

Lipocine Wins Dismissal of Patent Infringement Lawsuit Related to LPCN 1021

SALT LAKE CITY, Oct. 07, 2016 (GLOBE NEWSWIRE) -- [Lipocine Inc.](#) (NASDAQ:LPCN), a specialty pharmaceutical company, today announced that U.S. District Court in Delaware granted our motion to dismiss a lawsuit filed by Clarus Therapeutics, Inc. ("Clarus"). Clarus claimed that LPCN 1021 infringed Clarus' patent (U.S. Patent No. 8,828,428). LPCN 1021 is Lipocine's oral testosterone product candidate for testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency or absence of endogenous testosterone, also known as hypogonadism.

"We are pleased that the court has dismissed this lawsuit. Going forward, we will continue to aggressively defend our intellectual property," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "We believe that LPCN 1021 has the potential to improve the ease of use compared to the available formulations, including topical gels and injections, and to overcome inadvertent testosterone transference risk to children and partners that exist with topical gels."

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 clinical development pipeline includes three development programs LPCN 1021, LPCN 1111 and LPCN 1107. LPCN 1021, a twice-daily oral testosterone replacement therapy product candidate, was well tolerated and met primary efficacy end point in Phase 3 testing which utilized 24-hour pharmacokinetic data for dose adjustments. LPCN 1111, a novel prodrug of testosterone, originated with and is being developed by Lipocine as a next-generation oral testosterone product with potential for once-daily dosing and is currently in Phase 2 testing. LPCN 1107, the potentially first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth, has been granted orphan drug designation by the FDA. An End of Phase 2 meeting with the FDA was recently completed. 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 relating to our intention to defend our intellectual property, the potential uses and benefits of LPCN 1021 and the potential uses and benefits of our other product candidates. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, our available resources, the risks related to our products, expected product benefits, clinical and regulatory expectations and plans, regulatory developments and requirements, 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 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.

CONTACT:

Morgan Brown
Executive Vice President & Chief Financial Officer
Phone: (801) 994-7383
mb@lipocine.com

Investors:
John Woolford
Phone: (443) 213-0500
john.woolford@westwicke.com

<https://ir.lipocine.com/Lipocine-Wins-Dismissal-of-Patent-Infringement-Lawsuit-Related-to-LPCN-1021>