Lipocine Announces Financial and Operational Results for the First Quarter of 2014

SALT LAKE CITY, May 13, 2014 (GLOBE NEWSWIRE) -- Lipocine Inc. (Nasdaq:LPCN), a specialty pharmaceutical company, announced today announced financial results for the quarter ended March 31, 2014, as well as recent operational highlights.

Quarterly and Recent Highlights

- Completed enrollment of its Study of Oral Androgen Replacement ("SOAR") pivotal Phase 3 clinical study (http://clinicaltrials.gov/show/NCT02081300). The trial is designed to evaluate the safety and efficacy of LPCN 1021, oral testosterone undecanoate ("TU"), in hypogonadal men with low testosterone ("Low T"). The Company expects top-line efficacy data for the trial to be available in the third quarter of 2014, with a New Drug Application ("NDA") filing with the U.S. Food and Drug Administration ("FDA") anticipated in the second half of 2015.
- Received approval of its application to list the Company's common stock on the NASDAQ Capital Market by the NASDAQ Stock Market, a unit of the NASDAQ OMX Group, and its common stock began trading on the NASDAQ Capital Market.
- Appointed Dr. Stephen Hill, Mr. Jeffrey Fink, and Dr. R. Dana Ono to the Board of Directors, and announced the retirements of Chairman Dr. William Higuchi and Mr. Gordhan Patel. Dr. Mahesh Patel, Lipocine President and Chief Executive Officer, assumed the position of Chairman of the Board and Dr. Higuchi now serves as the Company's Chief Scientific Advisor.
- Initiated and completed enrollment in its Phase 1/2 pharmacokinetic study in healthy women with LPCN 1107, oral hydroxyprogesterone caproate. The Company expects to release results from the Phase 1/2 trial in the second quarter of 2014.

"We have already made substantial progress in 2014, with completion of enrollment for our pivotal Phase 3 study for LPCN 1021 and our uplisting to the NASDAQ Capital Market," said Dr. Mahesh Patel, President, CEO and Chairman of Lipocine Inc. "We have several other potential value-creating events expected for the remainder of 2014, most notably top-line efficacy data from the SOAR trial in the third quarter."

First Quarter 2014 Financial Results

Research and development expenses were $3.4 million in the first quarter of 2014, compared with $0.6 million in the first quarter of 2013. The increase was largely attributable to costs associated with development of product candidates, primarily LPCN 1021. General and administrative expenses were $1.9 million in the first quarter of 2014, compared with $0.7 million for the same period in 2013. The increase was primarily the result of higher professional fees associated with being a public company as well as in increase in personnel costs.

Lipocine reported a net loss of $5.3 million, or $0.41 per diluted share, for the first quarter of 2014, compared with a net loss of $1.4 million, or $0.30 per diluted share, for the first quarter of 2013.

As of March 31, 2014, Lipocine had cash and cash equivalents of $41.8 million, compared with cash and cash equivalents of $45.3 million as of December 31, 2013.

About LPCN 1021

The current testosterone market is dominated by topical products that are associated with poor patient compliance and FDA "black box" warnings related to inadvertent transfer of testosterone. 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 is expected to 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 expectations, clinical trials, 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, risks and uncertainties 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, Forms 10-Q and current 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.
