

LTR Pharma 2024 Full-Year Results

30 August 2024

Highlights:

- SPONTAN[®] achieved positive interim results demonstrating rapid absorption and faster onset of action compared to oral PDE5 inhibitors.
- The Company rapidly recruited patients and completed the clinical study for SPONTAN.
- LTR Pharma completed key manufacturing validation milestones for SPONTAN.
- As of 30 June 2024, the Company held a cash balance of \$3.10 million.
- Capital expenditure plans remain on track, aligning with the use of funds outlined in the IPO prospectus.
- Key achievements subsequent to 30 June 2024 include completion of a \$10.5 million placement, securing a global Co-Development Agreement with Aptar Pharm and the successfully prescribing of SPONTAN under the two TGA early access schemes.

LTR Pharma Limited (ASX:LTP) ("LTR Pharma", "the Company") is pleased to provide an update on its full-year results for the year ended 30 June 2024 (FY24). During FY24, LTR Pharma progressed significantly since its Initial Public Offering (IPO), including a successful clinical study and several commercially focused partnerships as the company advanced towards regulatory filings and commercialisation. These activities have been further supported by the recent prescription of SPONTAN[®] to qualifying patients through the Australian Therapeutic Goods Administration's (TGA) early access schemes.

Financial Highlights

On 11 December 2023, LTR Pharma completed its IPO, raising AU\$7 million from new and existing shareholders. The IPO was oversubscribed, demonstrating strong investor interest in the Company's innovative approach to ED treatment. The Company's shares commenced trading on the Australian Securities Exchange (ASX) under the ticker code ASX:LTP on 11 December 2023, marking a significant milestone in LTR Pharma's growth trajectory.

As of 30 June 2024, the Company maintained a robust cash balance of \$3.10 million, positioning it well to meet upcoming milestones and advance its clinical development and commercialisation program. The Company has since completed a \$10.5M placement to further strengthen its balance sheet and to support key clinical and commercial milestones.

Notably, the Company's capital expenditure program aligns with the projections outlined in the IPO prospectus, demonstrating LTR Pharma's commitment to efficient resource allocation and strategic execution of its development plans.

Operational Highlights

In March 2024, LTR Pharma announced the completion of recruitment and dosing for its pivotal pharmacokinetic clinical study of SPONTAN ("the Study"). The Study evaluated the relative bioavailability of SPONTAN nasal spray (5 mg vardenafil) compared to vardenafil tablets (10 mg vardenafil) in 18 healthy adult male subjects. In June 2024, the Company reported encouraging interim results from the Study:

- Achieved rapid absorption and faster onset of action compared to oral PDE5 inhibitors,
- Delivered a similar peak drug concentration (C_{max}) at half the oral tablet dose,

- Demonstrated a time-to-peak concentration (Tmax) in as little as 9 minutes, with an average of 12 minutes, compared to an average of 56 minutes for oral tablets,
- No serious adverse events were observed with SPONTAN.

The Company completed critical manufacturing validation steps for SPONTAN, including:

- Stability testing,
- Quality control checks,
- Product purity assessments,
- Packaging integrity evaluations.

These achievements met essential U.S. Food and Drug Administration (FDA) requirements, signifying LTR Pharma's quality and regulatory compliance commitment.

The Company's clinical data for SPONTAN was presented at the World Meeting on Sexual Medicine in Dubai in December 2023. LTR Pharma's key scientific and clinical advisor, Professor Eric Chung, was awarded the prestigious ISSM Emil Tanagho Prize for the most innovative research presented at the event.

Matters Subsequent to the end of the financial year

The Company has achieved several significant milestones since the end of the reported financial period.

On 24 July 2024, the Company completed a \$10.5 million share placement to accelerate SPONTAN's commercialisation and growth.

On 13 August 2024, LTR Pharma secured a global Co-Development Agreement with Aptar Pharma, a leader in drug delivery systems, to support SPONTAN's commercialisation in key markets, including the USA.

Additionally, SPONTAN has been successfully prescribed under the two Therapeutic Goods Administration (TGA) early access schemes. Initially, select patients received SPONTAN via the Special Access Scheme (SAS), followed by prescriptions through the Authorised Prescriber Scheme (APS) by internationally acclaimed urological expert Professor Eric Chung.

These developments underscore the market need for SPONTAN and align with the Company's Key Opinion Leader (KOL)-driven approach to market introduction.

LTR Pharma Chairman, Lee Rodne said: *"The 2024 financial year has been transformative for LTR Pharma, marked by our successful IPO, ASX listing, and significant advancements in our SPONTAN clinical program. The positive interim results from our pivotal clinical study underscore SPONTAN's potential to address the unmet need for a fast-acting, on-demand ED treatment. We thank our development partners, investors and the medical community for their ongoing support throughout the past year. With your support, we are well-positioned to continue our momentum and remain resolutely focused on bringing this innovative therapy to market."*

-Ends-

This announcement has been approved by the Board of Directors.

About LTR Pharma

LTR Pharma is focused on improving men's health, physically and mentally, through the commercialisation of an innovative nasal spray treatment for Erectile Dysfunction. ED is a pressing health issue for millions of men that can negatively impact self-esteem and relationships, across multiple age brackets. LTR Pharma's lead product SPONTAN® is set apart from existing ED therapies by its mechanism of action – intranasal delivery technology of a PDE5 inhibitor. The nasal cavity is a highly vascular part of the body supporting even and rapid absorption of the drug, empowering it to work within 10 minutes or less. LTR Pharma is proudly aiming to restore greater control over the timing, spontaneity, and enjoyment of sexual experiences.

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