# SPONTAN® to be Evaluated in Pulmonary Arterial Hypertension Following Ethics Approval

22 October 2026

## Highlights

- **Ethics approval received** for an investigator-initiated clinical study evaluating SPONTAN® in pulmonary arterial hypertension (PAH), a serious, progressive and currently incurable disease.
- **PAH represents a significant global therapeutics market,** estimated at US$8.0 billion in 2024 and forecast by third-party sources to reach up to US$17.9 billion by 2034.[1,2]
- **PDE5 inhibition is an established treatment approach in PAH;** the study will evaluate whether SPONTAN can produce a measurable haemodynamic effect within 15 minutes.
- **Study independently led by Professor David Celermajer,** Head of the Department of Cardiology at Royal Prince Alfred Hospital.
- **The study represents a further clinical evaluation of LTR's intranasal platform beyond erectile dysfunction,** exploring its potential application in another significant therapeutic area.

**LTR Pharma Limited (ASX: LTP) ("LTR Pharma" or "**the **Company")** is pleased to announce that the Bellberry Human Research Ethics Committee (HREC) has approved an investigator-initiated clinical study evaluating SPONTAN® in patients with newly diagnosed and untreated Pulmonary Arterial Hypertension (PAH). The study will be independently designed, led and conducted by Professor David Celermajer, Head of the Department of Cardiology at Royal Prince Alfred Hospital, Scandrett Professor of Cardiology at the University of Sydney and Clinical Director of the Heart Research Institute.

PAH is a serious, progressive and currently incurable disease in which narrowing of the pulmonary arteries increases resistance to blood flow and places increasing strain on the right side of the heart, potentially leading to right-heart failure. Despite advances in treatment, there remains a need for differentiated therapeutic approaches.

PDE5 inhibitors, including sildenafil and tadalafil, are established PAH therapies. However, oral administration requires gastrointestinal absorption before reaching systemic circulation, with peak blood concentrations typically occurring approximately 30 minutes to two hours after dosing.

SPONTAN is LTR Pharma's intranasal formulation of vardenafil, another PDE5 inhibitor. Previous pharmacokinetic studies have demonstrated rapid absorption following SPONTAN's administration. The PAH study will explore whether SPONTAN's rapid systemic exposure can translate into a measurable haemodynamic effect within 15 minutes, providing early clinical data on its potential as a differentiated treatment approach in PAH.

## About the Study

The investigator-initiated clinical study will evaluate whether a single intranasal dose of SPONTAN can rapidly reduce pulmonary vascular resistance (PVR) in newly diagnosed, untreated PAH patients. Haemodynamic effects will be assessed 15 minutes following administration, together with safety and tolerability.

The study is expected to commence in the coming quarter ending 31 December 2026. LTR Pharma will provide further updates as material milestones are achieved.

## Professor David Celermajer said:

*"Oral PDE5 inhibitors are an established part of PAH treatment. This study will directly measure whether intranasal SPONTAN can rapidly reduce pulmonary vascular resistance in newly diagnosed, untreated patients. The controlled haemodynamic assessment will provide important early clinical data on the potential of SPONTAN in PAH."*

## Strategic Significance

The PAH study represents a further evaluation of LTR Pharma's rapid-acting intranasal platform beyond erectile dysfunction and follows the OROFLOW® study in oesophageal motility disorders announced in June 2026. Together, these studies demonstrate the expanding clinical potential of LTR's intranasal platform across multiple therapeutic areas where rapid systemic exposure may offer meaningful clinical differentiation.

The study is expected to generate early clinical data on SPONTAN's potential in PAH. Positive results could provide a foundation for LTR Pharma to evaluate further clinical development and commercial opportunities in this significant therapeutic market.

Despite advances in treatment, PAH remains incurable and can progress to right-heart failure, sustaining demand for differentiated therapies. Grand View Research estimates the global PAH therapeutics market at US$8.0 billion in 2024, growing at 5.9% annually to reach US$13.3 billion by 2033,1 while GlobalData forecasts sales across 68 markets rising from US$10.1 billion in 2024 to US$17.9 billion by 2034.2 Market forecasts are third-party estimates and are not forecasts of LTR Pharma revenue.

The study is funded through an LTR Pharma research grant administered by the Sydney Local Health District. As an investigator-initiated study, it is designed, led and conducted independently by Professor Celermajer and his team.

## LTR Pharma Executive Chairman, Lee Rodne, said:

*"This study represents another important opportunity to evaluate LTR Pharma's intranasal platform in a serious disease with significant unmet need and a large global market.*

*PDE5 inhibition is already an established treatment approach in PAH. The opportunity we are exploring is whether SPONTAN can produce a rapid, measurable haemodynamic effect within minutes of administration.*

*Importantly, this investigator-initiated study is being independently led by Professor Celermajer and provides an efficient pathway to generate early clinical data in another potentially valuable therapeutic application. Together with OROFLOW, it further demonstrates the broader potential of our intranasal platform beyond erectile dysfunction."*

## About Pulmonary Arterial Hypertension

PAH is a rare, progressive and currently incurable disease characterised by narrowing of the pulmonary arteries, increasing resistance to blood flow and placing growing strain on the right side of the heart. Symptoms can include shortness of breath, fatigue, reduced exercise capacity, chest pain, palpitations, dizziness and fainting, with advanced disease potentially leading to right-heart failure.

**- ENDS -**

This announcement has been approved by the Board of Directors.

[1] Grand View Research, Pulmonary Arterial Hypertension Market Size, Share & Trends Analysis Report, 2025–2033 (base year 2024; published 2025).

[2] GlobalData, Pulmonary Arterial Hypertension – Global Drug Forecast and Market Analysis, 2024.

## About LTR Pharma

**LTR Pharma** is a commercial-stage pharmaceutical company delivering innovative therapies to address significant unmet medical needs through its proprietary rapid-acting intranasal platform. The Company has successfully commercialised its rapid-acting treatment technology in Australia and is expanding access whilst advancing regulatory pathways in the US and other key markets.

LTR's lead products, **SPONTAN®** and **ROXUS®**, are fast-acting intranasal sprays for the treatment of erectile dysfunction, enabling onset of action in 10 minutes or less. Building on this proven technology, the Company is now advancing **OROFLOW®**, a novel intranasal spray under development for the treatment of Oesophageal Motility Disorders (OMD) – a debilitating group of conditions affecting swallowing function.

Through strategic partnerships, LTR Pharma is expanding its pipeline and global footprint to deliver differentiated, patient-centric treatments that enhance quality of life.

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