

Lipocine Announces Issuance of U.S. Patent for LPCN 1021

SALT LAKE CITY, July 15, 2014 (GLOBE NEWSWIRE) -- [Lipocine Inc.](#) (Nasdaq:LPCN), a specialty pharmaceutical company, today announced that the United States Patent and Trademark Office (USPTO) has issued U.S. Patent number 8,778,922, entitled "Steroidal Compositions." This patent relates to pharmaceutical compositions having testosterone undecanoate. The patent is expected to provide protection through January 2029 for LPCN 1021.

"This addition to our intellectual property portfolio, which we believe will be listed in the Food and Drug Administration Orange Book, has the potential to significantly lengthen our exclusivity period for LPCN 1021," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "We look forward to presenting top-line data from our pivotal phase 3 study, or SOAR trial, for LPCN 1021 in the third quarter of this year."

LPCN 1021 is a twice-a-day, oral product with low gastro-intestinal drug exposure that we expect will overcome the major shortcomings of existing products with a more patient/physician friendly label that includes three simple dosing options and faster time to maintenance dose in most patients, which we expect will improve patient compliance. Unlike a selective estrogen receptor modulator ("SERM"), LPCN 1021 is not designed to interact with estrogen receptors and is targeted to address an unmet oral option needed in the established testosterone replacement market for chronic use.

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. Lipocine's lead product candidate, LPCN 1021, currently in Phase 3 and is targeted to treat symptoms of low testosterone for men in need of testosterone replacement therapy. Additional pipeline candidates include LPCN 1111, a next generation oral testosterone therapy product, and LPCN 1107, which has the potential to become the first oral hydroxyprogesterone caproate product indicated for the prevention of recurrent preterm birth.

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 includes statements that are not historical facts relating to the potential uses and benefits of Lipocine's product candidates and product development efforts. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks related to the receipt of regulatory approvals, the results 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 U.S. Securities and Exchange Commission (the "SEC"), including, without limitation, its Form 10-K and other reports on Form 8-K, all of which can be obtained on the Company's website at www.lipocine.com or 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.

<https://ir.lipocine.com/Lipocine-Announces-Issuance-of-U-S-Patent-for-LPCN-1021>