

# Lipocine Announces the Presentation of Clinical Data for Oral Testosterone Replacement Therapy Product Candidate TLANDO™ ("LPCN 1021") at the 2016 American Urological Association Annual Meeting

SALT LAKE CITY, May 02, 2016 (GLOBE NEWSWIRE) -- [Lipocine Inc.](#) (NASDAQ:LPCN), a specialty pharmaceutical company, today announced that clinical data for lead candidate TLANDO™ ("LPCN 1021"), will be presented in poster and podium presentations at the 2016 American Urological Association Annual Meeting being held May 6-10 in San Diego, CA. TLANDO is an oral testosterone replacement therapy ("TRT") product candidate being developed for adult males with conditions associated with a deficiency or absence of endogenous testosterone, also known as hypogonadism.

Details are as follows:

Title: [Hypogonadal Men with Sexual Function Disorder Benefit from LPCN 1021 \(Oral Testosterone\) — SOAR \(Study of Androgen Replacement Trial\)](#)

Abstract

No.: MP76-10

Date/Time: Monday, May 9, 2016, 3:30 — 5:30 p.m. PT

Location: San Diego Convention Center, Room 24

Presenter: Culley C. Carson III, MD

Rhodes Distinguished Professor, University of North Carolina Department of Urology  
President, American Society for Men's Health  
Congress President, International Society of Men's Health

Title: [Long-term Safety and Tolerability of Oral Testosterone \(LPCN 1021\) in Hypogonadal Men: Results from the 52-Week Phase 3 Study](#)

Abstract

No.: PD50-06

Date/Time: Tuesday, May 10, 2016, 10:30 a.m. — 12:30 p.m. PT

Location: San Diego Convention Center, Room 23AB

Presenter: Mohit Khera, MD

Associate Professor, Urology, Baylor College of Medicine  
Director, Laboratory for Andrology Research  
Medical Director, Houston Hospital for Specialized Surgery

## About TLANDO

TLANDO is a novel twice-a-day oral testosterone replacement therapy product candidate that is designed to help restore normal testosterone levels in hypogonadal men. The safety and efficacy of TLANDO is currently under FDA review. Lipocine expects TLANDO will help fulfill an unmet need in the treatment of hypogonadism. The current testosterone market primarily uses short-acting injectable products as well as topical products that carry an FDA "black box" warning related to inadvertent transfer of testosterone to others. According to the IMS Health database, an average of half a million prescriptions a month have been dispensed in 2016 for TRT.

## About Lipocine

Lipocine Inc. is a specialty pharmaceutical company developing innovative pharmaceutical products for use in men's and women's health using its proprietary drug delivery technologies. TLANDO, an oral testosterone replacement therapy product candidate, demonstrated positive efficacy and safety results in Phase 3 testing and has a New Drug Application under review with the FDA. LPCN 1111, a next-generation oral testosterone replacement therapy product with once-daily dosing, is currently in Phase 2 testing. LPCN 1107, which has the potential to become the first oral hydroxyprogesterone caproate product indicated for the prevention of recurrent preterm birth, is currently in Phase 1 testing 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 relating to Lipocine's common stock, the FDA review process relating to our product candidates and the possible outcome of such process, clinical trials, the potential uses and benefits of our product candidates, product development and commercialization efforts and the projected timing and outcome of regulatory filings and actions. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks related to our products, expected product benefits, clinical and regulatory expectations and plans, regulatory developments and requirements, risks related to the FDA's review of our NDA for TLANDO, the receipt of regulatory approvals, the results of clinical trials, patient acceptance of Lipocine's products, the manufacturing and commercialization of Lipocine's products, the risks related to market conditions for Lipocine's common stock 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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<https://ir.lipocine.com/Lipocine-Announces-the-Presentation-of-Clinical-Data-for-Oral-Testosterone-Replacement-Therapy-Product-Candidate-TLANDO-TM-LPCN-1021-at-the-2016-American-Urological-Association-Annual-Meeting>