

# Lipocine Announces Publication of LPCN 1144 Liver Fat Study ("LFS") Results

SALT LAKE CITY, Aug. 3, 2020 [/PRNewswire/](#) -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced the peer reviewed publication of LPCN 144 Liver Fat Study ("LFS") results, "LPCN 1144 Resolves Non-Alcoholic Fatty Liver Disease In Hypogonadal Males" in *Hepatology Communications*. Drs. Somaya Albhaisi and Arun Sanyal, from Virginia Commonwealth University, and Dr. Michael Charlton, from the University of Chicago, coauthored the publication. LPCN 1144 is an oral prodrug of bioidentical testosterone ("testosterone undecanoate" or "TU"). The publication can be accessed via:

<https://aasldpubs.onlinelibrary.wiley.com/doi/full/10.1002/hep4.1571>

The study aims were: (1) to determine the prevalence of NAFLD within a population of hypogonadal males and the relationship of circulating testosterone levels with the presence and severity of NAFLD, (2) to evaluate the impact of LPCN 1144 on hepatic steatosis and markers of liver injury in hypogonadal men, and (3) to assess the safety and tolerability of LPCN 1144 in this population.

"We are encouraged by the NAFLD resolution experienced with LPCN 1144 in hypogonadal men and look forward to results from our on-going Phase 2a *LiFT* clinical study in biopsy confirmed NASH subjects which are expected by the end of 2020," said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine.

## About Lipocine

Lipocine Inc. is a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders using its proprietary drug delivery technologies. Lipocine's clinical development pipeline includes: TLANDO, LPCN 1144, TLANDO XR, LPCN 1148 and LPCN 1107. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. Lipocine has resubmitted its NDA to the FDA for TLANDO and has a PDUFA date of August 28, 2020. LPCN 1144, an oral product of bioidentical testosterone, recently completed a proof-of-concept clinical study demonstrating the potential utility in the treatment of non-cirrhotic NASH. LPCN 1144 is currently being studied in a Phase 2 clinical study. TLANDO XR, a novel oral prodrug of testosterone, originated and is being developed by Lipocine as a next-generation oral testosterone product with potential for once-daily dosing. In a phase 2 clinical evaluation when administered as once daily or twice daily TLANDO XR met the typical primary and secondary end points. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the treatment of cirrhosis. LPCN 1107 is potentially the first oral hydroxyprogesterone caproate product candidate, with end of phase 2 meeting completed, indicated for the prevention of recurrent preterm birth and has been granted orphan drug designation by the FDA. 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 Lipocine's product candidates and related clinical trials, the timing of completion of clinical trials, outcomes of clinical trials of our product candidates, the potential uses and benefits of our product candidates, and our product development efforts. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that the FDA will 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, 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](http://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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