Reunion Neuroscience Announces Program Updates and Highlights Anticipated 2026 Milestones

-- Aligned with U.S. Food and Drug Administration (FDA) on Registrational Path for RE104 in Postpartum Depression (PPD); On Track to Initiate Phase 3 Trial in 2026 --
-- Enrolling Phase 2 REKINDLE Trial of RE104 in Adjustment Disorder (AjD); Initial Data Expected in 1Q 2027 --
-- On Track to Initiate Phase 2 RECLAIM Trial in Generalized Anxiety Disorder (GAD) in 1Q 2026 --

MORRISTOWN, New Jersey, January 12, 2026 – 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 program updates and anticipated 2026 milestones.

Program Updates and Upcoming Milestones:

RE104 is a proprietary, potential best-in-class, patented prodrug of 4-OH-DiPT, which is administered via a single subcutaneous injection. Reunion designed RE104 to deliver a shorter acute psychoactive experience when compared to longer experience duration psychedelics such as psilocybin or LSD. RE104 has potential across a range of mood and anxiety disorders, including in PPD, AjD and GAD, where Reunion is focusing its initial clinical development efforts.

Postpartum Depression (PPD): PPD is the most common complication of pregnancy and childbirth and affects 12.5 percent of new mothers within the first year of giving birth.

- In December 2025, Reunion completed an End-of-Phase 2 (EOP2) meeting with the FDA regarding its development plans for RE104 for PPD. The EOP2 meeting was supported by results from the multicenter, randomized, double-blind, dose-controlled Phase 2 RECONNECT clinical trial. As previously disclosed, RECONNECT met its primary endpoint, demonstrating a clinically-meaningful reduction in MADRS scores through Day 28, as well as a favorable safety and tolerability profile.
- Based on feedback from the FDA, Reunion expects that the results from a single additional Phase 3 trial, if successful, would complete the pivotal clinical studies required to support potential registration of RE104 in PPD.
- Additionally, after review of Reunion's lactation study, FDA feedback supports the enrollment of women who are actively breastfeeding into the planned Phase 3 trial; these women can expect to return to breastfeeding on the same day of treatment following discharge.
- Reunion expects to initiate Phase 3 development of RE104 in PPD in 2026.

"We are entering 2026 with tremendous momentum across our business," said Greg Mayes, President and Chief Executive Officer of Reunion Neuroscience. "Last year, we reported positive topline data from our Phase 2 RECONNECT trial in PPD, demonstrating that a single dose of RE104 can safely deliver clinically meaningful improvements in depression and anxiety scores. These results unlock a blockbuster opportunity in PPD, where we believe we are advancing a best-in-class therapy poised to disrupt a significant and still underserved market. Following a productive End of Phase 2 meeting with the FDA, we look forward to initiating a Phase 3 trial in PPD later this year, which – if successful – could enable us to submit our first new drug application for RE104."

Adjustment Disorder (AjD): AjD, which is defined as a disproportionate reaction to a stressful life event or change that impacts the ability to function, is among the most frequent diagnoses managed by psychiatrists globally. Cancer and other medical illnesses are known to be key precipitants of AjD.

- RE104 is currently being evaluated in REKINDLE, a randomized, double-blind, parallel-group, dose-controlled Phase 2 clinical trial evaluating the safety and efficacy of RE104 for the treatment of AjD in adult patients with cancer and other medical illnesses.

- Reunion expects to complete patient enrollment by year-end, and to report topline clinical data from the REKINDLE trial in the first quarter of 2027.

Generalized Anxiety Disorder (GAD): GAD is a chronic mental health condition, characterized by excessive and uncontrollable worry; a majority of patients fail to achieve remission with currently available therapies.

- Reunion plans to evaluate RE104 in RECLAIM, a multicenter, randomized, double-blind, placebo-controlled Phase 2 clinical trial evaluating the safety and efficacy of RE104 for the treatment of GAD in adult patients.
- Reunion expects to initiate the RECLAIM trial in the first quarter of 2026.

Mr. Mayes continued, "Beyond advancing our PPD program, the RECONNECT data are critical in de-risking our planned indication expansion strategy across other mental health disorders characterized by depression and anxiety. In the near term, we look forward to progressing our efforts in AjD and GAD, and longer term, to exploring the potential of RE104 across a broad range of other acute and chronic mood and anxiety disorders, as we work to deliver the full promise of psychedelic-inspired medicines to patients with mental health conditions."

RE245 is a non-psychedelic serotonergic neuroplastogen designed to deliver 5HT2A-mediated neuroplasticity, resulting in therapeutic mental health benefits without producing hallucinations or cardiotoxicity.

- Reunion plans to file an investigational new drug application (or foreign equivalent) in 2026 and commence a Phase 1 clinical trial in 2027.

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. Reunion is actively investigating the use of its lead product candidate, RE104, in postpartum depression, adjustment disorder and generalized anxiety disorder and may in the future expand to additional neuropsychiatric indications where there remains a significant unmet need that is not addressed by the current standard of care. Reunion has advanced a lead candidate, RE245, from its non-psychedelic discovery program and plans to file an IND in 2026. To learn more, visit https://reunionneuro.com, and follow Reunion on LinkedIn and Bluesky.

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