

## Successful maiden dosing of TRP-8803 (IV-infused psilocin) completed in global first

- Completion of first participant dosing for TRP-8803 (IV-infused psilocin) Healthy Human Volunteer Study – Trial being undertaken alongside CMAX Clinical Research in Adelaide and marks a world-first in psychedelic treatment
- Study aims to refine and optimise dosing and infusion rates of TRP-8803 to achieve precise blood levels of psilocin with an acceptable pharmacokinetics profile in up to 12 participants to determine TRP-8803's safety in humans – results will inform TYP's Phase 2a patient study pipeline
- Participant successfully underwent psilocin infusion over 140 minutes, progressed well through treatment and was discharged on completion
- 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 experience and a reduction in the duration of the intervention to a commercially feasible timeframe
- Successful first participant dosing reinforces management confidence in TRP-8803 and its potential
- Trial expected to completed during Q3 2024 with results to be reported thereafter – Positive results will provide Tryp with the potential to advance its clinical trial pipeline across multiple conditions

**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 may be used in conjunction with psychotherapy to address significant unmet medical needs, is pleased to advise that it has successfully and safely completed the world's first participant dosing using TRP-8803 (IV-infused psilocin) in a patient in Adelaide, South Australia.

The participant was administered TRP-8803 (IV-infused psilocin) as part of the Company's planned Healthy Human Volunteer Study, which is being undertaken by CMAX Clinical Research in Adelaide. The trial is an open-label design, undertaken with therapist support and aims to refine and optimise dosing and infusion rates of TRP-8803 to achieve precise blood levels of psilocin with an acceptable pharmacokinetics profile in up to 12 participants and to determine its safety prior to additional clinical studies which will be focused on particular need states.

Tryp advises that the participant was provided with TRP-8803, the Company's innovative IV-infused psilocin solution on Friday, 28 June for approximately 140 minutes and progressed through the treatment safely. The participant was discharged after dosing follow-up was completed.

TRP-8803, Tryp's lead program alleviates a number of significant shortcomings of oral psilocybin therapy. 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.



The Company will continue to work alongside CMAX Clinical Research to deliver the solution to the additional participants over the coming weeks. Tryp anticipates to receive interim results from the trial during Q3 2024, which will provide a greater understanding of the solution's potential in humans.

**Management commentary:**

**Tryp Chief Executive Officer, Mr. Jason Carroll said:** *"We are very pleased to have completed the world's first TRP-8803 treatment in a patient in Adelaide. Pleasingly, the maiden participant was delivered the infusion safely and was discharged on treatment conclusion, which provides management with confidence of TRP-8803 and the completion of this Healthy Human Volunteer Study.*

*"The trial, which being undertaken alongside CMAX is an incredibly important initiative for Tryp, as it will provide us with data highlighting TRP-8803's safety in humans at escalating doses. This will form the basis of the Company's clinical trial pipeline into other indications and ultimately our regulatory engagement.*

*"The Company expects that up to 12 participants to undertake infusion over the coming weeks and we look forward to provide further updates as the trial advances."*

For more information, please visit [www.tryptherapeutics.com](http://www.tryptherapeutics.com).

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

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**About Tryptamine Therapeutics Limited (ASX: TYP):**

Tryptamine Therapeutics Limited 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) that alleviates 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 is also dosing patients in a Phase 2a clinical trial in collaboration with University of Michigan for the treatment of Fibromyalgia and is preparing to initiate a Phase 2a clinical trial in collaboration with Harvard University & 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), which has the potential to further improve efficacy, safety, and patient experience.

### **Forward-Looking Information**

Certain information in this news release, constitutes forward looking information. In some cases, but not necessarily in all cases, forward-looking information can be identified by the use of forward-looking terminology such as "plans", "targets", "expects" or "does not expect", "is expected", "an opportunity exists", "is positioned", "estimates", "intends", "assumes", "anticipates" or "does not anticipate" or "believes", or variations of such words and phrases or state that certain actions, events or results "may", "could", "would", "might", "will" or "will be taken", "occur" or "be achieved". In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances contain forward-looking information. Statements containing forward-looking information are not historical facts but instead represent management's expectations, estimates and projections regarding future events.

Forward-looking information is necessarily based on a number of opinions, assumptions and estimates that, while considered reasonable by Tryp as of the date of this news release, are subject to known and unknown risks, uncertainties, assumptions and other factors that may cause the actual results, level of activity, performance or achievements to be materially different from those expressed or implied by such forward-looking information, including but not limited to the factors described in greater detail in the "Risk Factors" section of Tryp's Replacement Prospectus available at [www.asx.com.au](http://www.asx.com.au)

These factors are not intended to represent a complete list of the factors that could affect Tryp; however, these factors should be considered carefully. There can be no assurance that such estimates and assumptions will prove to be correct. The forward-looking statements contained in this news release are made as of the date of this news release, and Tryp expressly disclaims any obligation to update or alter statements containing any forward-looking information, or the factors or assumptions underlying them, whether as a result of new information, future events or otherwise, except as required by law.