

Reunion Neuroscience Announces Last Patient Dosed in RECONNECT Phase 2 Clinical Trial of RE104 for the Treatment of Postpartum Depression (PPD)

-- Enrollment Completed on Schedule; Topline Results Expected Q3 2025 --

-- Company to Present Poster Reviewing RE104 Phase 1 Results at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting on May 28, 2025 --

MORRISTOWN, New Jersey, May 19, 2025 – Reunion Neuroscience, Inc., a clinical-stage biopharmaceutical company committed to revolutionizing the treatment of underserved mental health disorders through the advancement of next-generation psychedelic-inspired therapeutic solutions, today announced the completion of patient enrollment and the last patient dosed in RECONNECT, a Phase 2 clinical trial evaluating RE104 in adult female patients with moderate-to-severe postpartum depression (PPD). Topline results from the study, which enrolled 84 patients, are anticipated in the third quarter of 2025.

“The completion of patient dosing in RECONNECT is a noteworthy accomplishment and reflects the significant enthusiasm from new mothers and their doctors for options that can offer rapid relief for the persistent depression and anxiety that characterizes PPD. Achieving this milestone on time and as planned per protocol also demonstrates the operational excellence of our team and clinical partners,” said Greg Mayes, President and Chief Executive Officer of Reunion. “We look forward to reporting initial safety and efficacy data in the third quarter, which will provide key insights into RE104’s potential as a fast-acting, short-duration psychedelic therapy for the treatment of PPD and other mental health disorders.”

The RECONNECT Phase 2 clinical trial ([NCT06342310](https://clinicaltrials.gov/ct2/show/study/NCT06342310)) is a multicenter (38 clinical research sites in U.S.), randomized, double-blind, parallel-group, active dose-controlled clinical trial evaluating the safety and efficacy of a single subcutaneous dose of RE104. The trial was over-enrolled to include 84 adult female patients with moderate-to-severe PPD. The primary endpoint of the trial is the change from baseline at Day 7 in total Montgomery-Åsberg Depression Rating Scale (MADRS) score, a 10-item clinician-rated scale measuring depression severity. Key secondary endpoints include the change in MADRS at other timepoints, response rates ($\geq 50\%$ MADRS reduction), remission rates (MADRS ≤ 10), change in Hamilton Anxiety Rating Scale (HAM-A), Clinical Global Impression of severity and improvement, as well as overall safety and tolerability.

Reunion will also evaluate RE104 for the treatment of adjustment disorder (AjD) in adult patients with cancer and other medical illnesses. The Company recently secured IRB approval and has initiated the site selection and activation process for REKINDLE, a randomized, double-blind, parallel-group, dose-controlled Phase 2 clinical trial evaluating the safety and efficacy of RE104 for AjD, and expects to enroll the first patient in mid-2025.

ASCP Annual Meeting Poster Presentation Session:

Reunion’s Chief Medical Officer, Mark Pollack, M.D., will present a poster reviewing previously disclosed safety, pharmacokinetics (PK) and pharmacodynamics (PD) results from the first-in-human Phase 1 clinical trial of RE104 at the ASCP Annual Meeting, taking place May 27-30, 2025 in Scottsdale, AZ. In this Phase 1 trial, a single dose of RE104 was found to be safe and generally well tolerated, with robust PD effects and a short induced psychoactive state of approximately four hours, supporting the advancement of RE104 into the Phase 2 RECONNECT and REKINDLE trials.

Details of the poster presentation session are as follows:

- **Poster Title:** RE104: A Novel Serotonergic Psychedelic 4-OH-DiPT Prodrug
- **Date:** May 28, 2025
- **Time:** 11:15 a.m. MT (1:15 p.m. ET)

About RE104

The Company's lead product candidate, RE104, is a proprietary, potential best-in-class, patented prodrug of 4-OH-DiPT. Reunion designed RE104 to deliver a short psychedelic experience compared to longer experience duration with psychedelics like psilocybin or LSD. In a Phase 1 clinical trial, RE104 produced an acute psychedelic state similar in intensity and quality to psilocybin, but lasting only about half the time (3-4 hours), while demonstrating a similar, favorable safety profile. RE104 is currently being evaluated in the RECONNECT Phase 2 ([NCT06342310](https://clinicaltrials.gov/ct2/show/study/NCT06342310)) clinical trial, a multicenter, randomized, double-blind, active dose-controlled clinical trial in moderate-to-severe postpartum depression (PPD) patients. Initial data from RECONNECT are expected in the third quarter of 2025. Reunion plans to initiate the REKINDLE Phase 2 clinical trial, a randomized, double-blind, parallel-group, dose-controlled trial in adjustment disorder in cancer and other medical illnesses in mid-2025.

About Reunion Neuroscience, Inc.

Reunion Neuroscience is a clinical-stage biopharmaceutical company committed to revolutionizing the treatment of underserved mental health disorders through the advancement of next-generation psychedelic-inspired therapeutic solutions. In 2023, Reunion became a private company and in 2024, the Company completed Series A financing co-led by MPM BioImpact and Novo Holdings. Reunion is actively investigating the use of its lead product candidate, RE104, in postpartum depression and adjustment disorder, as well as in additional neuropsychiatric indications where there remains a significant unmet need that is not addressed by the current standard of care. To learn more, visit <https://reunionneuro.com>, and follow Reunion on [LinkedIn](#) and [Bluesky](#).

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