**ASX Release** **14 October 2025**

# First patient enrolled in Binge Eating Disorder Trial

- **World-first open-label study will assess the efficacy and safety of TRP-8803 (IV-infused psilocin) with therapy support in adult Binge Eating Disorder (BED) patients**
- **First enrolment follows a strict patient health screening initiative and completion of clinician training**
- **The patient baseline assessment is now underway, collecting data on binge eating behaviours, BMI, and neuropsychiatric evaluation to support first dosing with TRP-8803 in the coming weeks**
- **Patient screening process is progressing well following strong interest – additional enrolments pending**

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**Melbourne, Australia** – Tryptamine Therapeutics Limited ('**Tryp**', '**TYP**' or the '**Company**') (**ASX: TYP**), a clinical-stage biotechnology company, is pleased to advise that the trial team from Swinburne University has successfully enrolled the first patient in the Company's clinical trial to treat Binge Eating Disorder (BED) using TRP-8803 (IV-infused psilocin).

The trial will recruit a total of 12 patients suffering from BED, in two cohorts. Each cohort will be administered two doses of TRP-8803, 14 days apart in a monitored setting together with supportive therapy. Cohort 1 will receive a mid-range dose and the Cohort 2 will be administered a high-range dose.

The primary endpoint is TRP-8803's safety when administered twice in BED patients and during follow up through the 4 and 12-week periods following the second dose. Secondary objectives include TRP-8803's ability to induce a psychedelic state in a BED patient population and clinical efficacy of TRP-8803 on binge-eating episodes in addition to anxiety, depression and weight-related indicators in a BED population.

First patient enrolment marks a major milestone for the Company and follows completion of a number of initiatives, including patient screening initiatives, face-to-face interviews, on-site clinician and therapist training, securing required regulatory permits and manufacturing of TRP-8803 for clinical use.

Following first patient enrolment, a 4-week baseline assessment is now underway, including binge eating behaviour, physical measurements such as Body Mass Index (BMI) and vital signs and comprehensive psychological and safety evaluations. Laboratory testing, including blood chemistry, haematology, serology and urinalysis, as well as neuropsychiatric assessments are being completed to provide a robust foundation for dosing in the weeks ahead.

Additional prospective patients are currently undergoing screening, with further enrolments expected shortly.

**Management commentary**

**Chief Executive Officer, Mr Jason Carroll, said:** *"Enrolling the first patient in this ground-breaking study marks a pivotal step forward for the Company's lead program and concludes a considerable amount of work undertaken alongside Swinburne University in its preparation."*

*"BED is one of the most common eating disorders in the world, affecting millions of people in the form of Binge Eating episodes and other comorbidities including anxiety and depression. Despite its prevalence, current treatment options remain limited and are often inadequate. To this end, we are confident that TRP-8803 has the potential to establish*

*a new treatment pathway for patients. We look forward to providing additional updates over the coming weeks."*

**Q&A**

**What is TRP-8803?**
TRP-8803 is Tryptamine Therapeutics' proprietary IV-infused psilocin formulation. It delivers psilocin (the active ingredient in psilocybin) directly into the bloodstream, avoiding the variability of oral psilocybin and enabling precise control of onset, intensity and therapy duration.

**Why is IV delivery and the precision of TRP-8803 important?**
Oral psilocybin is metabolised inconsistently – up to 30% of patients fail to reach the required level for therapeutic treatment. IV infusion ensures predictable blood concentrations, rapid onset (~15 minutes), and titratable or controllable dosing.

**How does TRP-8803 differ from oral psilocybin?**
The key benefits of TRP-8803 when compared to oral dosing, are as follows:

- **Onset:** 15 minutes (TRP-8803) vs. 1–3 hours (oral dosing)
- **Duration:** 1–2 hours (TRP-8803) vs. 8–10 hours (oral dosing)
- **Control:** Infusion can be paused or adjusted in real time, which cannot occur with oral dosing
- **Safety:** TRP-8803 can be immediately reversed in case of adverse events – this is not possible with oral dosing

**How scalable is TRP-8803 compared to oral psilocybin?**
Shorter treatment sessions (1–2 hours) make TRP-8803 commercially feasible for outpatient clinics, compared to 8 to 10+ hour sessions using oral dosing that strain resources and reimbursement models.

**What conditions is the Company targeting for use with TRP-8803?**
Lead indications include Binge Eating Disorder (BED), Fibromyalgia (FMS) and Irritable Bowel Syndrome (IBS). Broader potential spans depression, anxiety, Post Traumatic Stress Disorder (PTSD) and pain syndromes.

**What is the Company's intellectual property position?**
TRP-8803 will be protected by a global patent portfolio covering formulation, infusion methods and disease-specific applications (BED, FMS, IBS). Additional filings cover salts, co-formers, and biomarker integration.

**What is the mechanism of action?**
Psilocin is a 5-HT2A receptor agonist, inducing cortical network reorganisation, increased entropy and enhanced neuroplasticity—mechanisms linked to rapid and durable psychiatric benefit.

**Will the Company benefit from previous studies undertaken using oral psilocybin?**
Yes, Tryptamine believes that any studies highlighting the benefit of oral psilocybin use may yield better results if undertaken in a similar manner with TRP-8803, primarily due to the delivery methods superiority over oral dosing.

**What differentiates TRP-8803 from competitors?**

- IV precision vs oral variability
- Short, controllable sessions vs prolonged, unpredictable experiences
- Potential for Biomarker integration (EEG entropy) vs anecdotal endpoints
- Strong IP vs a crowded oral psilocybin space

**What is the design of this clinical trial?**
This is a world-first open-label study enrolling 12 patients in two cohorts. Each patient will receive two IV doses of TRP-8803, 14 days apart, in a monitored clinical setting with supportive therapy.

**What are the endpoints in the BED trial?**
Safety and tolerability of two IV doses, with follow-up at 4 and 12 weeks after the second dose. Secondary endpoints include reduction in binge episodes and changes in anxiety, depression and weight-related measures.

**Why is BED an important unmet medical need?**
Despite its extremely high prevalence, BED has very limited treatment options. Current therapies often fail to provide sustained benefit, leaving millions of patients without effective solutions. TRP-8803 has the potential to establish a new treatment pathway.

**Where is the BED trial being conducted?**
The study is being conducted at Swinburne University in Melbourne, Australia, under the supervision of trained clinicians and therapists.

**How many patients have been enrolled so far?**
The first patient has now been enrolled, marking a major milestone for the program. Additional patients are undergoing screening, with further enrolments expected shortly.

**When will first patient dosing occur?**
The Company anticipates first patient dosing in approximately four weeks, following completion of baseline testing. Additional updates in this regard will be provided to market.

**How is patient safety being managed?**
Patients undergo a 4-week baseline assessment including binge-eating behaviour, BMI, vital signs, laboratory testing, and neuropsychiatric evaluation. Dosing occurs in a controlled environment with direct medical supervision.

**What prior evidence supports TRP-8803 in BED?**
A Phase 2a study using oral psilocybin (TRP-8802) at the University of Florida demonstrated an average reduction in binge-eating episodes of over 80% as well as sustained reductions in Anxiety and Depression over a 14-week follow-up period.

**How large is the market opportunity?**

- BED: Millions affected globally; limited approved therapies.
- FMS & IBS: Chronic, high-burden conditions with unmet need.
- Broader psychiatric and pain indications expand the addressable market to multi-billion-dollar potential.

**Why should investors be excited about TRP-8803?**
TRP-8803 represents a paradigm shift in psychedelic medicine: precision-engineered, biomarker-guided and commercially scalable. It positions Tryptamine Therapeutics as a leader in next-generation neuropsychiatric therapeutics.

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

**-ENDS-**

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**About Tryptamine Therapeutics Limited**

Tryp 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 has initiated 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.

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

**Register for updates**

The Company encourages investors to register their details with Automic Group investor portal. This also provides shareholders with the opportunity to elect communication methods to electronic only. This can be done by:

- *Go to investor.automic.com.au*
- *If you're an existing user, log in with your username and password*
- *If you're a new user, click 'register', select 'Tryptamine Therapeutics Limited'. Enter your Holding Number and postcode of the registered address on your holding. If your address is outside Australia, select the country. Follow the prompts to set up a username and password.*
- *Once you have created your account, you will need to update your communication method by clicking 'my details' under the 'profile' section of the investor portal account, then navigating to 'communication preferences' and select 'electronic only'*

**Risks associated with Psilocin**

*All medicines carry risks and specialist prescribers, such as registered psychiatrists are best placed to assess the suitability of a new medication against a patient's individual circumstances and medical history before proceeding. Adverse effects of psilocybin and similar compounds, such as psilocin, can include temporary increase in blood pressure and a raised heart rate. There may be some risk of psychosis in predisposed individuals. These effects of psilocybin and its derivatives are unlikely at low doses and in the treatment regimens used in psychedelic-assisted psychotherapy and appropriately managed in a controlled environment with direct medical supervision.*

**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 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.*