Lipocine Provides Progress Update on LPCN 1154 Phase 3 Clinical Trial in Postpartum Depression (PPD)

One-Third of Patients Randomized; Topline Results Expected in 2Q 2026

DSMB Safety Review Update Planned for 4Q 2025

SALT LAKE CITY, Sept. 30, 2025 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company leveraging its proprietary technology platform to develop innovative products with effective oral delivery, today provided an update on its ongoing pivotal Phase 3 clinical trial evaluating LPCN 1154 (oral brexanolone) for the treatment of postpartum depression (PPD). The study is progressing on track with one-third of planned patients randomized. Topline results are anticipated in the second quarter of 2026.

A meeting of the independent Data Safety Monitoring Board (DSMB) to review safety data from the study in the one-third patients randomized will be held, and the Company plans to provide a safety update in the fourth quarter of 2025 post DSMB review.

"We are very encouraged by the steady enrollment momentum in our pivotal Phase 3 trial and are pleased to see the program advance as planned," said Mahesh Patel, CEO of Lipocine. "LPCN 1154 is designed to be differentiated from existing options for PPD, with its 48-hour dosing schedule, and potential for rapid, meaningful clinical benefit. We believe it has the potential to become the standard of care for women suffering from this condition. We intend to use the data from this Phase 3 trial to support a 505(b)(2) NDA submission in 2026."

The pivotal, randomized, double-blind study is evaluating LPCN 1154 compared to placebo in women aged 15 years and older diagnosed with severe PPD. Following constructive feedback from the U.S. Food and Drug Administration (FDA), the trial is being conducted entirely in an outpatient setting and does not require medical monitoring by a healthcare provider. For more information, refer to clinicaltrials.gov: NCT06979544.

Virtual Investor Event on LPCN 1154

Lipocine hosted a virtual research and development (R&D) investor event to discuss LPCN 1154 on July 9, 2025. The event featured a discussion by Kristina M. Deligiannidis, MD (Zucker Hillside Hospital, Northwell Health, New York), who was joined by company management to discuss the current treatment landscape and unmet needs in PPD. To access the webinar replay, click here.

About LPCN 1154

LPCN 1154 is an oral formulation of brexanolone in development targeted for administration resulting in rapid relief of PPD. LPCN 1154 is expected to have characteristics that could be particularly appealing to patients with PPD, acutely elevated suicide risk, and in whom rapid improvement is a priority while presenting no significant risk of adverse reactions to breastfed infants from exposure to brexanolone.

About Postpartum Depression and Unmet Needs

PPD is a major depressive disorder with onset either during pregnancy or within four weeks of delivery, with symptoms persisting up to 12 months after childbirth. Hormonal changes leading to GABA dysfunction are common in depression and pregnancy. Symptoms of PPD include hallmarks of major depression, including, but not limited to, sadness, depressed mood, loss of interest, change in appetite, insomnia, sleeping too much, fatigue, difficulty thinking/concentrating, excessive crying, fear of harming the baby/oneself, and/or thoughts of death or suicide. Results from a recent survey (Truist Securities Research, January 2024) show that obstetricians believe approximately 20-40% of their patients may suffer from PPD. Further, obstetricians are comfortable making a diagnosis and prescribing antidepressants for PPD. Traditional antidepressants, not approved for PPD, have slow onset of action, side effects such as weight gain, and do not demonstrate adequate remission post-acute treatment.

About Lipocine

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to develop innovative products with effective oral delivery. Lipocine has drug candidates in development as well as drug candidates for which we are exploring partnerships. Our drug candidates represent enablement of differentiated, patient friendly oral delivery options for favorable benefit to risk profile which target large addressable markets with significant unmet medical needs.

Lipocine's clinical development candidates include: LPCN 1154, oral brexanolone, for the potential treatment of postpartum depression, LPCN 2101 for the potential treatment of epilepsy, LPCN 2203 an oral candidate targeted for the management of

essential tremor, LPCN 2401 an oral proprietary anabolic androgen receptor agonist, as an adjunct therapy to incretin mimetics, as an aid for improved body composition in obesity management and LPCN 1148, a novel androgen receptor agonist prodrug for oral administration targeted for the management of symptoms associated with liver cirrhosis. Lipocine is exploring partnering opportunities for LPCN 1107, our candidate for prevention of preterm birth, LPCN 1154, for rapid relief of postpartum depression, LPCN 2401 for obesity management, LPCN 1148, for the management of decompensated cirrhosis, and LPCN 1144, our candidate for treatment of metabolic dysfunction-associated steatohepatitis (MASH). TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate developed by Lipocine, is approved by the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. For more information, please visit www.lipocine.com.

Forward-Looking Statements

This release contains "forward-looking statements" that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and include statements that are not historical facts regarding our product candidates and related clinical trials, our development of our product candidates and related efforts with the FDA, including with respect to LPCN 1154, our Phase 3 safety and efficacy study relating to LPCN 1154, the timing and potential results of the safety and efficacy study relating to LPCN 1154, potential partnering of our product candidates with third parties, and the potential uses and benefits of our product candidates. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that we may not be successful in developing product candidates, we may not have sufficient capital to complete the development processes for our product candidates or we may decide to allocate our available capital to other product candidates, we may not be able to enter into partnerships or other strategic relationships to monetize our assets, safety and efficacy studies, including those relating to LPCN 1154, may not be successful or may not provide results that would support the submission of a NDA, the FDA may not approve any of our products, risks related to our products, expected product benefits not being realized, clinical and regulatory expectations and plans not being realized, new regulatory developments and requirements, risks related to the FDA approval process including the receipt of regulatory approvals and our ability to utilize a streamlined approval pathway for LPCN 1154, the results and timing of clinical trials, patient acceptance of Lipocine's products, the manufacturing and commercialization of Lipocine's products, and other risks detailed in Lipocine's filings with the SEC, including, without limitation, its Form 10-K and other reports on Forms 8-K and 10-Q, all of which can be obtained on the SEC website at www.sec.gov. Lipocine assumes no obligation to update or revise publicly any forward-looking statements contained in this release, except as required by law.

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