

Completion of Phase 2a clinical study for the treatment of fibromyalgia at the University of Michigan

- Total of five patients dosed with TRP-8802 (oral psilocybin) and administered psychotherapy to explore the use for the treatment of patients with fibromyalgia, a condition associated with widespread pain
- Trial was initiated by the University of Michigan ('UOM') in January 2024, one of the top-ranked public universities in the USA, in collaboration with Tryptamine Therapeutics
- Fibromyalgia represents a large global market opportunity affecting over 1m people in Australiaⁱ and an estimated 10mⁱⁱ people in the US for a combined market size of A\$8Bnⁱⁱⁱ
- UOM researchers plan to present trial results at the International Association for the Study of Pain Conference held 5 to 9 August 2024 in the Netherlands – This is expected to provide Tryp with exceptional exposure to leading industry participants
- Results will inform future clinical studies in fibromyalgia patients using TRP-8803 (IV-infused psilocin), Tryp's proprietary psilocin formulation which may address many of the limitations associated with orally administered psilocybin
- TRP-8803's potential advantages include a significant reduction in onset of the psychedelic state, more precise control of the depth and duration of the psychedelic experience and a reduction in the overall duration of the intervention to a commercially feasible timeframe
- Additional clinical trials continue to progress well with first 3 participants having completed dosing in TRP-8803 healthy human volunteer study, while work towards commencement of Phase 2a trial with Massachusetts General Hospital for treatment of irritable bowel syndrome advancing

Melbourne, Australia – Tryptamine Therapeutics Limited ('Tryp' or the 'Company') (ASX: TYP), a clinical-stage biotechnology company focused on the development of an innovative and scalable intravenous-infused psilocin formulation which can be used in conjunction with psychotherapy to address significant unmet medical needs, is pleased to advise that the Phase 2a clinical trial conducted in collaboration with the University of Michigan has been completed.

The trial commenced in January 2024 and seeks to evaluate TRP-8802 (oral psilocybin) in conjunction with psychotherapy in patients with fibromyalgia, a condition associated with widespread pain and tenderness. The trial was undertaken by the UOM, a top-ranked public university in the US in collaboration with Tryp.

During the trial, a total of five patients were dosed with TRP-8802 and administered psychotherapy to explore TRP-8802's utility in patients with fibromyalgia. Researchers from the University of Michigan aim to present results from this study at the International Association of Pain Conference, which is being held in the Netherlands from 5 to 9 August this year. This is expected to provide the Company with exceptional exposure to industry experts, as well as potential collaborators and partners.

The results will be used to inform additional clinical studies utilising TRP-8803 (IV-infused psilocin), which has the potential to further improve efficacy, and safety, along with enhancing both the patient and therapist experience.



Potential advantages of the Company's IV-infused psilocin solution include a significant reduction in the time to onset of the psychedelic state, more precise control of the depth and duration of the psychedelic experience and a reduction in the overall duration of the intervention to a commercially feasible timeframe.

Management commentary:

Chief Executive Officer, Mr. Jason Carroll said: *"We are very pleased to have completed this study and had the opportunity to collaborate with the University of Michigan. The University has extensive experience and expertise in the conduct of pain studies, with a particular focus on fibromyalgia and their involvement in this study highlights the potential for the Company's offering."*

"Up to 30% of US fibromyalgia patients may resort to the use of opioids^{iv} to alleviate their pain and traditional treatment approaches only address the symptom, not its cause. Our firm belief is that the use of psychedelic assisted therapy can provide a significant benefit to these patients, which would focus on addressing the cause of their pain and not merely masking the symptom."

"We are excited for UOM to publish this data and have confidence that it will further our work towards commercialising TRP-8803. We look forward to providing further updates on the results, particularly as they are being presented at such a prestigious event in August."

About Tryptamine Therapeutics Limited

Tryp Therapeutics is a clinical-stage biotechnology company focused on developing proprietary, novel formulations for the administration of psilocin in combination with psychotherapy to treat diseases with unmet medical needs. Tryp's lead program, TRP-8803, is a proprietary formulation of IV-infused psilocin (the active metabolite of psilocybin) with potential to alleviate numerous shortcomings of oral psilocybin including: significantly reducing the time to onset of the psychedelic state, controlling the depth and duration of the psychedelic experience, and reducing the overall duration of the intervention to a commercially feasible timeframe. The Company has completed a Phase 2a clinical trial for the treatment of binge eating disorder at the University of Florida, which demonstrated an average reduction in binge eating episodes of greater than 80%. The Company also has also just completed a Phase 2a clinical trial for the treatment of fibromyalgia in collaboration with the University of Michigan and is preparing to initiate a Phase 2a clinical trial in collaboration with Massachusetts General Hospital for the treatment of abdominal pain and visceral tenderness in patients suffering from irritable bowel syndrome. Each of the studies is utilising TRP-8802 (synthetic, oral psilocybin) to demonstrate clinical benefit in these indications. Where a positive clinical response is demonstrated, subsequent studies are expected to utilise TRP-8803 (IV-infused psilocin), that has the potential to further improve efficacy, safety, and patient experience. TRP-8803 is currently being evaluated in a Phase 1 Healthy Volunteer Study in Adelaide, Australia.

For more information, please visit www.tryptherapeutics.com.

This announcement has been authorised for release by the Board of Tryptamine Therapeutics Limited.

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ⁱ [https://fibromyalgiaaustralia.org.au/patients/what-is-fibromyalgia/#:~:text=Estimates%20are%20that%20as%20many,\(IBS\)%20and%20chronic%20headaches.](https://fibromyalgiaaustralia.org.au/patients/what-is-fibromyalgia/#:~:text=Estimates%20are%20that%20as%20many,(IBS)%20and%20chronic%20headaches.)

ⁱⁱ <https://www.fmaware.org/fibromyalgia-prevalence/>

ⁱⁱⁱ Based on internal calculations

^{iv} <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3778468/>