September 21, 2017

Lipocine Announces Motions Decision by USPTO in Interference Against Clarus

SALT LAKE CITY , Sept. 21, 2017 (GLOBE NEWSWIRE) -- Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced that the Patent Trial and Appeal Board ("PTAB") of the United States Patent and Trademark Office ("USPTO") issued a Motions Decision based on each party's motions in the interference case, Patent Interference No. 106,045, between Clarus Therapeutics, Inc. ("Clarus") U.S. Patent No. 8,828,428 (the "Clarus '428 Patent"), and Lipocine Inc. ("Lipocine"), U.S. Patent Application No. 14/713,692 (the "Lipocine '692 Application").

The PTAB granted Lipocine's motion to deny Clarus' previously accorded priority date for the '428 Patent. Therefore, Clarus has a new priority date of April 16, 2014 for the Clarus '428 patent. The PTAB also granted Clarus' motion to deny Lipocine's accorded priority date. Therefore, Lipocine's has an accorded priority date of May 15, 2015 for the Lipocine '692 Application. As a consequence of this decision, the PTAB has redeclared the interference and named Clarus as the senior party and Lipocine as the junior party. All other motions were denied. A conference call with the PTAB is scheduled for October 4, 2017 to discuss the next steps, including priority schedule.

"The outcome of the PTAB decision weakens the validity of the '428 patent's priority date from its April 14, 2006 date to its April 16, 2014 filing date. Given pertinent disclosures by both parties that pre-date Clarus's new priority date we are excited about potential options made available to Lipocine to enforce and defend our intellectual property through this decision," said Dr. Mahesh Patel, Chairman, President and CEO of Lipocine."

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 TLANDO™, LPCN 1111 and LPCN 1107. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, is designed to help restore normal testosterone levels in hypogonadal men. TLANDO was well tolerated and met the primary efficacy end-points in Phase 3 testing with twice daily dosing and is currently under FDA review. LPCN 1111, 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 and is currently in Phase 2 testing. LPCN 1107 is potentially the first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth and has been granted orphan drug designation by the FDA. An End of Phase 2 meeting with the FDA has been 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 regarding Lipocine's options to enforce and defend our intellectual property, product candidates and related clinical trials and the FDA review process relating to its product candidates, the expected timing of the FDA review process related to our resubmitted NDA, the path to approvability by the FDA of Lipocine's development programs, 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, the risk that Bone, Reproductive and Urologic Drugs Advisory Committee may make a negative recommendation to the Commissioner of the FDA with respect to TLANDO, risks related to our ability to enforce and defend our intellectual property, 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 that the FDA will determine there are deficiencies in our resubmitted NDA, 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. 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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