Neurala Biosciences

MEDIA RELEASE

Neurala Biosciences Reports Phase 1 Data Supporting Advancement of Second-Generation DMT–Harmala Candidates NBX-100 and NBX-200

- **World's first clinical study of a fully standardised, multi-alkaloid DMT–harmala formulation designed for regulated medical use**
- **Acute effect scores on MEQ-30 and 5D-ASC exceeded those reported in prior psilocybin and LSD studies using these standardised measures**
- **Psychedelic effects were strongly associated with persisting psychological benefits, including enhanced wellbeing and more positive life attitudes.**
- **Results support advancement of Neurala's proprietary second-generation product candidates, NBX-100 and NBX-200**
- **NBX-100 GMP product completed release testing in January 2026; Phase 1 PK/PD study to commence shortly at CMAX Clinical Research, with all ethics, regulatory and site approvals in place**

MELBOURNE, Australia, February 2026 — Neurala Biosciences (Neurala), a clinical-stage biotechnology company developing next-generation psychedelic neuromedicines, today announced results from its Phase 1 proof-of-concept study published in *Scientific Reports*, a Nature Portfolio journal.

The study represents the world's first controlled clinical evaluation of a fully standardised, multi-alkaloid DMT–harmala formulation designed for regulated medical use. The results demonstrated that an intentionally designed multi-alkaloid product can generate a robust acute psychedelic experience strongly associated with persisting psychological benefits, while maintaining a favourable tolerability profile. Building on these results, Neurala's second-generation product candidates, NBX-100 and NBX-200, incorporate proprietary structural refinements to the harmala alkaloids that enhance therapeutic targeting, safety, and intellectual property protection.

Designing the therapeutic experience

"This study represents an important milestone as the first controlled clinical evaluation of a fully standardised, multi-alkaloid DMT–harmala formulation," said Dr Daniel Perkins, Chief Executive Officer and co-founder of Neurala Biosciences. "From the outset, our goal was not simply to standardise, but to design a composition capable of eliciting a psychedelic experience of optimal intensity to drive clinically meaningful change. The data support this precision formulation approach, with acute effect scores exceeding those reported in prior psilocybin and LSD studies."

Dr Perkins added: “Importantly, the intensity of the experience was strongly associated with persisting psychological benefits. These results provide the clinical rationale for advancement of our second-generation candidates. We look forward to commencing the NBX-100 Phase 1 PK/PD study at CMAX shortly, which will generate the pharmacokinetic and pharmacodynamic data package required to inform dose selection for patient efficacy studies.”

Phase 1 study overview and results

The Phase 1 proof-of-concept study was conducted at St Vincent’s Hospital Melbourne and included 17 supervised dosing sessions in healthy volunteers.

Participants receiving the high-dose formulation reported mean total scores of approximately 76 on the MEQ-30 and approximately 56 on the 5D-ASC scale, exceeding those reported in prior psilocybin and LSD studies using these measures. Across participants, the intensity of the acute psychedelic experience was associated with persisting psychological benefits, including enhanced wellbeing and more positive life attitudes. The formulation was well tolerated, with no serious adverse events observed.

Pipeline and next steps

Building on these results, Neurala is advancing two differentiated product candidates derived from its proprietary second-generation DMT–harmala chemistry platform. **NBX-100** is a medium duration (3–5 hour) oral formulation being developed for substance use disorders, including alcohol use disorder and stimulant use disorder. **NBX-200** is a short-acting (30–50 minute) intranasal formulation being developed for chronic depressive illness.

NBX-100 will commence a Phase 1 pharmacokinetic and pharmacodynamic study at CMAX Clinical Research in Adelaide shortly, with Human Research Ethics Committee and regulatory approvals already granted. The GMP drug product completed final release testing in January 2026, and all clinical and CRO contracts are in place, enabling rapid commencement of dosing. A Phase 2a efficacy study in alcohol use disorder and chronic depression, supported by a $2 million non-dilutive government grant, will commence as soon as the Phase 1 data package is available.

Formulation development and GMP manufacture of NBX-200 is being undertaken at Ab Initio Pharma via funding from an Australian government grant.

Neurala’s DMT–harmala platform

Neurala’s platform represents a significant evolution beyond other psychedelic programs relying primarily on 5-HT2A agonism, leveraging differentiated multi-target pharmacology informed by decades of human data, that engages multiple neuroreceptor systems implicated in neuroplasticity and therapeutic response. The platform provides unique flexibility to design products with differing durations and intensity, enabling therapeutic profiles to be matched to specific indications and clinical contexts.

Structural refinements to the active compounds enhance therapeutic targeting and provide a proprietary chemistry platform with robust, defensible intellectual property protection, addressing a core limitation of programs built on known compounds with extensive prior art. The company has completed multiple FDA consultations confirming alignment on its development approach.

About Neurala Biosciences

Neurala Biosciences is a Melbourne-based clinical-stage biotechnology company developing second-generation psychedelic neuromedicines for mental health and addiction. Emerging from more than a decade of research at the University of Melbourne, Neurala combines precision formulation design with advanced pharmaceutical science to deliver scalable, transformative therapies for mental health and addiction. The company's leadership team brings deep expertise in psychedelic therapeutics, CNS drug development, medicines regulation, and commercialisation. The company is backed by University of Melbourne commercialisation funds Tin Alley Ventures and Genesis Pre-Seed Fund, alongside significant non-dilutive funding from competitive commercial grant programs. Learn more at www.neurala.co. Follow Neurala Biosciences on LinkedIn.

Original publication

Perkins, D., et al. Acute experiences and persisting psychological effects associated with an encapsulated DMT-harmala alkaloid combination: results of a phase 1 study. *Scientific Reports* (2025). https://doi.org/10.1038/s41598-025-25767-x

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