

# Lipocine Announces FDA Labeling Changes for Testosterone Products

SALT LAKE CITY, March 12, 2025 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a biopharmaceutical company leveraging its proprietary technology platform to augment therapeutics through effective oral delivery, today announced that the U.S. Food and Drug Administration (FDA) has recently informed sponsors of approved testosterone products about class-wide labeling changes. This decision follows the Agency's review of the findings from the [Testosterone Replacement Therapy for Assessment of Long-term Vascular Events and Efficacy Response in Hypogonadal Men \(TRAVERSE\) clinical trial](#) and the results from required post market ambulatory blood pressure (ABPM) studies.

Based on the TRAVERSE trial results, the FDA has recommended that the Boxed Warning related to an increased risk of adverse cardiovascular outcomes be removed from the labels of testosterone products. Additional recommendations include adding the results of the TRAVERSE trial to all testosterone products and retaining "Limitation of Use" language for age-related hypogonadism. The FDA is also requiring all labels to include product-specific information on increased blood pressure for testosterone products based on the results of ABPM studies.

"We are excited about these label changes, including the removal of the Boxed Warning, as we expect the changes to be beneficial to our approved testosterone replacement therapy product as well as for our obesity management and liver disease development candidates," said Dr. Mahesh Patel, President and Chief Executive Officer of Lipocine. "With this important regulatory update, developers and regulators can now be guided by the updated evidence-based labels, ensuring that both the benefits and risks of testosterone are considered."

The company has an exclusive license agreement with Verity Pharma (entered into in 2024) under which Verity Pharma has the rights to market its testosterone replacement therapy product in the United States and also in Canada, if approved. Lipocine's pipeline also includes additional unique testosterone-based product candidates including: LPCN 2401 (in development for obesity management), LPCN 1148 (in development for management of liver cirrhosis), and LPCN 1144 (in development for metabolic dysfunction-associated steatohepatitis (MASH)).

## About Lipocine

Lipocine is a biopharmaceutical company leveraging its proprietary technology platform to augment therapeutics through effective oral delivery to develop differentiated products. 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 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 cirrhosis, and LPCN 1144, our candidate for treatment of non-cirrhotic NASH. 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](http://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 current intention to conduct a 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 non-core assets, safety and efficacy studies.

SOURCE Lipocine Inc.

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