest immediately and the fair value of the assets acquired or liabilities extinguished is not readily determinable, the transaction is recorded at fair value based on the quoted price of the Shares at the date of issue. The acquisition is then recorded as an asset or expensed in

accordance with accounting standards.

(h) Research and Development

Research costs are expensed in the period in which they are incurred. Development costs are capitalised when it is probable that the project will be a success considering its commercial and technical feasibility; the consolidated entity is able to use or sell the asset; the consolidated entity has sufficient resources and intent to complete the development; and its costs can be measured reliably.

(i) Consolidation

**Principles of consolidation**

The consolidated financial statements incorporate the assets and liabilities of all subsidiaries of LTR Pharma Limited ('company' or 'parent entity') as at 30 June 2023 and the results of all subsidiaries for the year then ended. LTR Pharma Limited and its subsidiaries together are referred to in these financial statements as the 'consolidated entity' or 'Group'.

Subsidiaries are all those entities over which the consolidated entity has control. The consolidated entity controls an entity when the consolidated entity is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the consolidated entity. They are de-consolidated from the date that control ceases.

Intercompany transactions, balances and unrealised gains on transactions between entities in the consolidated entity are eliminated. Unrealised losses are also eliminated unless the transaction provides evidence of the impairment of the asset transferred. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the consolidated entity.

**Key judgements**

*Share based payments*

The Group recognises share based payments in accordance with the policy at Note 1(g).

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NOTE 2. CASH AND CASH EQUIVALENTS	Audited		Pro forma	Pro forma
	30 June 2023	Subsequent transactions	Minimum Subscription	Maximum Subscription
	\$	\$	\$	\$
<b>Audited balance of LTP at 30 June 2023</b>	1,728,742		1,728,742	1,728,742
<i>Pro forma adjustments</i>				
Milestone payment SDS Licence Agreement see section 8.3(f)			(792,079)	(792,079)
Issue of Investor Offer Shares – section 8.3(a)			6,000,000	7,000,000
Lead Manager Offer (cash payment) – section 8.3(c)			(360,000)	(420,000)
Transaction Costs – Offers – section 8.3(d)			(389,701)	(391,939)
Transaction Costs – Paid pre-30 June 2023 – section 8.3(d)			20,000	20,000
<b>Pro forma Balance</b>			<b>6,209,962</b>	<b>7,144,724</b>

NOTE 3. ISSUED CAPITAL	Audited	Pro forma	Pro forma
	30 June 2023	Minimum Subscription	Maximum Subscription
	\$	\$	\$
<b>Audited balance of LTP at 30 June 2023</b>	4,526,979	4,526,979	4,526,979
<i>Pro forma adjustments:</i>			
Issue of Investor Offer and Grannus Offer Shares – section 8.3(a)		6,020,000	7,020,000
Capital raising costs – sections 8.3(c) and 8.3(d)		(664,429)	(772,386)
<b>Pro forma Balance</b>		<b>9,882,550</b>	<b>10,774,593</b>

As part of the Offer, Grannus will be issued 250,000 shares to satisfy the Company's obligations under its agreement for services provided.

Movement in Number of Ordinary Shares	Audited 30 June 2023	Pro forma Minimum Subscription	Pro forma Maximum Subscription
<b>Audited balance of LTP at 30 June 2023</b>	104,170,252	104,170,252	104,170,252
<i>Pro forma adjustments:</i>			
Issue of Investor Offer Shares – section 8.3(a)		30,000,000	35,000,000
Grannus Offer — section 8.3(b)		250,000	250,000
<b>Pro forma Balance</b>		<b>134,420,252</b>	<b>139,420,252</b>

NOTE 4. Accumulated Losses	Audited 30 June 2023	Pro forma Minimum Subscription	Pro forma Maximum Subscription
	\$	\$	\$
<b>Audited balance of LTP at 30 June 2023</b>	(2,522,829)	(2,522,829)	(2,522,829)
<i>Pro forma adjustments:</i>			
Milestone payment SDS Licence Agreement (Section 13.7(a)(ii))		(792,079)	792,079
Transaction Costs – Offers – section 8.3(d)		(325,272)	(319,553)
Board Options – section 8.3(e)		(227,908)	(227,908)
<b>Pro forma Balance</b>		<b>(3,868,088)</b>	<b>(3,862,369)</b>

NOTE 5. Reserves	Audited 30 June 2023	Pro forma Minimum Subscription	Pro forma Maximum Subscription
	\$	\$	\$
<b>Audited balance of LTP at 30 June 2023</b>	68,334	68,334	68,334
<i>Pro forma adjustments:</i>			
Lead Manager Offer – section 8.3(c)		240,000	280,000

Board Options – section 8.3 (e)	227,908	227,908
<b>Pro forma Balance</b>	<b>536,242</b>	<b>576,242</b>

Movement in Number of Options	Audited 30 June 2023	Pro forma Minimum Subscription	Pro forma Maximum Subscription
<b>Audited balance of LTP at 30 June 2023</b>	-	-	-
Audited balance of LTP at 30 June 2023		-	-
<i>Pro forma adjustments:</i>			
Lead Manager Offer – section 8.3(c)		2,393,438	2,792,344
Board Options – section 8.3 (e)		2,000,000	2,000,000
<b>Pro forma Balance</b>		<b>4,393,438</b>	<b>4,792,344</b>

Each Option entitles the holder to subscribe for one Share upon exercise of the Option. The Exercise Price, Vesting Date and Expiry Date of each Option issued to the Directors and the Lead Manager is set out in the table below and Sections 7.2(d) and 13.7(c(i)) of this Prospectus.

Option Class	Number	Exercise price	Vesting Date	Expiry Date	Value option (\$)	per	Total expense to be recognised over vesting period (\$) m
Tranche 1 Lead manager Offer (Min)	2,393,438	0.26	Upon Listing	3 years from the date of issue	0.1002		\$240,000
Tranche 2 Lead manager Offer (Max)	2,792,344	0.26	Upon Listing	3 years from the date of issue	0.1002		\$280,000
Tranche 3 Board options	2,000,000	0.22	Upon Listing	5 years from the date of issue	0.11395		\$227,908

The above Options were valued using the Black-Scholes valuation model using the following inputs

Option Class	Tranche 1		Tranche 2		Tranche 3 Board options
	Lead Manager (Min)	Offer	Lead Manager (Max)	Offer	
Exercise price	0.26		0.26		0.22
Expected spot price	0.20		0.20		<b>0.20</b>
Risk free rate	4.02%		4.02%		4.02%
Median Volatility	90%		90%		90%

#### Note 6. Contingent liabilities

As at 30 June 2023, the Company reported contingent liabilities which exist in relation to potential milestone payments arising under the SDS Licence Agreement. These contingent liabilities total US\$4.0 million and are dependent upon the high-risk nature of the granting/approval of relevant patents which are the subject matter of the SDS Licence Agreement, as well as future decisions regarding the clinical focus of the Company which may depend on the success of the Company's clinical research / trials, and are therefore not recognised in the statement of financial position.

Subsequent to 30 June 2023, LTP agreed to pay US\$500,000 and a further amount of US\$300,000 under a variation to the SDS Licence Agreement. The aggregate of the remaining milestone payments which may become payable under this Agreement subject to the achievement of certain milestones is US\$3,000,000, net of the loan of US\$200,000 which the Company previously paid under the Agreement.

For personal use only

## 9. Investigating Accountants Report

**WilliamBuck**

ACCOUNTANTS & ADVISORS

The Board of Directors  
LTR Pharma Limited  
9/204 Alice Street,  
Brisbane QLD 4000

Dear Directors,

### **INDEPENDENT LIMITED ASSURANCE REPORT ON LTR PHARMA LIMITED HISTORICAL FINANCIAL INFORMATION AND PRO FORMA HISTORICAL FINANCIAL POSITION**

#### **Introduction**

William Buck Consulting (WA) Pty Ltd have been engaged by LTR Pharma Limited ("LTP" or the "Company") to report on the Historical Financial Information and Pro Forma Historical Financial Position of the Company as at 30 June 2023 for inclusion in the prospectus ("Prospectus") dated 1 November 2023 and in a Replacement Prospectus to be issued on or about 9 November 2023. The Prospectus and Replacement Prospectus are in connection with the Company's proposed capital raising and listing on the Australian Securities Exchange ("ASX") pursuant to which the Company is offering to the general public ("Public Offer") up to 35,000,000 shares at an issue price of \$0.20 each, to raise a minimum of A\$6,000,000 up to a maximum of A\$7,000,000 (before costs).

Expressions and terms defined in the Prospectus and Replacement Prospectus have the same meaning in this Report.

#### **Background**

LTR Pharma Limited is an unlisted public company which was incorporated in October 2020 as a result of being spun-out of LTR Medical Pty Ltd ABN 47 625 901 573 ("LTM"). The principal focus of the Company is to change the method of administration of an existing and approved drug already on the market for the treatment of ED named Vardenafil. LTP is preparing to launch its lead nasal spray product (SPONTAN®) which is based on the formula of Vardenafil.

#### **Scope**

##### **Historical Financial Information**

You have requested William Buck Consulting (WA) Pty Ltd to review the following historical financial information of the Company included in Section 8 of the Prospectus and Replacement Prospectus comprising:

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PO Box 748, South Perth WA 6951

+61 8 6436 2888

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[williambuck.com](http://williambuck.com)

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- The historical consolidated statements of profit or loss and other comprehensive income for the financial years ended 30 June 2023, 30 June 2022 and the period ended 30 June 2021;
- The historical consolidated statements of cashflows for the financial years ended 30 June 2023, 30 June 2022 and the period ended 30 June 2021; and
- The historical consolidated statements of financial position as at 30 June 2023, 30 June 2022 and 30 June 2021

Together referred to as the “Historical Financial Information”.

The Historical Financial Information has been prepared in accordance with the stated basis of preparation, being the recognition and measurement principles contained in Australian Accounting Standards and the Company’s adopted accounting policies.

The Historical Financial Information has been extracted from the annual financial reports for the years ended 30 June 2023, 30 June 2022 and the period ended 30 June 2021. The annual financial reports have been audited by HLB Mann Judd (WA Partnership) in accordance with Australian Auditing Standards. The audit reports issued for the years ended 30 June 2023 and 30 June 2022 and the period ended 30 June 2021 included unmodified audit opinions.

The Historical Financial Information is presented in the Prospectus and Replacement Prospectus in an abbreviated form, insofar as it does not include all of the presentation and disclosures required by Australian Accounting Standards and other mandatory professional reporting requirements applicable to general purpose financial reports prepared in accordance with the *Corporations Act 2001*.

### **Pro Forma Historical Financial Position**

You have requested William Buck Consulting (WA) Pty Ltd to review the pro forma historical statement of financial position as at 30 June 2023 referred to as “the Pro Forma Historical Financial Position” as set out in section 8 of the Prospectus and Replacement Prospectus.

The Pro Forma Historical Financial Position has been derived from the historical statement of financial position of the Company as at 30 June 2023, after adjusting for the effects of the pro forma transactions and subsequent events described in section 8 of the Prospectus and Replacement Prospectus. The stated basis of preparation is the recognition and measurement principles contained in Australian Accounting Standards applied to the historical financial information and the events or transactions to which the pro forma transactions relate, as described in section 8 of the Prospectus and Replacement Prospectus, as if those events or transactions had occurred as at the date of the historical statement of financial position. Due to its nature, the Pro Forma Historical Financial Position does not represent the Company’s actual or prospective financial position.

### **Directors’ responsibility**

The Directors of the Company are responsible for the preparation of the Historical Financial Information and Pro Forma Historical Financial Position, including the selection and determination of pro forma adjustments made to the Historical Financial Information and included in the Pro Forma Historical Financial Position. This includes responsibility for such internal controls as the Directors determine are necessary to enable the preparation of Historical Financial Information and Pro Forma Historical Financial Position that are free from material misstatement, whether due to fraud or error.



## Our responsibility

Our responsibility is to express a limited assurance conclusion on the Historical Financial Information and the Pro Forma Historical Financial Position based on the procedures performed and the evidence we have obtained. We have conducted our engagement in accordance with the Standard on Assurance Engagements ASAE 3450 *Assurance Engagements involving Corporate Fundraisings and/or Prospective Financial Information*.

A review consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain reasonable assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Our engagement did not involve updating or re-issuing any previously issued audit or review report on any financial information used as a source of the financial information.

## Conclusions

### Historical financial information

Based on our review, which is not an audit, nothing has come to our attention that causes us to believe that the Historical Financial Information, as set out in section 8 of the Prospectus and Replacement Prospectus, and comprising:

- The historical consolidated statements of profit or loss and other comprehensive income for the financial years ended 30 June 2023, 30 June 2022 and the period ended 30 June 2021;
- The historical consolidated statements of cashflows for the financial years ended 30 June 2023, 30 June 2022 and the period ended 30 June 2021; and
- The historical consolidated statements of financial position as at 30 June 2023, 30 June 2022 and 30 June 2021;

are not presented fairly, in all material respects, in accordance with the stated basis of preparation as described in section 8 of the Prospectus and Replacement Prospectus.

### Pro Forma Historical Financial Position

Based on our review, which is not an audit, nothing has come to our attention that causes us to believe that the Pro Forma Historical Financial Position as set out in section 8 of the Prospectus and Replacement Prospectus being the Statement of Financial Position as at 30 June 2023 is not presented fairly in all material respects, in accordance with the stated basis of preparation as described in section 8 of the Prospectus and Replacement Prospectus.

## Restriction on Use

Without modifying our conclusions, we draw attention to section 8 of the Prospectus and Replacement Prospectus which describes the purpose of the Historical Financial Information and Pro Forma Historical Position, being for inclusion in the Prospectus and Replacement Prospectus. As a result, the Historical Financial Information and Pro Forma Financial Position, may not be suitable for use for another purpose.

We disclaim any assumptions of responsibility for any reliance on this Report or on the financial information to which this report relates for any purpose other than the purpose for which it was prepared. This Report should be read in conjunction with the Prospectus and Replacement Prospectus.

## Consent

William Buck Consulting (WA) Pty Ltd has consented to the inclusion of this Investigating Accountant's Report in the Prospectus and Replacement Prospectus in the form and context in which it is so included. At the date of this Report our consent has not been withdrawn. William Buck Consulting (WA) Pty Ltd makes no representation regarding, and takes no responsibility for any other statements, or material in, or omissions from, the Prospectus and Replacement Prospectus.

William Buck Consulting (WA) Pty Ltd has not authorised the issue of the Prospectus and Replacement Prospectus and our report should not be taken as an endorsement of the Company or a recommendation by William Buck Consulting (WA) Pty Ltd of any participation in the share issue by any intending investors.

## General Advice Limitation

This report has been prepared and included in the Prospectus and Replacement Prospectus to provide investors with general information only and does not take into account the objectives, financial situation or needs of any specific investor. It is not intended to take the place of professional advice and investors should not make specific investment decisions in reliance on this information contained in this report. Before acting or relying on information, an investor should consider whether it is appropriate for their circumstances having regard to their objectives, financial situation or needs.

## Disclosure of Interest

William Buck Consulting (WA) Pty Ltd does not have any interest in the outcome of the issue of shares other than in connection with the preparation of this report for which normal professional fees will be received.

Yours faithfully

*William Buck*

**William Buck Consulting (WA) Pty Ltd**

ABN 74 125 178 734

*Amar Nathwani*

Amar Nathwani

Director

Dated this 9<sup>th</sup> day of November 2023

# 10. Patent Report

## GRIFFITH—HACK

Directors  
LTR Pharma Limited  
9/204 Alice Street  
Brisbane  
QLD 4000

27 October 2023

Dear Sirs

### Intellectual Property Report

#### 1. Background

Griffith Hack has been instructed by LTR Pharma Limited to prepare this report for the initial public offering (IPO) by LTR Pharma Limited.

Griffith Hack has been informed that LTR Pharma Limited is a company formed to undertake clinical research in relation to treatment of erectile dysfunction with an intranasal vardenafil formulation. The technology related to this research has been licensed by LTR Pharma Limited from Strategic Drug Solutions, Inc.

Griffith Hack has been instructed to provide the details and status of patent matters in the intellectual property portfolio referred to in this report.

The report is current as at 26 September 2023. Griffith Hack is not aware of any material changes expected to occur to the status of the matters outlined below unless indicated.

#### 2. Overview of Intellectual Property Protection

Intellectual property (IP) may be protected through various IP rights including patents, trade marks, designs, Plant Breeders Rights, and trade secrets.

##### 2.1 Patent protection

A patent is one way to protect an invention such as an improved product, device, system, method, composition, or process, in a country in which the patent is granted.

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Melbourne VIC 3001 Australia  
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Suite 4.01, Level 4  
100 Arthur Street  
North Sydney NSW 2060 Australia  
GPO Box 4164  
Sydney NSW 2001 Australia  
T +61 2 9925 5900

**PERTH**  
Level 22  
77 St Georges Terrace  
Perth WA 6000 Australia  
T +61 8 9213 8300

**BRISBANE**  
Suite 1402, Level 14  
110 Eagle Street  
Brisbane QLD 4000 Australia  
GPO Box 3125  
Brisbane QLD 4001 Australia  
T +61 7 3232 1700

### **2.1.1 What is a Patent**

A patent is a temporary monopoly granted by a government to an inventor in return for fully disclosing the invention to the public in a patent specification. The disclosure is accomplished by providing a description of the invention, supported by drawings where appropriate, in sufficient detail to enable a competent person in the technical field of the invention to put the invention into practice. The monopoly provides the patentee with the exclusive right to exploit the invention, assuming the invention does not infringe a third party's prior patent or contravene other laws. Once the monopoly ends, the invention described in the specification becomes public property and may be freely used by anyone.

In most jurisdictions, the monopoly that is granted is usually 20 years. However, in some jurisdictions, this 20-year monopoly can be extended for a limited period under certain circumstances. An example of one circumstance where the 20 year term can be extended is where a patent is for a pharmaceutical substance and the pharmaceutical substance has obtained marketing approval in that jurisdiction.

In order for an invention to be patentable, it must meet the patent law requirements in the jurisdiction it is to be patented. In most jurisdictions, the invention must be novel, involve an inventive step (not be obvious) and be useful at the time of filing the patent application.

A patent application remains confidential for 18 months from its earliest filing date, after which time the specification, which contains a detailed description of the invention, is published.

In order to obtain patent protection in the jurisdictions of interest, a patent application is filed in each jurisdiction where patent protection is to be sought. The patent application is examined under the patent laws that apply in that jurisdiction, and if found to comply with the patent laws, a patent is granted in that jurisdiction.

### **2.1.2 International conventions relating to Intellectual Property**

Australia is a signatory to a number of international conventions relating to intellectual property. Some of the most important conventions that are relevant to IP protection are administered by the World Intellectual Property Organisation (WIPO). Set out below are extracts from WIPO summarising the Paris Convention for the Protection of Industrial Property and the Patent Cooperation Treaty.

### 2.1.2.1 Paris Convention for the Protection of Industrial Property

The Paris Convention applies to industrial property in the widest sense, including patents, trademarks, industrial designs, utility models (a kind of "small-scale patent" provided for by the laws of some countries), service marks, trade names (designations under which an industrial or commercial activity is carried out), geographical indications (indications of source and appellations of origin) and the repression of unfair competition.

The substantive provisions of the Paris Convention fall into three main categories: (a) national treatment, (b) right of priority, and (c) common rules.

#### (a) National Treatment

Under the provisions on national treatment, the Convention provides that, as regards the protection of industrial property, each Contracting State must grant the same protection to nationals of other Contracting States that it grants to its own nationals. Nationals of non-Contracting States are also entitled to national treatment under the Convention if they are domiciled or have a real and effective industrial or commercial establishment in a Contracting State.

#### (b) Right of Priority

The Convention provides for the right of priority in the case of patents (and utility models where they exist), marks and industrial designs. This right means that, on the basis of a regular first application filed in one of the Contracting States, the applicant may, within a certain period of time (12 months for patents and utility models; 6 months for industrial designs and marks), apply for protection in any of the other Contracting States. These subsequent applications will be regarded as if they had been filed on the same day as the first application. In other words, they will have priority (hence the expression "right of priority") over applications filed by others during the said period of time for the same invention, utility model, mark or industrial design. Moreover, these subsequent applications, being based on the first application, will not be affected by any event that takes place in the interval, such as the publication of an invention or the sale of articles bearing a mark or incorporating an industrial design. One of the great practical advantages of this provision is that applicants seeking protection in several countries are not required to present all of their applications at the same time but have 6 or 12 months to decide in which countries they wish to seek protection, and to organize with due care the steps necessary for securing protection.

(c) Common Rules

The Convention lays down a few common rules that all Contracting States must follow. The most important are:

(i) Patents

Patents granted in different Contracting States for the same invention are independent of each other: the granting of a patent in one Contracting State does not oblige other Contracting States to grant a patent; a patent cannot be refused, annulled or terminated in any Contracting State on the ground that it has been refused or annulled or has terminated in any other Contracting State.

The inventor has the right to be named as such in the patent.

(ii) Marks

The Paris Convention does not regulate the conditions for the filing and registration of marks which are determined in each Contracting State by domestic law. Consequently, no application for the registration of a mark filed by a national of a Contracting State may be refused, nor may a registration be invalidated, on the ground that filing, registration or renewal has not been effected in the country of origin. The registration of a mark obtained in one Contracting State is independent of its possible registration in any other country, including the country of origin; consequently, the lapse or annulment of the registration of a mark in one Contracting State will not affect the validity of the registration in other Contracting States.

Where a mark has been duly registered in the country of origin, it must, on request, be accepted for filing and protected in its original form in the other Contracting States. Nevertheless, registration may be refused in well-defined cases, such as where the mark would infringe the acquired rights of third parties; where it is devoid of distinctive character; where it is contrary to morality or public order; or where it is of such a nature as to be liable to deceive the public.

If, in any Contracting State, the use of a registered mark is compulsory, the registration cannot be cancelled for non-use until after a reasonable period, and then only if the owner cannot justify this inaction.

Each Contracting State must refuse registration and prohibit the use of marks that constitute a reproduction, imitation or translation, liable to create confusion, of a mark used for identical and similar goods and considered by the competent authority of

that State to be well known in that State and to already belong to a person entitled to the benefits of the Convention.

(iii) Industrial Designs

Industrial designs must be protected in each Contracting State, and protection may not be forfeited on the ground that articles incorporating the design are not manufactured in that State.

(iv) Trade Names

Protection must be granted to trade names in each Contracting State without there being an obligation to file or register the names.

(v) Indications of Source

Measures must be taken by each Contracting State against direct or indirect use of a false indication of the source of goods or the identity of their producer, manufacturer or trader.

(vi) Unfair competition

Each Contracting State must provide for effective protection against unfair competition.

### **2.1.2.2 Patent Cooperation Treaty**

The Patent Cooperation Treaty (PCT) makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an "international" patent application. Such an application may be filed by anyone who is a national or resident of a PCT Contracting State.

Filing an international application has the effect of automatically designating all Contracting States bound by the PCT on the international filing date. The effect of the international application is the same in each designated State as if a national patent application had been filed with the national patent office of that State.

The international application is subjected to an international search. That search is carried out by one of the competent International Searching Authorities (ISA) under the PCT and results in an International Search Report, that is, a listing of the citations of published documents that might affect the patentability of the invention claimed in the international application. In

addition, a preliminary and non-binding Written Opinion on whether the invention appears to meet patentability criteria, which takes into account the search report results, is also issued.

The International Search Report and Written Opinion are communicated to the applicant. If objections are raised in the Written Opinion, the applicant may file a response to address the objections raised in the Written Opinion by filing a request for International Preliminary Examination together with a response in which the claims may be amended to distinguish them from the citations identified in the Written Opinion, and/or submit arguments.

Alternatively, as the Written Opinion is non-binding on the national offices, the applicant may choose not to file a response to the Written Opinion and, instead, address the objections, if raised, during examination in the jurisdictions of interest.

The international application is published by the International Bureau 18 months from the earliest priority date of the application, typically together with the International Search Report. At the same time, the Written Opinion is made publicly available.

One of the main advantages of filing an international application is that it allows the applicant to delay national filing for up to 18 months (19 months in some jurisdictions). However, in order to obtain patent protection based on the international application, the applicant must within 30 months (or 31 months in some jurisdictions) of the earliest priority date, file national applications in the PCT contracting states of interest (national and regional phase applications).

The national phase applications are then examined by the national patent offices under the patent laws of each of those jurisdictions.

### **2.1.3 Other conventions relating to Patent Protection**

A convention commonly relied on for patent protection in Europe is the European Patent Convention.

#### **2.1.3.1 European Patent Convention**

The European Patent Convention (EPC) provides a single European procedure for the grant of a patent based on a single European application. Under the EPC, a single European application is filed and examined by the European Patent Office (EPO). The EPO conducts a



search and issues an examination report, and once the application is in order for allowance, a European patent is granted on the application.

Following grant of a European patent, in order to be enforceable in a contracting state, the European patent must be validated in that contracting state, and/or must become a Unitary Patent.

The contracting states of the EPC are: Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

A patentee may validate their European patent in the countries of interest, and/or obtain a Unitary Patent.

Not all contracting states of the EPC are covered by a Unitary Patent. Therefore, for those states not covered by a Unitary Patent, validation is required if protection is needed in those contracting states not covered by the Unitary Patent. The countries that are currently participants in the Unitary Patent are: Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Slovenia, and Sweden.

If validated in a contracting state, infringement and validity of a European patent is dealt with by national law.

If the European patent becomes a Unitary Patent, infringement and validity of a European patent is dealt with by the Unified Patent Court.

#### **2.1.4 Patent procedure overview**

The usual first step towards patent protection is to file a provisional patent application, which establishes a priority date in accordance with the Paris Convention. The priority date is the date at which novelty and inventive step is assessed. In order to maintain the priority date established by filing of the provisional patent application, a complete patent application must be filed within 12 months of the filing of the provisional patent application.

The complete patent application may be filed directly as a national application in the jurisdictions of interest, or as an international (PCT) application filed under the Patent Cooperation Treaty as mentioned in section 2.1.2.2 above.

After filing the patent applications in the jurisdictions of interest (either by direct national filings, or through national phase entry from an international (PCT) application), the patent applications will then be examined by the national Office in each of the jurisdictions in which the patent applications are filed under the national laws for that jurisdiction. If a national Office has grounds to object to a patent being granted, they will issue an Office Action stating the grounds of objection. The applicant will be given an opportunity to address the grounds of objection (through amendment and/or argument). Once a national Office is satisfied that a patent application complies with its laws, and provided the application is not opposed by a third party, the national Office will then grant a patent in that jurisdiction.

In order for a patent to be enforceable in a jurisdiction, it must be granted in that jurisdiction and it must not have lapsed.

### **2.1.5 Patent renewal fees**

Patent applications and patents are subject to payment of renewal fees over the life of the patent in order to maintain patent rights. Failure to pay renewal fees may result in lapsing of the patent or patent application.

## **2.2 Trade mark protection**

### **2.2.1 What is a trade mark**

A trade mark is a word, phrase, letter, number, sound, smell, shape, logo, picture or aspect of packaging used to distinguish goods or services from those of other traders. A trade mark may be protected through registration of the trade mark in jurisdictions of interest.

Trade mark protection may also arise for a trade mark without registration where that trade mark has developed a substantial reputation in the market place.

Trade mark registrations remain valid for 10 years from the filing date and may be renewed every 10 years upon payment of applicable fees.

The owner of a registered trade mark has the exclusive right to use, license or sell the trade mark for the goods and/ or services for which it is registered. A registered trade mark owner is also entitled to take legal action to prevent unauthorised use of the trade mark.

Applicants for a trade mark must use, or have an intention to use, the subject trade mark in relation to the goods or services included in a trade mark application.

Trade marks may be protected in jurisdictions of interest by filing separate National applications in each jurisdiction of interest, by filing an application for a European Union Trade Mark, or by filing an international application to register a trade mark designating one or more members of the Madrid System, which is administered by the World Intellectual Property Organization.

## **2.2.2 International protection of Trade Marks**

### **2.2.2.1 Madrid System**

An application for international registration under the Madrid System may be filed by a national of a country that is party to the Madrid Agreement or the Madrid Protocol. The Madrid System makes it possible to protect a mark in a large number of countries by obtaining an international registration that has effect in each of the designated Contracting Parties. Under the Madrid System, an applicant can register and manage protection of a trade mark in over 128 countries at the same time in one application.

Filing an international application under the Madrid System has a number of advantages. The main advantage is that the process of obtaining trade mark protection in multiple jurisdictions is easier and more cost-effective as only one application needs to be filed in a single language with the payment of a single fee.

### **2.2.3 Trade mark procedure overview**

An application to register a trade mark is filed at a national trade mark office by providing a copy of the trade mark with a description of the goods and/or services for which the trade mark protection is sought.

The trade mark office will conduct a search and examine the trade mark to establish, among other things, whether the trade mark is adapted to distinguish the goods and services for which the registration is sought, and whether the trade mark is not similar to an existing trade

mark for the same or similar goods and services. If the application meets all the requirements for trade mark registration, the trade mark application will be accepted, and the acceptance published and open for opposition. Provided the application is not opposed, the trade mark will then be registered. Registration is initially for 10 years, and may be renewed at 10 year intervals thereafter upon payment of applicable fees.

Applications for trade marks in foreign jurisdictions (e.g., by filing separate national applications in each jurisdiction of interest or by filing an international application under the Madrid System) may be filed with 6 months of the initial filing date to maintain a priority date of the trade mark. Alternatively, trade marks can be filed in jurisdictions of interest when commercially appropriate for the trade mark owner (e.g., when business expands to other countries).

#### **2.2.4 Maintaining a trade mark registration**

Trade mark registrations remain valid subject to payment of applicable fees and use of the trade mark in the course of trade. It is important that registered trade mark owners use their trade marks to avoid potential cancellation of their registration for non-use.

### **3 Patent Portfolio**

Annexure 1 to this report provides details of the patents in the licensed patent portfolio.

As shown in Annexure 1, the patent portfolio relates to one invention covered by national and regional phase applications and an International PCT application. These patent applications are open for public inspection.

The national and regional phase applications will proceed to examination in due course where an Examiner will review each application and raise any objections relating to patentability of the claims. These objections may be addressed by amendment or argument.

For pending PCT applications, applications in each contracting state of interest will need to be filed either 18 or 19 months from the filing date of the International PCT application depending on the rules of the Contracting State, i.e. by 26 November 2023 or 26 December 2023.

### **4 Ownership**

The licensor, Strategic Drug Solutions, Inc. is listed as the owner/applicant on each of the patent applications in Annexure 1 and has provided representations, warranties and covenants

that it has full corporate power and authority to enter into the exclusive licensing agreement with LTR Pharma Pty Limited.

## **5 Trade mark portfolio**

Annexure 2 to this report provides details of the trade mark registration owned by LTR Pharma Limited.

The trade mark is currently registered in the previous corporate name of LTR Pharma Pty Ltd. A request was submitted to IP Australia on 26 October 2023 to change the owner name to LTR Pharma Limited.

## **6. Limitations and Disclaimers**

### ***Grant of a patent provides no guarantee of validity***

Grant of a patent by a national patent office provides an indication of validity, but not a guarantee of validity. In most jurisdictions, a patent application is subject to examination in relation to validity, but a patent once granted may still be challenged by way of revocation proceedings undertaken in a court or may be subject to re-examination proceedings by a Patent Office.

### ***Freedom to operate***

Grant of a patent provides that a patentee is entitled to exploit the patented invention. However, grant of a patent does not mean that working the patented invention will not infringe an earlier patent of a third party.

### ***Scope of claims may vary before grant***

During examination of a patent application, amendments may be made to define the invention more clearly or to avoid earlier publications. Accordingly, the claims may vary in scope in each country in which a patent is pursued and the claims granted may be of different scope to those claims that are pending before or during examination. It is the scope of the claims as granted that forms the scope of the monopoly provided by the patent.

### ***Changes to Patent Law***

From time to time, legislation that governs grant of patents in each country are amended. Furthermore, court decisions may also result in variations in interpretation of legislation. These changes may affect the validity of patents or the scope of protection that may be obtained.

**Search Limitations**

Patent Offices and Search Authorities may produce search reports detailing publications that may affect the validity of claims pending in a patent application. These searches may not identify all documents relevant to the claims of a patent application. Searches cannot identify documents that have not been published. In most countries, patents are published 18 months after the earliest filing date. Therefore, there is a period of time in which relevant documents may not be located. Delays between official publication and uploading into databases may also occur. The accuracy and scope of the databases searched and the search criteria used may also affect the search results and whether it identifies relevant documents. In light of this, no search can be considered entirely exhaustive. Furthermore, a search of databases may not identify oral presentations, public uses or commercial exploitations that may not be the subject of public documents.

**Griffith Hack's Interest**

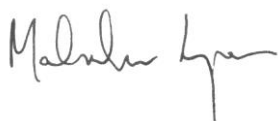
Griffith Hack has been asked to provide this report based on information provided to it by LTR Pharma Limited. Griffith Hack is not responsible for providing patent services in relation to the patents in Annexure 1. Information derived in Annexure 1 is available publicly.

Griffith Hack's associated law firm Griffith Hack Law Pty Ltd provides trade mark services in relation to the trade mark in Annexure 2. Information in Annexure 2 has, however, been derived from the public records of the Australian Trade Mark Office.

**Consent**

Consent for inclusion of this Report in an IPO for LTR Pharma Limited, in the form in which it now appears, has been granted by Griffith Hack.

Yours faithfully  
GRIFFITH HACK



**Dr Malcolm Lyons**  
**Principal**

malcolm.lyons@griffithhack.com.au

# GRIFFITH—HACK

## Annexure 1

Jurisdiction	Application No.	Filing date	Title	Applicant	Status
USA	63/029,881	26 May 2020	Formulations and methods for treating erectile dysfunction	Strategic Drug Solutions, Inc.	Expired, continued as PCT/US2021/034334
WIPO	PCT/US2021/034334	26 May 2021	Formulations and methods for treating erectile dysfunction	Strategic Drug Solutions, Inc.	Expired, continued as national and regional phase applications
Australia	2021280285	26 May 2021	Formulations and methods for treating erectile dysfunction	Strategic Drug Solutions, Inc.	Pending
Brazil	112022024098	26 May 2021	Formulations and methods for treating erectile dysfunction	Strategic Drug Solutions, Inc.	Pending
Canada	3179630	26 May 2021	Formulations and methods for treating erectile dysfunction	Strategic Drug Solutions, Inc.	Pending
China	202180076999	1 December 2021	Formulations and methods for treating erectile dysfunction	Strategic Drug Solutions, Inc.	Pending
Europe	21811862	26 May 2021	Formulations and methods for treating erectile dysfunction	Strategic Drug Solutions, Inc.	Pending
Hong Kong	62023071402.9	26 May 2021	Formulations and methods for treating erectile dysfunction	Strategic Drug Solutions, Inc.	Pending
Israel	29843222	26 May 2021	Formulations and methods for treating erectile dysfunction	Strategic Drug Solutions, Inc.	Pending
Singapore	11202301972T	1 December 2021	Formulations and methods for treating erectile dysfunction	Strategic Drug Solutions, Inc.	Pending
WIPO	PCT/US2021/061488	1 December 2021	Formulations and methods for treating erectile dysfunction	Strategic Drug Solutions, Inc.	Pending

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**Annexure 2**

<b>Jurisdiction</b>	<b>Number</b>	<b>Registered owner</b>	<b>Trade Mark</b>	<b>Filing Date</b>	<b>Date entered on Register</b>	<b>Status</b>
Australia	2259335	LTR Pharma Pty Ltd	SPONTAN	29 March 2022	7 November 2022	Registered  Renewal due 29 March 2032

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## 11. Risk Factors

This section identifies some, but not all, of the major risks associated with an investment in the Company. Intending Applicants should read the whole of this Prospectus in order to fully appreciate such matters and the manner in which the Company intends to operate before any decision is made to subscribe for Shares.

### 11.1 Speculative nature of investment

Any potential investor should be aware that subscribing for Shares involves various risks. The Shares to be issued pursuant to the Prospectus carry no guarantee with respect to the payment of dividends, returns of capital or the market value of those Shares. An investment in Shares of the Company should therefore be considered very speculative.

### 11.2 Business risks associated with the Company

(a) Sufficiency of funding

The funding proposal (incorporated in the Company's Expenditure Program) detailed in this Prospectus is based on the Company's best estimation of cash flow projections and estimated expenditures for a 24-month period post Listing. The Company has limited operating history and may face difficulties encountered by similar early-stage companies.

LTP has finite financial resources and will need to raise additional funds from time to time to finance the complete development and commercialisation of its products and achievement of its other longer-term objectives. LTP product development activities may never generate revenues and LTP may never achieve profitability. LTP's ability to raise additional funds will be subject to, among other things, factors beyond the control of LTP and its board, including cyclical factors affecting the economy and share markets generally.

(b) Innovative technological development – early clinical state of development:

LTP's candidate product is proceeding to a bioequivalence trial. 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. Substantial further clinical development may be necessary beyond the anticipated bioequivalence trial contemplated by the Company in order to commercialise SPONTAN<sup>®</sup>.

If it is ultimately shown to be ineffective for therapeutic purposes, the Company's business, the value of its assets and resulting value of its Shares may be materially harmed. However, an investigator lead, human proof of concept study completed in February 2020 has already shown positive outcomes in a separate clinical study (see section 5.7 for more information).

(c) 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. While competition in the ED drug market is limited, 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. As noted earlier, LTP anticipates market exclusivity protection in the United States for SPONTAN<sup>®</sup> for a period of 3 years subject to receiving regulatory approval by the FDA.

(d) 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.

(e) 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

(f) Expenditure program

LTP has entered into contracts for a number of the material items anticipated to be covered by the expenditure program set out in the Expenditure Program. The Directors have determined that following the successful close of the Offers, the Company will be well positioned to negotiate the exact terms of all remaining contracts related to its Expenditure Program.

It is possible that actual expenditure may be more than estimated by the Company in its anticipated Expenditure Program. This could, depending on the difference in actual costs, require the Company to seek to raise additional funding.

The Directors and management have relevant industry experience and have prepared the anticipated Expenditure Program based partly on discussions with, or indicative quotes obtained from, potential suppliers of those services and their own experience of the likely costs for those expenditure items. While the Directors are confident that the Company will be able to source suitable suppliers, there is a risk that the Company may not be able to source those suppliers at the estimated expenditure in the Expenditure Program.

(g) Bioequivalence clinical trials - regulatory requirements

The active drug in SPONTAN<sup>®</sup>, Vardenafil, has been proven safe for humans in human trials for ED (when used as an oral tablet), and is therefore significantly de-risked for administration in humans, albeit clinical trials will still be required for bioequivalence as a nasal delivery product. Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory and legal requirements.

Even at its advanced stage of development, LTP's trial design can change which may have an adverse impact on cost and time of LTP's proposed clinical trials. Clinical trials of the LTP's product may take several years to complete. There is a risk that the FDA and/or the TGA may not approve LTP's proposed regulatory approval application, and this may require LTP to undertake more trials and cause a delay in the LTP's product launch.

Clinical development of LTP's product may also fail for a number of other reasons, including lack of efficacy or presence of adverse side effects. Failure can occur at any stage of the trials, requiring LTP to abandon or repeat clinical trials. LTP and/or the relevant regulatory authorities, human research ethics committees and institutions where the clinical trials are conducted, may suspend LTP's clinical trials at any time if it appears that the trials are exposing the trial participants and/or the staff involved in conducting the clinical trial to unacceptable health risks. Clinical trial participants may also suffer unintentional harm when participating in the trial despite Vardenafil having previously been proven safe for human consumption (when used as an oral tablet) – this risk exposes LTP to significant monetary and reputational damage. In that event, the Company's liability may exceed the Company's insurance coverage. To the extent that any study participant is injured, LTP proposes to adhere to the "Guidelines for Compensation for Injury Resulting from Participation in a Company-sponsored Clinical Trial" published by Medicines Australia.

LTP has existing positive clinical data and a clearly defined path to market; however, as for all biotechnology and pharmaceutical development companies, there is the risk that despite conducting the relevant clinical trial in compliance with regulatory requirements, the results of the trial do not support any further development or result in a rejection by the relevant regulator. As a result, LTP may fail to commercialise or out-license any products.

(h) 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.

(i) 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. There is also no guarantee that the intellectual property rights LTP has licenced under the SDS Licence Agreement

comprise all of the rights that LTP may require to freely develop and commercialise the 'licensed products'.

Patent applications in significant markets have been lodged in the name of SDS. However, there is no assurance that those patent applications will result in granted patents in all desired jurisdictions.

Even though these patent applications may be successful (resulting in granted patents) a competitor may at any time challenge granted patents and a court may find that although a patent has been granted it is deemed to be invalid or unenforceable or is revoked. It is possible a court may find that SDS or the Company's entitlement is subsequently revealed not to have existed, may not have any exclusive patent rights or any patent rights at all and may be prevented from developing and/or commercialising its products. If SDS or 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 the SDS Licence Agreement (refer to section 13.7(a) for further details). If this licensing arrangement was to be jeopardised, it could have significant detrimental effects on the Company's business.

(j) 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. Non-disclosure agreements exist between the Company, its employees and any contract resource organisations, advisers, consultants and service providers with whom LTP engages.

(k) Infringements of third-party intellectual property

If a third party accuses the Company of infringing its intellectual property rights or if a third party commences litigation against LTP or SDS 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. In the event of a successful claim of infringement against LTP, it may be required to pay damages and obtain one or more licenses from the prevailing third party, or may not be in a position to continue with product development.

(l) 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 possible risks of disruption to its

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business operations. A disruption in the Company's operations / service access may have an adverse impact on the Company's growth prospects, operating results and financial performance.

(m) Dependence on service providers

The Company intends to operate a significant amount of its key clinical activities (and ultimately manufacturing and distribution 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. Such failure can lead to termination and/or significant damage to the Company's product development efforts.

(n) 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. The Company has no plans at this stage to hedge its foreign currency payments.

(o) Contractual and counterparty risks

As a party to many contracts, the Company will have various contractual rights in the event of non-compliance by a contracting party. However, no assurance can be given that all contracts will be fully performed by all contracting parties and that the Company will be successful in securing compliance with the terms of each contract by the counterparties to its contracts.

The Company's material contracts contain provisions providing for early termination of the contracts, on giving notice and paying a termination amount (which varies between the contracts). The early termination of any of these contracts, for any reason, may mean that the Company will not realise the full value of the contract, which is likely to adversely affect the growth prospects, operating results and financial performance of the Company.

(p) Litigation

The Company is not currently involved in any material contractual disputes or litigation, arbitration or government prosecution matters. There is a risk that the Company may in the future have disputes and this may have an adverse impact on the Company's growth prospects, operating results and financial performance.

### 11.3 Intellectual property

(a) Intellectual property

SDS has lodged various patent applications (as detailed in section 10) relating to the SDS-089 formulation. Patent applications are commonly drafted with a very broad ambit scope of claims - as different claim scopes are often allowed in different jurisdictions. This approach is important initially so as not to unduly

limit the potential coverage of the relevant patent application. An initial rejection by a patent examiner of such broad ambit claims is also commonly received and then the applicant in conjunction with discussions with the patent examiner narrows the claims for that particular jurisdiction to achieve allowance of the more narrow claims and subsequent patent grant. No assurance is given that the patent applications will result in granted patents.

Furthermore, even if some the patent applications are successful (i.e., resulting in granted patents) investors should note that a competitor may at any time challenge granted patents and a court may find that although a patent has been granted it is invalid or unenforceable or revoked. It is possible a court may find that the Company's entitlement is subsequently revealed not to have existed, may not have any exclusive patent rights or any patent rights at all and may be prevented from developing and/or commercialising its products. If the relevant intellectual property rights are ever challenged SDS and/or the Company may not have the funds to oppose the challenge.

Until such time that the licenced patent rights have been assigned to LTP (pursuant to the terms of the SDS Licence Agreement, see section 13.7(a)), LTP may not be able to enforce its rights to the licensed patent rights in Australia and may have to rely on SDS to do this. Further, until such time that the patents rights licensed to LTP under the SDS Licence Agreement have been assigned to LTP, LTP is (subject to the SDS Licence Agreement) dependent on SDS to prosecute and maintain the patents in its name. If SDS does not prosecute and/or maintain the patents rights, the value of the licence may significantly diminish, and may also affect the intellectual property ultimately assigned to LTP (if any).

(b) Trade secrets

The Company relies on trade secrets, which include information relating to the manufacture, development and administration of its therapeutic products. The protective measures employed may not provide adequate protection for those trade secrets. This could erode the Company's competitive advantage and materially harm its business. The Company 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.

(c) Infringement of third-party intellectual property

If a third party accuses SDS or the Company of infringing its intellectual property rights or if a third party commences litigation against the Company for the infringement of patent or other intellectual property rights, the Company may incur significant costs in defending such action, whether or not it ultimately prevails (and depending on the circumstances, may not have effective or sufficient recourse against SDS (where relevant), see section 13.7(a) for more details in relation to SDS' liability under the SDS Licence Agreement).

Costs that the Company incurs in defending third party infringement actions would also include diversion of management's and technical personnel's time. In the event of a successful claim of infringement against the Company, it may be required to pay damages and obtain one or more licences from the prevailing third party. If it is not able to obtain these licences at a reasonable cost, if at all, it could encounter delays in product introductions and loss of substantial resources while it attempts to develop alternative products.

(d) Ownership of improvement of intellectual property and enforcement

To the extent an agreement that the Company is a party to is silent on the ownership of improvements to intellectual property. If any improvements have been made, or are likely to have been made, to the Company's background intellectual property under that agreement, the ownership of such developments may come into dispute if the developed intellectual property is claimed by the counterparty to such relevant agreements.

LTP's scope of rights to undertake research and development with respect to the intellectual property licensed to it under the SDS Licence Agreement is not expressly stated. If any party makes a claim against LTP's relevant intellectual property and associated rights, the Company would vigorously defend its position. The Company is of the view that its relevant rights are adequately protected, however, in circumstances where a claim is made against LTP, and if ultimately such a claim is successful, the value of LTP's intellectual property may be diminished, and this may in turn adversely affect the value of the Company and its Shares.

For more information in relation to the Company's material agreements, please refer to section 13.7.

#### 11.4 General risks

Most of the general risks discussed below are outside the control of the Company and the Directors and cannot be mitigated.

(a) Market for Shares

Prior to the Offers there has been no public market for the Shares. No assurance can be given that an active market will develop in the Shares or that the Shares will trade at or above the Offer Price after the Shares have been listed on the Official List and after Official Quotation.

(b) Stock market volatility

The price of Shares may rise or fall depending upon a range of factors beyond the Company's control and which are unrelated to the Company's operational performance. Investors who decide to sell their Shares after the Company's listing may not receive the entire amount of their original investment. The price of Shares listed on ASX may also be affected by a range of factors including the Company's financial performance and by changes in the business environment.

The Shares carry no guarantee in respect of profitability, dividends, return on capital, or the price at which they may trade on ASX.

There are a number of national and international market factors that may affect the Share price including movements on international stock markets, economic conditions and general economic outlook, interest rates and exchange rates, inflation rates, commodity supply and demand, government taxation and royalties, legislation, monetary and other policy changes and general investors' perceptions. Neither the Company nor its Directors have control over these factors.

(c) General economic conditions

The general economic climate may affect the performance of the Company. These factors include the general level of international and domestic economic activity, inflation and interest rates. These factors are beyond the control of the Company and their impact cannot be predicted.

(d) Taxation

There are tax implications arising from buying and selling Shares, the receipt of dividends (both franked and unfranked) (if any) from the Company and participation in any on-market Share buy-back. Investors should seek their own independent taxation advice before applying for Shares.

(e) Insurance risks

Although the Company maintains insurance, no assurance can be given that adequate insurance will continue to be available to the Company in the future on commercially acceptable terms.

(f) Government actions and other events

The impact of actions by domestic and international governments may affect the Company's activities, including in relation to its infrastructure, compliance with environmental regulations, export, taxation and royalties.

Events may occur within or outside Australia that could impact on the world economy, the market for the Company's product candidates, the Company's operations and the price of the Shares. These events include war, acts of terrorism, civil disturbance, political intervention and natural disasters. The Company has only a limited ability to insure against some of these risks.

(g) Foreign regulatory structures and laws

Any changes to the laws and regulations in relation to the regulatory approval and sale of therapeutic goods (including the laws and regulations of the FDA) could also adversely affect the Company's clinical trials, NDA and commercialisation.

(h) Unforeseen expenses

The proposed expenditure on the Company's projects may be adversely affected by any unforeseen expenses which arise in future and which have not been considered in this Prospectus.

## 11.5 Expenditure Program

LTP has entered into contracts for a number of the material items anticipated to be covered by the expenditure program set out in the Expenditure Program. The Directors have determined that following the successful close of the Offers, the Company will be well positioned to negotiate the exact terms of all remaining contracts related to its Expenditure Program. The Directors have extensive experience in the therapeutic goods industry and have prepared the anticipated expenditure detailed in section 5.12 based on executed contracts and discussions with potential suppliers of those services and their own experience of the likely costs for those expenditure items.



## **11.6 No independent valuation**

No independent valuation has been undertaken of LTP for the purposes of the listing. Valuations of biotechnology before commercial use can be imprecise.

## **11.7 Prospective information**

No assurance as to future profitability or dividends can be given as they are dependent on successful product development, future earnings and the working capital requirements of the Company.

There can be no guarantee that the assumptions on which the financial forecasts and development strategies of the Board, or those upon which the Company bases its decisions to proceed, will ultimately prove to be valid or accurate. The forecasts and development strategies depend on various factors many of which are outside the control of the Company.

Changes in interest rates, exchange rates, government budgetary measures, relevant taxation and other legal regimes and Government policies may adversely affect the Company.

The Directors expect that the proceeds of the public capital raising, and borrowings will provide sufficient capital resources to enable the Company to achieve its current business objectives. The Directors can give no assurance, however, that such objectives can be met without future financing or, if future financing is necessary, that it can be obtained on favourable terms.

## **11.8 Concluding comment**

The above list of risk factors ought not to be taken as an exhaustive one of the risks faced by the Company or by investors in the Company. The above factors, and others not specifically referred to above, may in the future materially affect the financial performance of the Company and the value of the Shares offered under this Prospectus. Therefore, the Shares to be issued pursuant to this Prospectus carry no guarantee with respect to the payment of dividends, returns of capital or the market value of those Shares. Investment in the Company must be regarded as highly speculative and neither the Company nor any of its Directors, or any other party associated with the preparation of this Prospectus, guarantees that any specific objectives of the Company will be achieved or that any particular performance of the Company or of the Shares, including those offered by this Prospectus, will be achieved.

## 12. Taxation

### 12.1 Overview of taxation

The information in this Section provides a general overview of the tax implications for shareholders who acquire Shares under this Prospectus and that hold Shares in the Company on capital account for income tax purposes.

This summary does not constitute financial product advice as defined in the Corporations Act. This summary is confined to Australian taxation implications and is only one of the matters which need to be considered by Shareholders before deciding about an investment in the Shares.

Investors should note that tax laws are subject to ongoing change, and this section does not consider any changes in administrative practice or interpretation by the relevant tax authorities, or any changes in law by judicial decision or legislation following the Prospectus Date. To the extent that there are any changes in law after the Prospectus Date, including those having retrospective effect, Shareholders should consider the tax consequences, taking into account their own individual circumstances, and should consider taking advice from a professional advisor before making a decision about an investment to acquire Shares under this Prospectus.

There will be tax implications for the acquisition and disposal of Shares which will affect individual Shareholders differently depending on an individual's circumstances, and it is recommended that Shareholders consult their own independent advisors regarding taxation consequences, including stamp duty, income tax and Australian goods and services tax (**GST**) consequences of the acquisition, ownership and disposal of Shares. This summary is general in nature and does not cover all income tax consequences that could apply in all circumstances of any Shareholder.

The categories of Shareholders considered in this Section are limited to individuals, companies (other than life insurance companies), trusts, partnerships and complying superannuation funds that hold their Shares on capital account, and it does not consider Shareholders that hold Shares on revenue account, carry on a business of trading in Shares, are exempt from Australian tax, insurance companies, banks or Shareholders who are subject to the Taxation of Financial Arrangements rules contained in Division 230 of the *Income Tax Assessment Act 1997* (Cth).

This Section also assumes that each Shareholder (together with its associates) holds at all relevant times less than 10% of the Shares in the Company.

To the maximum extent permitted by law, the Company, its officers and each of their respective advisors accept no liability and responsibility with respect to the taxation consequences of subscribing for Shares under this Prospectus.

All legislative references are to the *Income Tax Assessment Act 1997* (Cth) and the *Income Tax Assessment Act 1936* (Cth) (collectively referred to as the **Tax Act**), unless stated otherwise.

### 12.2 Taxation treatment of the acquisition of Shares

The Offers include the acquisition of Shares which will constitute an equity interest for Australian tax purposes. There are no immediate income tax consequences to the acquirer on the acquisition of equity interests.

## 12.3 Taxation treatment of dividends

### Overview

The treatment of the dividends which may be paid to investors whilst holding shares will vary depending on whether or not the investor is an Australian resident or non-resident Shareholder. The taxation treatment will also vary depending on the extent to which any dividends are franked.

### Dividends received by Australian resident investors

Dividends received by Australian resident investors will be assessable income for Australian tax purposes. Generally, both the amount of the cash dividend received and an amount equal to the franking credits attached to a franked dividend must be included in assessable income in the year of receipt. An Australian resident shareholder would be entitled to a franking offset against the income tax on this assessable dividend income. However, it is important to note that securities must be held 'at risk' for a period of more than 45 days, in order for any investor to be able to claim an offset for franking credits.

The level of franking credits attached to such dividends will depend on the level of franking credits generated and available to the Company, through the payment by it of Australian company tax.

The tax treatment in respect of the dividends from ordinary shares will vary depending on the nature of the investor, as follows:

#### (i) Individual Investors

An individual receiving a dividend that is unfranked will include the amount of the dividend in their assessable income, with tax being paid at the individual's marginal rate of tax.

Where the dividend is fully or partly franked, the individual's assessable income is grossed up to include the franking credit attaching to the dividend. The individual should then be entitled to a tax offset equal to the amount of the franking credit.

Where the individual's marginal rate of tax is greater than the applicable corporate tax rate (which is currently 30%, unless the company qualifies for the lower base rate entity tax rate of 25.0% for the income year), further tax will be payable on the grossed up dividend. This is commonly referred to as "top-up tax".

Where the individual's marginal rate of tax is less than the applicable corporate tax rate, a tax offset is available to reduce tax payable on other income or alternatively results in a refund of the excess franking credits.

#### (ii) Corporate investors

A corporate investor receiving an unfranked dividend will pay tax on this dividend (net of any allowable deductions) at the applicable corporate tax rate (which is currently 30%, unless the company qualifies for the lower base rate entity tax rate of 25%).

Where dividends are franked, the corporate investor will gross up its assessable income by the amount of the franking credit. The corporate investor should then be entitled to offset the franking credit against its tax liability for the year. To the extent that the franking credit exceeds the corporate investor's tax liability, the excess can be converted into a carry forward loss and offset against future taxable profits (subject to the loss testing rules for companies). Generally a corporate investor cannot receive a refund of franking credits.

Further, the franked dividend may give rise to a franking credit in the corporate investor's franking account.

**(iii) Complying Superannuation Funds**

Complying superannuation funds (which include self-managed superannuation funds) are assessable on the dividend and gross up the franked dividend in the same way as individuals and corporate investors.

A complying superannuation fund investor receiving an unfranked dividend will pay tax on this dividend (net of any allowable deductions) at the rate of 15% (current, as at the date of this Prospectus).

Where dividends are franked, the complying superannuation fund investor will include in its assessable income the amount of dividend received and the amount of any franking credits attached to that dividend. The complying superannuation fund tax rate of 15% is then applied to the grossed up dividend.

The franking credit is available to offset tax payable on other income of the complying superannuation fund or alternatively results in a refund of the excess franking credits.

**(iv) Trusts and partnerships**

Investors who are trustees (other than trustees of complying superannuation funds) or partnerships should include the dividend received and the franking credit in determining the net income of the trust or partnership. The relevant beneficiary or partner may be entitled to a share of the tax offset equal to the beneficiary's or partner's share of the net income of the trust or partnership.

**(b) Dividends received by non-resident investors**

The taxation treatment of dividends received by non-resident investors will depend on whether the dividends paid are franked or unfranked, as outlined below.

**12.4 Franked dividends**

Non-resident investors will not be subject to Australian withholding tax on that part of the dividend that is fully franked. However, non-resident investors may be subject to income tax on the receipt of such dividends in their local jurisdictions.

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## 12.5 Unfranked dividends

It may be necessary for the Company to withhold tax from unfranked dividends paid to non-resident Shareholders and remit the tax to the Australian Taxation Office. Where unfranked dividends are paid to non-resident Shareholders, and the unfranked dividend is not declared to be “conduit foreign income”, dividend withholding tax must be deducted from the gross dividends paid.

The withholding tax rate on the payment of unfranked dividends per Australia’s domestic income tax law is 30%. However, where the investor is resident of a country which Australia has entered into a double tax treaty with, then the rate at which withholding tax is applied will generally be lower, typically ranging from nil to 15%.

Again, non-resident Shareholders may still be subject to income tax on the receipt of such dividends in their local jurisdictions but may be entitled to a credit for the Australian withholding tax applied.

## 12.6 Taxation treatment of disposal of Shares

As noted above, the following overview of Australian tax implications associated with the disposal of Shares is confined to investors who hold their shares on capital account.

### (a) Disposal of Shares by Australian resident investors

The disposal of a Share by a Shareholder will give rise to a capital gains tax (CGT) event where the investor holds their Share on capital account. Australian tax resident investors will:

- (i) make a capital gain where the capital proceeds received on the disposal of the Share exceed the cost base of the Share; or
- (ii) make a capital loss where the capital proceeds received on the disposal of the Share are less than the reduced cost base of the Share.

The capital proceeds will generally be equal to the amount received for the disposal of the Share. Broadly, the cost base and reduced cost base (subject to modifications) of a Share will be equal to the original Offer Price of the Share plus any incidental costs of acquisition and disposal (such as brokerage).

If investor Shareholder is an individual or complying superannuation entity and has held the Share for at least 12 months or more before disposal of the Share, the Shareholder will generally be entitled to a “CGT discount” for any capital gain made on the disposal of the Share. Where the CGT discount applies, any capital gain arising (after applying any available capital losses) may be reduced by:

- 50% in the case of individuals; or
- one-third in the case of complying superannuation entities.

Investors that are companies are not entitled to a CGT discount. Any resulting net capital gain is included in an investor’s assessable income.

Where the disposal results in a net capital loss and the investor has no remaining capital gains to offset, the capital loss is carried forward and may be

available to be offset against capital gains in future years (subject to the satisfaction of any applicable loss recoupment rules). Capital losses cannot be used to reduce ordinary assessable income (only capital gains).

(b) **Disposal of Shares by non-resident investors**

Generally, for Australian income tax purposes, non-resident Shareholders can disregard the capital gain or capital loss arising from the disposal of shares in Australian resident companies under Division 855 of the Tax Act.

Notwithstanding the above comments, certain non-resident Shareholders will still be subject to Australian CGT where the Shares constitute Taxable Australian Property (**TAP**). Broadly, the Shares should only constitute TAP if both of the following requirements are satisfied:

- the investor (together with any associates) holds an interest of at least 10% of the Shares in the Company at the time of the disposal, or for a 12-month period in the 24 months preceding the disposal; and
- more than 50% of the market value of the Company's assets is comprised of Australian real property interests.

Based on the understanding that the Company does not hold a significant amount of Australian real property interests, any capital gain or loss arising to a non-resident investor on disposal of the Shares is not expected to relate to TAP and should therefore be disregarded. However, this would need to be assessed at the time of disposal.

## **12.7 Quotation of Tax File Number**

It is not compulsory for Australian resident Shareholders to provide the Company with details of their Tax File Number (**TFN**) or Australian Business Number (**ABN**). However, a failure to quote a TFN or ABN (or proof of exemption) to a public company will result in the company being required to withhold and remit tax at the top marginal rate (currently 45% plus 2% Medicare levy) from unfranked dividends paid to the relevant Australian resident Shareholder. The amount withheld in these circumstances should be available as a credit against the investor's tax liability.

## **12.8 Goods & Services Tax (GST)**

No GST is applicable to the issue or transfer of the Shares given that, under current law, shares in a company are an input-taxed financial supply for GST purposes. However, Shareholders may incur GST on costs that relate to their participation in the proposed Offers and should seek their own independent advice in relation to the GST implications.

## **12.9 Stamp duty**

On the basis that the Company is not a landholder for stamp duty purposes in any Australian jurisdiction, no stamp duty should be payable by Shareholders on acquisition of the Shares.

## 13. Additional information

### 13.1 Company information

The Company was incorporated on 7 October 2020 under the Corporations Act as a public company limited by shares. The Company will be taxed as a public company and its statutory accounts will be made up to 30 June annually.

### 13.2 Share capital structure

Following the completion of the Offer the shareholding structure in the Company will be as follows:

Category*	Number of Shares – at Minimum Subscription	% ownership interest	Number of Shares – at Maximum Subscription	% ownership interest
Existing Shares on issue	104,170,252	77.50%	104,170,252	74.90%
New Shares offered under this Prospectus	30,250,000	22.32%	35,250,000	25.10%
Total number of Shares on issue on completion of the Offer	134,420,252	100.00%	139,420,252	100.00%

\* At the date of this Prospectus, the Company has 2,000,000 options on issue. The material rights attaching to such options are described in section 7.2(d) of this Prospectus.

### 13.3 Major Shareholders

Details of Shareholders who hold 5% or more of the Shares on issue as at the date of this Prospectus, and who will hold more than 5% after completion of the Offer, are set out below.

Shareholder	Shares held at date of Prospectus <sup>1</sup>	% of total Shares at date of Prospectus	Shares held after completion of Offers <sup>2</sup>	% of total Shares after completion of Offers (Minimum Subscription)	% of total Shares after completion of Offers (Maximum Subscription)
LTR Medical	46,373,750	44.52%	46,373,750	34.50%	33.26%
SDS	5,933,000	5.70%	5,933,000	4.41%	4.26%

Important Notes:

<sup>1</sup> Ignoring any related party interests.

<sup>2</sup> Assuming these shareholders do not participate in the Offers.

## 13.4 Company's Constitution

The Shares offered under this Prospectus are fully paid ordinary shares in the capital of the Company. A summary of the more significant rights attaching to the Shares is set out below. This summary is not exhaustive, nor does it constitute a definitive statement of the rights and liabilities of the Company members.

- » **Ranking** — The Shares will be ordinary shares and will rank equally in all respects with the ordinary shares in the Company on issue prior to the date of this Prospectus.
- » **Reports and notices** — Members are entitled to receive all notices, reports, accounts and other documents required to be furnished to members under the Constitution of the Company and the Corporations Act.
- » **General meetings** — Members are entitled to receive at least 28 days' notice of a general meeting and subject to any preferential or special rights attaching to any shares that may be issued by the Company in the future, members are entitled to be present in person, or by proxy, attorney or representative to speak and to vote at general meetings of the Company. Members may requisition general meetings in accordance with the Corporations Act and the Constitution of the Company.
- » **Voting** — At a general meeting of the Company every ordinary member present in person, or by proxy, attorney or representative shall on a show of hands have one vote and upon a poll every member present in person or by proxy, attorney or representative has one vote for every share held.
- » **Use of Meeting Technology** — Subject to the Corporations Act, Meeting Technology can be used for the purpose of holding a meeting at more than one physical venue or virtually or by a combination of those methods.
- » **Reduction of capital** — Subject to the Corporations Act and Listing Rules, the Company may resolve to reduce its share capital by any lawful manner as the Directors or shareholders may approve.
- » **Winding up** — Members will be entitled in a winding up to share in any surplus assets of the Company in proportion to the capital paid up, or which ought to have been paid up, at the commencement of the winding up on the shares held by them respectively.
- » **Transfer of Shares** — Shares in the Company may be transferred in any form authorised by the Corporations Act or approved by the Directors and in the manner prescribed by the Constitution of the Company, the Corporations Act, the Listing Rules or the ASX Settlement and Operating Rules. The Directors may subject to the Listing Rules and the ASX Settlement and Operating Rules, request an ASX approved clearing and settlement facility to apply a holding lock to prevent any transfer of shares. The Directors may refuse to register a paper-based transfer of a share in particular circumstances.
- » **Issue of further Shares** — The Directors control the allotment, issue, grant of options in respect of and disposal of shares. Subject to restrictions on the allotment of shares and grant of options to Directors or their associates and the Corporations Act, the Directors may allot, grant options or otherwise dispose of shares on such terms and conditions as they see fit.



- » **Takeover approval provisions** – Any proportional takeover scheme must be approved by those members holding shares included in the class of shares in respect of which the offer to acquire those shares was first made. The registration of the transfer of any shares following the acceptance of an offer made under a scheme is prohibited until that scheme is approved by the relevant members.
- » **Application of Listing Rules** – On admission to the Official List of the ASX then, despite anything in the Constitution of the Company, if the Listing Rules prohibit an act being done, the act must not be done. Nothing in the Constitution prevents an act being done that the Listing Rules require to be done. If the Listing Rules require an act to be done or not to be done, authority is given for that act to be done or not to be done (as the case may be). If the Listing Rules require a Constitution to contain a provision or not to contain a provision, the Constitution is deemed to contain that provision or not to contain that provision (as the case may be). If a provision of the Constitution is or becomes inconsistent with the Listing Rules, the Constitution is deemed not to contain that provision to the extent of that inconsistency.

### 13.5 CHESSE

The Company will apply to be admitted to participate in CHESSE, in accordance with the ASX Listing Rules and the ASX Settlement and Operating Rules. On admission to CHESSE, the Company will operate an electronic issuer-sponsored sub-register and an electronic CHESSE sub-register. The two sub-registers together will make up the Company's principal register of Shares.

The Company will not issue certificates to Shareholders. Shareholders who elect to hold Shares on the issuer-sponsored sub-register will be provided with a holding statement (similar to a bank account statement), which sets out the number of Shares allotted to the Shareholder under this Prospectus. For Shareholders who elect to hold the Shares on the CHESSE sub-register, the Company will issue an advice that sets out the number of Shares allotted to the Shareholder under this Prospectus. At the end of the month of allotment, CHESSE (acting on behalf of the Company) will provide Shareholders with a holding statement that confirms the number of Shares (as the case may be) held.

A holding statement (whether issued by CHESSE or the Company) will also provide details of a Shareholder's Holder Identification Number in the case of a holding on the CHESSE sub-register or Shareholder Reference Number in the case of a holding in the issuer-sponsored sub-register. Following distribution of these initial holding statements to all Shareholders, a holding statement will also be provided to each Shareholder at the end of any subsequent month during which the balance of that Shareholder's holding of Shares changes.

### 13.6 Restricted securities and escrow arrangements

ASX may, as a condition of granting the Company's application for Official Quotation of its Shares, classify certain of its Existing Shares as restricted securities. Any such classification will restrict the transfer of effective ownership or control of any restricted securities without the written consent of the ASX and for such period as the ASX may determine. The terms of any such restriction or escrow arrangements will be determined by the ASX in accordance with the ASX Listing Rules. Details of any such restriction or escrow arrangements will be disclosed prior to commencement of Official Quotation of the Company's Shares.

## 13.7 Material contracts

### (a) License Agreement

The Company has a licence agreement (as varied) with SDS, under which LTP is granted a licence by SDS to certain intellectual property from which SDS-089 is derived (**SDS Licence Agreement**).

#### (i) Details

Under the SDS Licence Agreement, LTP is granted a licence to certain patent rights to manufacture, have manufactured, use, offer for sale, sell and/or import 'licensed products' (defined below) and to perform 'licensed services' (defined below) in the relevant field (i.e. use of a particular 'licensed product' that is consistent with the label approved by the FDA or applicable foreign regulatory authority, including the treatment of erectile dysfunction) worldwide. No other party (including SDS) has an equivalent licence or rights to the patent rights licenced to LTP.

A 'licensed product' is one which the manufacture, use, sale, offer for sale or import of which is covered by a valid claim, or which incorporates or uses any licensed patent rights or which is made using a 'licensed process' (being a method or process whose practice or use is covered by a valid claim and / or incorporates or uses the licensed patent rights). 'Licensed services' means the performance of a service using a 'licensed product', or the practice of a 'licensed process'.

The patent rights licensed under the SDS Licence Agreement are patent applications described in the Patent Report in Section 10 of this Prospectus.

SDS is required to assign each Patent to LTP once the applicable patent application has been granted and SDS has received certain milestone payments (as detailed below) from LTP.

Further, the agreement provides that SDS will engage with LTP with respect to any new products it develops (subject to a small exclusion), which may be used for the treatment of ED or other indications which are to be administered to patients, as a first right of refusal.

The agreement is governed by the laws of the United States of America and the State of California.

#### (ii) Fees and other payments

The license granted to LTP is subject to LTP's payment of the relevant fees and other payments to SDS under the SDS Licence Agreement.

In summary, LTP has made a payments of US\$500,000 to SDS under this agreement, as well as having provided a loan of US\$200,000.

LTP is required to make a further payment of US\$300,000 by the earlier of 26 April 2024 or 120 days of Listing. LTP is also required to make a number of further payments to SDS subject to the achievement of certain milestones, including the approval of SDS-089 nasal spray NDA by the

FDA (or similar approval in another jurisdiction), and approval of intranasal Vardenafil formulation patent being granted by United States Patent and Trademark Office and/or by the World Intellectual Property Organization of the patent the subject of the Patent Cooperation Treaty patent application - the aggregate of the milestone payments (other than the US\$300,000 noted above), which may become payable under this agreement is US\$3,000,000. If any of the majority of the national patents applied for are granted, then the US\$200,000 loan to SDS is not required to be repaid.

(iii) Term

The term of the SDS Licence Agreement commenced on 1 October 2020. The term expires on the later of 30 September 2040 or the date all patents issued under the patent rights have expired and the patent applications under the patent rights (if any) are cancelled, withdrawn or abandoned.

(iv) Termination by SDS

SDS may terminate the SDS Licence Agreement or LTP's rights with respect to any part of the licensed patent immediately by written notice if:

- (A) LTP becomes in arrears in any payments due under the SDS Licence Agreement for a period of more than 30 days from the payment due date; or
- (B) LTP is in breach of any non-payment provisions of the SDS Licence Agreement and does not rectify that breach within 30 days of receiving a written notice from SDS.

SDS may also terminate the SDS Licence Agreement immediately by written notice if LTP is in material breach of any of its material obligations and does not rectify that breach within 120 days of receiving a written notice from SDS.

The SDS Licence Agreement will also terminate immediately, without any action having to be taken by SDS, if LTP becomes insolvent, LTP's board of directors elect to liquidate its assets or dissolve its business, LTP ceases its business operations, LTP makes an assignment for the benefit of creditors or if the business or assets of LTP are otherwise placed in the hands of a receiver, assignee or trustee (whether by a voluntary act of LTP or otherwise).

(v) Termination by LTP

LTP may terminate the SDS Licence Agreement:

- (A) immediately if SDS is in material breach of any of its material obligations and does not rectify that breach with 120 days of receiving a written notice from LTP; or
- (B) on 30 days' notice for any reason.

If LTP elects to terminate prior to payment of the first milestone payment, it will not be repaid the US\$200,000 loan it has provided to SDS under the SDS Licence Agreement.

(vi) Warranties provided by SDS

SDS provides a number of warranties to LTP under the SDS Licence Agreement including the following:

- (A) it is the owner or agent of the entire right, title and interest in and to the licensed patents rights;
- (B) it has the right to grant the licences granted under the SDS Licence Agreement;
- (C) it has not knowingly granted and will not knowingly grant licences or other rights under the licensed patent rights that are in conflict with the terms of the SDS Licence Agreement; and
- (D) the execution, delivery and performance of the SDS Licence Agreement does not conflict with any agreement, instrument or understanding to which SDS is a party of by which it is bound, nor violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over SDS.

Other than customary corporate adequacy and execution related warranties, no additional (express or implied) representations or warranties are provided by SDS under the SDS Licence Agreement, including other warranties that may ordinarily be included in a licence agreement of this nature.

(vii) Limitation of liability

SDS' liability under the SDS Licence Agreement is limited to 50% of the amount that SDS has received from LTP for the prior 12 months from the date of the liability.

**(b) Service agreements**

**(i) Southern Star Research Pty Ltd (Southern Star)**

LTP has engaged Southern Star to provide contract clinical research services to LTP in accordance with terms of work orders. To date, the parties have entered into various work order that provide for services such as the development of a protocol and an investigator brochure for the bioequivalent trial (**Southern Star MSA**).

The initial term of the Southern Star MSA is five years from 27 May 2021 to 26 May 2026. The parties may agree to extend the term of the Southern Star MSA beyond the initial term. Either party may terminate the Southern Star MSA or a work order by giving the other party 60 days' written notice of termination.

Each party indemnifies the other party (and its directors, officers, employees, agents, representatives, sub-contractors and affiliates) for

any third-party claims and liabilities (including legal fees) incurred by a breach of the Southern Star MSA or its negligence or wilful misconduct. A settlement to any indemnity claim requires the consent of the other party and neither party will admit fault on behalf of the other party without prior written approval.

Under this Southern Star MSA, each party's liability is limited to \$2,000,000 and any action must be brought within 2 years of the action occurring.

All intellectual property rights created or subsisting in any work undertaken by Southern Star will vest in and transfer to LTP subject to the full payment of fees due and payable to Southern Star.

(ii) **Scientia Clinical Research Limited (Scientia)**

LTP has executed a Clinical Trial Research Agreement with Scientia (**CTRA**) to conduct its bioequivalence trial at its institution (see section 5.8). Scientia is a world-class clinical trial expert in bioequivalence studies located in Sydney, NSW. The Scientia CTRA has been prepared using (and is on materially identical terms to) Medicines Australia's Standard Form Clinical Trial Research Agreement.

Either party may terminate the CTRA by giving the other party 30 days' written notice of termination if there is a breach of the CTRA, the other party is declared insolvent or the CTRA is assigned to a person considered unsuitable to perform the CTRA. A party may also terminate the CTRA immediately by written notice to the other party if it believes on reasonable grounds that continuing the study poses an unacceptable risk to the rights, interests, safety or well-being of participants and terminating the CTRA is the most appropriate way to respond to that risk.

Under the Scientia Indemnity (as is required under the CTRA), LTP agreed to indemnify Scientia for all claims and proceedings made or brought by or on behalf of participants for personal injury to them arising from use of the product under investigation or from any clinical intervention or procedure to which participants would not be exposed but for participation in the study. The Scientia Indemnity has been prepared using (and is on materially identical terms to) Medicines Australia's Form of Indemnity for Clinical Trials.

The CTRA commenced on 18 September 2023 and in the ordinary course of events, terminates when LTP makes its final payment to Scientia.

(iii) **Bellberry Limited (Bellberry)**

LTP has an ongoing relationship with Bellberry, as detailed in section 5.8. Bellberry Limited is a national, private not-for-profit organisation providing streamlined scientific and ethical review of human research projects across Australia. LTP has secured ethics approval for the commencement of the bioequivalence clinical trial from Bellberry and may be required to re-engage with Bellberry with respect to the conduct of the bioequivalence trial.

(iv) **360biolabs Pty Ltd (360biolabs)**

LTP and 360biolabs are parties to the 360biolabs master services agreement (**360biolabs Agreement**), whereby LTP engaged 360biolabs to provide services to LTP in accordance with work orders entered into by the parties in accordance with its terms. 360biolabs has agreed to conduct specialist pharmacokinetic analysis from its bioequivalence clinical trial of SDS-089 nasal spray versus its comparator in the bioequivalence trial (Vardenafil ODT 10mg tablets) and, at the completion of the analysis, deliver a bioanalytical study report for registration and clinical trial publication purposes.

The initial term of the 360biolabs Agreement is two years from 15 December 2022. Both parties may terminate the 360biolabs Agreement by mutual agreement. Otherwise, either party may terminate the agreement if the other party breaches the agreement, becomes insolvent or ceases to carry on business.

The parties have agreed to a mutual indemnity in respect of any loss incurred or suffered as a result of claims by a third party to the extent arising from any breach of the 360biolabs Agreement or any negligent act, error or omission in connection with performance of the 360biolabs Agreement, provided that the loss is not caused or contributed to by the indemnitee. Further, 360biolabs' liability for any breach of the 360biolabs Agreement is limited to the payments made under all work orders in the preceding year. LTP's liability under the 360biolabs Agreement is not capped.

(v) **Nanopharm Ltd (Nanopharm)**

LTP has engaged Nanopharm on its formulation optimisation program in preparation for its bioequivalence clinical trial in accordance with terms of work orders entered into in accordance with the Nanopharm Services Proposal Contract (**Services Proposal**). This agreement is governed by and references the laws of England and Wales.

Nanopharm is a pharmaceutical product development company specialising in the development of orally inhaled and nasal therapies. It was recently acquired by AptarGroup Inc. Various work orders have been since entered into by the parties. Nanopharm is required to ensure that the services and deliverables it provides are provided as described in the quotation, and are free from material defects in design, material and workmanship. The sole remedy for breach of this is re-performance of the affected service or re-delivery of the affected deliverable at no additional costs.

The Services Proposal is not subject to a specified term. However, either party may terminate by giving the other party 30 days' written notice if the other party commits a material breach of the terms and does not remedy within 30 days of the party being notified; or enters administration or suffers an insolvency event; or ceases to carry on all of a substantial part of its business. Nanopharm may terminate with immediate effect by giving LTP written notice if there is a change of control (control being defined by section 1124 of the *Corporation Tax Act 2010*), or if LTP owes any fees to Nanopharm after being notified for at least 14 days.

(vi) **Mayne Pharma Services (Mayne)**

LTP has engaged Mayne as its commercial contract manufacturing organisation to manufacture Vardenafil HCl nasal spray for a pivotal bioequivalence study for regulatory submissions in accordance with terms of work orders entered into in accordance with the Mayne Services Proposal Contract (**Mayne Services Proposal**). Various work orders have since been entered into by the parties and in the past 12 months, LTP has successfully transferred its proprietary manufacturing methods and processes to Mayne and Mayne has been manufacturing product batches for LTP. Mayne is currently engaged in product packaging studies and services in preparation for commercial launch in Australia.

The Mayne Services Proposal Contract is not subject to a specified term and does not include any explicit termination rights. Rather, the specific work orders indicate the specified timeframe for the delivery of services. Further, if LTP cancels or delays a batch of product being manufactured under a work order it may be obligated to pay a fee.

Under the Mayne Services Proposal, neither party shall be liable to the other for indirect, incidental, special or consequential damages arising out of performance of services under the Services Proposal, including without limitation, loss of revenues, profits or data, whether in contract or tort, even if LTP has been advised ahead of the possibility of such damages.

Mayne's liability is limited to the amount paid by LTP under the Mayne Services Proposal Contract. There is no limitation on liability for LTP.

(vii) **Grannus Securities Pty Ltd (Grannus Securities)**

LTP and Grannus Securities entered an agreement for Grannus Securities to provide corporate finance services to LTP. The term of the agreement remains in effect until the completion of the Company's Listing unless terminated earlier by the parties in writing.

The parties have agreed that Grannus Securities will be paid \$40,000 (plus GST) and \$20,000 in shares in LTP at an agreed price of \$0.08 per share to be issued on the Listing of the Company.

Under this agreement LTP indemnifies Grannus each of its related bodies corporate and their respective directors, employees and agents (**Grannus Securities Group**), and agrees to hold the Grannus Securities harmless from and against all actions, claims, demands or proceedings which may be instituted against; and all liabilities, losses, damages, costs and expenses (including reasonable legal costs and expenses) which may be suffered or incurred by, any member of the Grannus Securities Group in connection with or arising out of this engagement or any transaction contemplated by or during the course of this engagement.

(c) **Lead Manager's Mandate**

The Company and the Lead Manager has entered into a letter agreement dated 24 May 2023 (**Lead Manager Mandate**), under which the Company appoints

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the Lead Manager (on an exclusive basis) to act as book runner and lead manager to the Investor Offer, on the following key terms.

**(i) Fees**

The fees to which the Lead Manager is entitled pursuant to the Lead Manager Mandate are as follows:

- (A) a management fee equivalent to 2% of the proceeds raised under the Investor Offer;
- (B) a selling fee equivalent to 4% of the proceeds raised under the Investor Offer; and
- (C) equity options equivalent to 4% of the proceeds raised under the Offer, as determined by the Black Scholes options model (expected to be up to 2,792,344 options for Share in the Company). These options will be unlisted but transferable and will have an exercise price that is at a 30% premium to the Offer Price (that is, \$0.26 per Option), and have an expiry date of three (3) years from the date of issue.

**(ii) Termination**

The Lead Manager or the Company may terminate the Lead Manager Mandate for a number of reasons, including a breach of the agreement or changes to market and economic conditions. Under certain circumstances, termination may be undertaken by either party immediately and without any cost or liability. Unless otherwise terminated by the Lead Manager or the Company, the Lead Manager Mandate and the rights and obligations of the parties under it terminate on completion of the Offers.

**(iii) First right of refusal**

The Lead Manager will have a first right of refusal to be appointed as the lead manager for any proposed financing with respect to the Company in the 18-month period following the successful Listing of the Company.

**(iv) Indemnity**

The Company and the Lead Manager have agreed that, unless certain limited exceptions apply (such as fraud, negligence, recklessness, wilful misconduct or break of the Lead Manager Mandate by the Lead Manager), the Company indemnifies the Lead Manager from and against losses directly suffered or incurred by the Lead Manager in connection with the Investor Offer, the Prospectus or the appointment of the Lead Manager.

**(d) Agreements: Staff and Consultants**

The Company has entered into agreements with staff and consultants. Each of these agreements contains a confidentiality clause. The terms of those agreements with regards to confidentiality are standard in that they impose restrictions on the disclosure of confidential information and restrictions on the



use of confidential information, except for the purposes for which it has been disclosed. The agreements are subject to the usual exclusions in relation to information that was in the public domain when disclosed, that comes into the public domain after disclosure, other than as a result of the recipient's breach of the agreement or was in the recipient's possession when disclosed. Some agreements contain other exclusions relating to disclosure required by law to the extent required to be so disclosed.

**(e) Directors' deeds of indemnity, insurance and access**

The Company has entered into a deed of indemnity, insurance and access with each of its Directors. The key features of this deed may be summarised as follows:

- (i) to the extent permitted by law, the Company:
  - » indemnifies each of the Directors against any liability (excluding liability for legal costs) incurred by the Director as an officer or former officer of the Company;
  - » indemnifies the Director against any reasonable legal costs incurred as a result of the Director defending an action for any liability incurred by the Director as an officer or former officer of the Company; and
  - » releases the Director from any present, future or contingent claims that arise directly or indirectly from the Director's position acts or omissions as an officer or former officer of the Company;
- (ii) the Company must, where possible, maintain appropriate insurance cover in favour of the Director during the term of the Director's appointment for at least a period of 7 years after the Director ceases to be an officer of the Company on terms that are reasonably prudent to the Company;
- (iii) the Director, during his or her appointment and for a period of 10 years after the Director ceases to be an officer of the Company, may inspect any books and records of the Company in certain circumstances and for particular purposes; and
- (iv) the Director is entitled to retain any board documents, including minutes of board meetings or committees. These documents will become the property of the Director at the time they are supplied to the Director. Notes of board meetings or other communications made by the Director will remain the property of the Director.

The Company has also entered into a deed of indemnity, insurance and access with its CFO on the terms as above.

### **13.8 Interests of experts**

Except as disclosed in this Prospectus:

- (a) no expert, or firm in which any expert is a partner, has any interest that existed when a copy of the Prospectus was lodged with the ASIC for registration, nor

had any such interest within 2 years before lodgement of the Prospectus for registration, in the promotion of the Company or has received or is entitled to receive any sum for services rendered by the expert or the firm in connection with the promotion or formation of the Company, or in any property proposed to be acquired by the Company in connection with the promotion or formation; and

- (b) no amounts have been paid or agreed to be paid to any expert, or any firm in which any expert is a partner, for services rendered in connection with the promotion or formation of the Company.

In accordance with the terms of its engagement, William Buck Consulting (WA) Pty Limited (**William Buck**) has prepared its Investigating Accountant's Report which forms part of this Prospectus. In aggregate, William Buck, as Investigating Accountant for the Company, will be paid \$25,000 (plus GST) for services provided in connection with this Offer and may receive further payments in accordance with its normal time-based charges.

HLB Mann Judd (WA Partnership) (**HLB Mann Judd**) has acted as the auditor of the Company since the Company's inception. On 24 October 2023 ASIC provided its consent to HLB Mann Judd's resignation as auditor, effective the date of the Company's next Annual General Meeting (**AGM**), which was held on 31 October 2023. The Company has appointed William Buck Audit (WA) Pty Ltd ACN 125 012 124 (**William Buck Audit**) as the auditor of the Company. In accordance with their respective terms of engagement, neither William Buck Audit or HLB Mann Judd will be paid any amounts for services provided in connection with the Offers. However, HLB Mann Judd has received audit fees in relation to previous audit services provided to the Company, and William Buck Audit may receive further payments in accordance with its normal time-based charges.

In accordance with the terms of its engagement, K&L Gates as Australian Legal Advisers for the Company will be paid \$200,000 (plus GST) for services provided in connection with this Offer and may receive further payments in accordance with its normal time-based charges. During the 24 months preceding lodgement of this Prospectus with ASIC, K&L Gates provided corporate legal services to the Company, the total amount of these services was approximately \$83,500 (excluding GST and disbursements).

In accordance with the terms of its engagement, Frost & Sullivan Australia Pty Ltd (**Frost & Sullivan**), as an independent market expert for the Company, will be paid \$21,300 (plus GST) for the provision of the independent market report and services provided in connection with the Offer.

In accordance with the terms of their engagement, Griffith Hack as Patent Attorneys for the Company has been paid \$26,310.91 (excluding GST) for the provision of services, including the provision of the Patent Attorney Report (which forms part of this Prospectus), and may receive further payments in accordance with their normal time-based charges.

Alpine Capital Pty Ltd (previously named Wentworth Securities Pty Ltd) as Lead Manager to the Offer will receive those fees set out in section 13.7(c) following completion of the Offers for their service as Lead Manager. During the 24 months preceding lodgement of this Prospectus with ASIC, Alpine Capital Pty Ltd has received \$27,000 in fees from the Company in relation to the provision of corporate advisory services.

### 13.9 Consents of experts

(a) William Buck Consulting (WA) Pty Ltd – Investigating Accountant

William Buck has given and not withdrawn its written consent to being named as Investigating Accountant for the Company in the Prospectus in the form and context in which it is named.

William Buck was not involved in the preparation of any part of the Prospectus and did not authorise or cause the issue of any other part of the Prospectus.

William Buck does not make, or purport to make, any statement in this Prospectus and is not aware of any statement in this Prospectus which purports to be based on a statement made by it and makes no representation, expressed or implied, regarding and takes no responsibility for any statement in or omissions from this Prospectus.

(b) William Buck Audit (WA) Pty Ltd – Auditor

William Buck Audit has been recently appointed as the auditor of the Company, and has given and not withdrawn its written consent to being named as Auditor for the Company in the Prospectus in the form and context in which it is named.

William Buck Audit was not involved in the preparation of any part of the Prospectus and did not authorise or cause the issue of any other part of the Prospectus.

William Buck Audit does not make, or purport to make, any statement in this Prospectus and is not aware of any statement in this Prospectus which purports to be based on a statement made by it and makes no representation, expressed or implied, regarding and takes no responsibility for any statement in or omissions from this Prospectus.

(c) HLB Mann Judd – Auditor

HLB Mann Judd has acted as the auditor of the Company since the Company's inception and was recently replaced. HLB Mann Judd has given and not withdrawn its written consent to being named as Auditor for the Company in the Prospectus in the form and context in which it is named.

HLB Mann Judd was not involved in the preparation of any part of the Prospectus and did not authorise or cause the issue of any other part of the Prospectus.

HLB Mann Judd does not make, or purport to make, any statement in this Prospectus and is not aware of any statement in this Prospectus which purports to be based on a statement made by it and makes no representation, expressed or implied, regarding and takes no responsibility for any statement in or omissions from this Prospectus.

(d) K&L Gates – Legal Adviser

K&L Gates has given and not withdrawn its written consent to be named in this Prospectus as Australian Legal Advisers to the Company in the form and context in which it is so named. K&L Gates does not make, or purport to make,

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any statement in this Prospectus and is not aware of any statement in this Prospectus which purports to be based on a statement made by it and makes no representation, expressed or implied, regarding and takes no responsibility for, any statements in or omissions from this Prospectus.

(e) Griffith Hack – Patent Attorney

Griffith Hack has given and not withdrawn its written consent to be named in this Prospectus as Patent Attorneys to the Company in the form and context in which it is so named. Other than the expert report contained in section 10, Griffith Hack does not make, or purport to make, any statement in this Prospectus and is not aware of any statement in this Prospectus which purports to be based on a statement made by it and makes no representation, expressed or implied, regarding and takes no responsibility for, any statements in or omissions from this Prospectus.

(f) Frost and Sullivan – Industry Market Expert

Frost & Sullivan has given and not withdrawn its written consent to be named in this Prospectus as independent market expert to the Company in the form and context in which it is so named. Other than the market report contained in section 4 Frost & Sullivan does not make, or purport to make, any statement in this Prospectus and is not aware of any statement in this Prospectus which purports to be based on a statement made by it and makes no representation, expressed or implied, regarding and takes no responsibility for, any statements in or omissions from this Prospectus.

(g) Automic – Share Registry

Automic has given and not withdrawn its written consent to be named in this Prospectus as the Share Registry to the Company in the form and context in which it is so named. Automic does not make, or purport to make, any statement in this Prospectus and is not aware of any statement in this Prospectus which purports to be based on a statement made by it and makes no representation, expressed or implied, regarding and takes no responsibility for, any statements in or omissions from this Prospectus.

(h) Alpine Capital Pty Ltd – Lead Manager

Alpine Capital Pty Ltd has given, and at the time of lodgement of this Prospectus, has not withdrawn its consent to be named as Lead Manager to the offer of securities under this Prospectus, in the form and context in which it is named.

Alpine Capital Pty Ltd was not involved in the preparation of any part of this Prospectus and did not authorise or cause the issue of this Prospectus. Alpine Capital Pty Ltd makes no express or implied representation or warranty in relation to the Company, this Prospectus or the offer and does not make any statement in this Prospectus, nor is any statement in it based on any statement made by Alpine Capital Pty Ltd. To the maximum extent permitted by law, Alpine Capital Pty Ltd expressly disclaims and takes no responsibility for any material in, or omission from, this Prospectus other than the reference to its name.

### **13.10 ASX / ASIC**

No ASIC relief or modification of the Corporations Act have been obtained or relied on.

The Company has not sought any waivers from the ASX as at the date of this Prospectus.

### **13.11 Costs of the Offer**

If the Offer proceeds, the total estimated costs of the Offer, including legal fees incurred, registration fees, fees for other advisers, prospectus design, printing and advertising expenses and other miscellaneous expenses, will be approximately \$391,939.

If the Offer proceeds, the Lead Manager will be paid aggregate fees equal to 6% of the proceeds received by the Company from the Shares issued under the Offer (plus any applicable GST). There are also non-cash expenses of the Offer being up to 2,792,344 options issued to the Lead Manager.

### **13.12 Legal proceedings**

There is no litigation of a material nature or threatened which may significantly affect the Company or its activities.

### **13.13 Governing law**

This Prospectus and the contracts that arise from the acceptance of Applications are governed by the law applicable in Victoria and each Applicant submits to the exclusive jurisdiction of the courts of Victoria.

### **13.14 Directors responsibility statement**

The Directors of the Company state that for the purposes of section 731 of the Corporations Act, they have made all enquiries that were reasonable in the circumstances and have reasonable grounds to believe that any statements by them in this Prospectus are true and not misleading or deceptive, and that with respect to any other statements made in this Prospectus by persons other than the Directors, the Directors have made reasonable enquiries and have reasonable grounds to believe that persons making the statement or statements were competent to make such statements, those persons have given the consent required by section 716(2) of the Corporations Act and have not withdrawn that consent before lodgement of this Prospectus with ASIC.

Each Director consents to the lodgement of this Prospectus with ASIC, and has not withdrawn that consent prior to this Prospectus being lodged.

This Prospectus is prepared on the basis that:

- » certain matters may be reasonably expected to be known to professional advisers of the kind with whom Applicants may reasonably be expected to consult; and
- » information is known to Applicants or their professional advisers by virtue of any legislation or laws of any State or Territory of Australia or the Commonwealth of Australia.

### 13.15 Authorisation

This Prospectus is issued by the authority of the Board of the Company.

**Dated: 9 November 2023**



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**Lee Rodne**  
**Executive Chairman**  
**LTR Pharma Limited**

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## 14. Glossary

Unless the context requires otherwise:

- (a) terms defined in the independent experts' reports included in this Prospectus have the same meaning when used throughout this Prospectus; and
- (b) each term below has the meaning set out below, unless this is inconsistent with the context in which the expression is used.

**\$ or A\$** means Australian dollars.

**AEDT** means Australian Eastern Daylight Time.

**Applicant** means a person who makes an application for Shares.

**Application** means an application for Shares under this Prospectus made by an Applicant under an Application Form.

**Application Form** means the form accompanying or attached to this Prospectus by which an Applicant may apply for Shares under the Offer.

**Application Monies** means amounts received under the Investor Offer with respect to an Application.

**AptarGroup Inc.** means AptarGroup, Inc. (NYSE:ATR).

**ASIC** means the Australian Securities and Investments Commission.

**ASX** means the ASX Limited ACN 008 624 691 or the Australian Securities Exchange as the context requires.

**ASX Listing Rules** means the official listing rules of the ASX.

**ASX Settlement and Operating Rules** means the rules established under the Corporations Act for settlement of transactions of securities of a company for which Clearing House Electronic Sub-Register System (CHES) approval has been given.

**Automic** means Automic Pty Ltd ACN 152 260 814.

**Board** means the board of Directors of the Company.

**Business Day** means a day that is not a Saturday or Sunday or a public holiday in Victoria.

**CHES** means the clearing house electronic sub-register system.

**Closing Date** means the date on which the Offer closes, which is set out in the 'Key Offer Information' section and may be varied by the Company.

**Company** means LTR Pharma Limited ACN 644 924 569.

**Constitution** means the constitution of the Company.

**Corporations Act** means the *Corporations Act 2001 (Cth)*.

**Director** means a director of the Company from time to time.

**ED** means Erectile Dysfunction or Erectile Disorder.

**EIP** means the employee incentive plan of LTP.

**Executive Chairman** means the non-independent chair of the Board of Directors.

**Existing Shares** means the issued Shares immediately prior to the allotment of Shares under the Offer.

**Expenditure Program** means the anticipated expenditures to be incurred by the Company and funded by the capital raising under this Prospectus as detailed in section 5.12.

**Exposure Period** means the period of 7 days (or 14 days if extended by ASIC) after the lodgement of the Prospectus with the ASIC during which the Company may not accept Applications.

**FDA** means the United States Food and Drug Administration.

**General Public Offer** means the offer of Shares to investors as described in section 6.13 of this Prospectus.

**Grannus Offer** means the offer of Grannus Securities as described in section 6.6 of this Prospectus.

**Grannus Securities** means Grannus Securities Pty Ltd ACN 110 846 323.

**Group** means LTP and its subsidiary LTR Inc.

**Investor Offer** means the offer of up to 35,000,000 ordinary Shares under this Prospectus, and is comprised of the Broker Firm Offer, the Institutional Offer, and the General Public Offer.

**Lead Manager** means Alpine Capital Pty Ltd ACN 155 409 653.

**Lead Manager Offer** means the offer of the Lead Manager Options as described in section 6.7 of this Prospectus.

**Listing** or **Listed** means the admission of the Shares to quotation on the ASX in accordance with ASX Listing Rules.

**LTR Inc** means LTR Pharma Inc UBI Number 608 684 057, a company incorporated in Washington, United States.

**LTR Medical** means LTR Medical Pty Ltd ACN 625 901 573.

**Mayne Pharma** means Mayne Pharma International Pty Ltd ABN 88 007 870 984.

**Maximum Subscription** means the maximum total amount of subscriptions to be raised under this Prospectus, being \$7 million.

**Meeting Technology** has the meaning given to that term in the Constitution;



**Minimum Subscription** means the minimum total amount of subscriptions to be raised under this Prospectus, being \$6 million.

**NDA** means new drug application under section 505(b)(2) of US Federal Food, Drug and Cosmetic Act.

**Non-executive Director** means an independent director of the company.

**Offers** comprise of the Investor Offer, the Grannus Offer and the Lead Manager Offer.

**Offer Price** means \$0.20 per Share.

**Official List** means the official list of the ASX.

**Official Quotation** means official quotation of the Shares on the Official List.

**Opening Date** means the date the Offer opens, which is set out in the 'Key Offer Information' section and may be varied by the Company.

**Original Prospectus** means the prospectus dated 1 November 2023 lodged with ASIC on that date.

**Patent Cooperation Treaty** means the treaty administered by the World Intellectual Property Organization (WIPO).

**Patent Report** means the Patent Report in section 10.

**PDE5 Inhibitors** means the class of agents known as type-5 phosphodiesterase inhibitors which are commonly used for the management of ED.

**Prospectus** means this replacement prospectus as modified or varied by any supplementary prospectus made by the Company and lodged with ASIC from time to time.

**Primary Participant** has the meaning given to it in Part 7.12, Division 1A of the Corporations Act.

**Related Person** has the meaning given to it in Part 7.12, Division 1A of the Corporations Act.

**Scientific Advisory Board** means the Company's scientific advisory board comprising of Professor Eric Chung and Professor Russ Chess-Williams.

**SDS** means Strategic Drug Solutions Inc.

**SDS Licence Agreement** means the licence agreement between SDS and LTP as detailed in section 13.7(a).

**Share** means a share in the issued capital of the Company.

**Shareholder** means a person who holds Shares.

**Share Registry** means Automic Pty Ltd.

**Trexapharm Inc.** means Trexapharm LLC UBI number 604605607.



## CORRECT FORMS OF REGISTRABLE TITLE

Type of Investor	Correct Form of Registration	Incorrect Form of Registration
Individual	Mr John Richard Sample	J R Sample
Joint Holdings	Mr John Richard Sample & Mrs Anne Sample	John Richard & Anne Sample
Company	ABC Pty Ltd	ABC P/L or ABC Co
Trusts	Mr John Richard Sample <Sample Family A/C>	John Sample Family Company
Superannuation Funds	Mr John Sample & Mrs Anne Sample <Sample Family Super A/C>	John & Anne Superannuation Fund
Partnerships	Mr John Sample & Mr Richard Sample <Sample & Son A/C>	John Sample & Son
Clubs/Unincorporated Bodies	Mr John Sample <Health Club A/C>	Health Club
Deceased Estates	Mr John Sample <Estate Late Anne Sample A/C>	Anne Sample (Deceased)

## INSTRUCTIONS FOR COMPLETING THE FORM

### YOU SHOULD READ THE PROSPECTUS CAREFULLY BEFORE COMPLETING THIS GENERAL PUBLIC OFFER APPLICATION FORM.

This is an Application Form for fully paid ordinary Shares in LTR Pharma Limited (ACN 644 924 569) (**Company**) made under the terms of the General Public Offer set out in the Replacement Prospectus dated 9 November 2023 (**Prospectus**).

Capitalised terms not otherwise defined in this document has the meaning given to them in the Prospectus. The Prospectus contains important information relevant to your decision to invest and you should read the entire Prospectus before applying for Shares. If you are in doubt as to how to deal with this Application Form, please contact your accountant, lawyer, stockbroker or other professional adviser. To meet the requirements of the Corporations Act, this Application Form must not be distributed unless included in, or accompanied by, the Prospectus and any supplementary Prospectus (if applicable). While the Prospectus is current, the Company will send paper copies of the Prospectus, and any supplementary Prospectus (if applicable) and an Application Form, on request and without charge.

- Shares Applied For & Payment Amount** - Enter the number of Shares & the amount of the application monies payable you wish to apply for. Applications must be for a minimum of \$2,000 worth of Shares (10,000 Shares) and thereafter, in multiples of \$500 worth of Shares (2,500 Shares).
- Applicant Name(s) and Postal Address** - ONLY legal entities can hold Shares. The Application must be in the name of a natural person(s), companies or other legal entities acceptable by the Company. At least one full given name and surname is required for each natural person. Refer to the table above for the correct forms of registrable title(s). Applicants using the wrong form of names may be rejected. Next, enter your postal address for the registration of your holding and all correspondence. Only one address can be recorded against a holding.
- Contact Details** - Please provide your contact details for us to contact you between 9:00am and 5:00pm (AEDT) should we need to speak to you about your application. In providing your email address you elect to receive electronic communications. You can change your communication preferences at any time by logging in to the Investor Portal accessible at <https://investor.automic.com.au/#/home>
- CHES Holders** - If you are sponsored by a stockbroker or other participant and you wish to hold Shares allotted to you under this Application on the CHES subregister, enter your CHES HIN. Otherwise leave the section blank and on allotment you will be sponsored by the Company and a "Securityholder Reference Number" ("SRN") will be allocated to you.
- TFN/ABN/Exemption** - If you wish to have your Tax File Number, ABN or Exemption registered against your holding, please enter the details. Collection of TFN's is authorised by taxation laws but quotation is not compulsory and it will not affect your Application.
- Payment** - Payments for Applications made using a paper Application Form can only be made by cheque. Your cheque must be made payable to "**LTR Pharma Limited**" and drawn on an Australian bank and expressed in Australian currency and crossed "**Not Negotiable**". Cheques or bank drafts drawn on overseas banks in Australian or any foreign currency will NOT be accepted. Any such cheques will be returned and the acceptance deemed to be invalid. Sufficient cleared funds should be held in your account as your acceptance may be rejected if your cheque is dishonoured. Completed Application Forms and accompanying cheques must be received before 5:00pm (AEDT) on the Closing Date by being delivered or mailed to the address set out in the instructions below.

Applicants wishing to pay by BPAY® or EFT should complete the online Application, which can be accessed by following the web address provided on the front of the Application Form. Please ensure that payments are received by 5:00pm (AEDT) on the Closing Date. Do not forward cash with this Application Form as it will not be accepted.

## DECLARATIONS

### BY SUBMITTING THIS APPLICATION FORM WITH THE APPLICATION MONIES, I/WE DECLARE THAT I/WE:

- Have received a copy of the Prospectus, either in printed or electronic form and have read the Prospectus in full;
- Have completed this Application Form in accordance with the instructions on the form and in the Prospectus;
- Declare that the Application Form and all details and statements made by me/us are complete and accurate;
- I/we agree to provide further information or personal details, including information related to tax-related requirements, and acknowledge that processing of my application may be delayed, or my application may be rejected if such required information has not been provided;
- Agree and consent to the Company collecting, holding, using and disclosing my/our personal information in accordance with the Prospectus;
- Where I/we have been provided information about another individual, warrant that I/we have obtained that individual's consent to the transfer of their information to the Company;
- Acknowledge that once the Company accepts my/our Application Form, I/we may not withdraw it;
- Apply for the number of Shares that I/we apply for (or a lower number allocated in a manner allowed under the Prospectus);
- Acknowledge that my/our Application may be rejected by the Company in its absolute discretion;
- Authorise the Company and their agents to do anything on my/our behalf necessary (including the completion and execution of documents) to enable the Shares to be allocated;
- Am/are over 18 years of age;
- Agree to be bound by the Constitution of the Company; and
- Acknowledge that neither the Company nor any person or entity guarantees any particular rate of return of the Shares, nor do they guarantee the repayment of capital.

## LODGEMENT INSTRUCTIONS

The Offer opens on 10 November 2023 and is expected to close on 24 November 2023. The Directors reserve the right to close the Offer at any time once sufficient funds are received or to extend the Offer period. Applicants are encouraged to submit their Applications as early as possible. Completed Application Forms and payments must be submitted as follows:

### Paper Application and Cheque

#### By Post:

OR  
LTR Pharma Limited  
C/- Automic Pty Ltd  
GPO Box 5193  
SYDNEY NSW 2001

#### By Hand Delivery:

LTR Pharma Limited  
C/- Automic Pty Ltd  
Level 5, 126 Phillip Street  
SYDNEY NSW 2000

### Online Applications and BPAY® or EFT Payments

#### Online:

<https://apply.automic.com.au/LTRPharma>

## ASSISTANCE

Need help with your application, no problem. Please contact Automic on:



#### PHONE:

1300 288 664 within Australia  
+61 (2) 9698 5414 from outside Australia



#### LIVE WEBCHAT:

Go to [www.automicgroup.com.au](http://www.automicgroup.com.au)



#### EMAIL:

[corporate.actions@automic.com.au](mailto:corporate.actions@automic.com.au)

