Lipocine Announces Financial and Operational Results for the Full Year 2014

SALT LAKE CITY, March 11, 2015 (GLOBE NEWSWIRE) -- Lipocine Inc. (Nasdaq:LPCN), a specialty pharmaceutical company, today announced financial results for the full year ended December 31, 2014, as well as recent operational highlights.

Quarterly and Recent Highlights

- Lipocine presented data from its ongoing Study of Oral Androgen Replacement ("SOAR") pivotal Phase 3 clinical study (http://clinicaltrials.gov/show/NCT02081300) evaluating efficacy and safety of LPCN 1021, an Oral Testosterone product, in hypogonadal men with low testosterone ("Low T") at ENDO 2015 in San Diego, CA. Overall, the study demonstrated positive results with respect to the trial's primary efficacy endpoint with no drug related serious adverse events to date.
- Lipocine announced successful top-line results of a Phase 1b study of LPCN 1107, the company's oral hydroxyprogesterone caproate ("HPC") product candidate. The primary objectives of the study were to determine the pharmacokinetics and bioavailability of LPCN 1107 relative to an intramuscular ("IM") HPC, as well as safety and tolerability in pregnant women. Results from this study demonstrated significant HPC absorption following oral administration in healthy pregnant women. In this study, LPCN 1107 was well tolerated with no serious adverse events observed. Lipocine plans to review the development plan with FDAbefore deciding next steps in the program.
- Lipocine presented data from a successful Phase 1a study of LPCN 1107 at theSociety for Maternal-Fetal Medicine 35th Annual Meeting in San Diego, CA. The study was designed to determine the pharmacokinetics and bioavailability of LPCN 1107 relative to an intramuscular (IM) HPC, as well as safety and tolerability, in healthy non-pregnant female volunteers.
- Lipocine successfully completed a Phase 2a clinical study of LPCN 1111, a next-generation novel testosterone TRT product candidate, in hypogonadal males with Low T. The primary objective of the study was to determine the feasibility of once daily dosing of LPCN 1111 in hypogonadal males. Based on these positive results, a Phase 2b study is planned to begin post clarity from the FDA on the "TRT" class label with the objective of determining the optimal once daily dosing regimen of LPCN 1111.

"We continue to make progress with LPCN 1021, both progressing the SOAR Phase 3 study and receiving confirmation from the FDA regarding our ability to file an NDA based on the SOAR Phase 3 design," said DrMahesh Patel, President and CEO of Lipocine Inc. "In addition, we also made important strides with our other two clinical candidates, delivering positive clinical data for LPCN 1107 and LPCN 1111."

Full Year 2014 Financial Results

For the full year of 2014, research and development expenses were$15.5 million, compared with $5.1 million for the full year of 2013. The increase was largely attributable to external service provider costs associated with development of product candidates, primarily LPCN 1021, partially offset by a reduction in manufacturing and drug purchase costs.

For the full year of 2014, general and administrative expenses were$5.0 million, compared with $3.6 million for the same period in 2013. The increase was primarily due to increased compensation expense, including increases in equity compensation due primarily to accelerated vesting and/or extension of exercise dates for retiring directors and a terminated officer; as well as increased compensation expense for new administrative personnel and severance payments to a terminated officer.

Lipocine reported a net loss of $20.4 million, or $1.60 per diluted share, for the full year of 2014, compared with a net loss of $10.6 million, or $1.44 per diluted share, for the full year of 2013.

As of December 31, 2014, Lipocine had cash and cash equivalents of$27.7 million, compared with cash and cash equivalents of $45.3 million as of December 31, 2013.

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, demonstrated positive top-line efficacy results in Phase 3 testing and is targeted for testosterone replacement therapy. Additional pipeline candidates include LPCN 1111, a next generation oral testosterone therapy product with once daily dosing, that is currently in Phase 2 testing, and LPCN 1107, which has the potential to become the first oral hydroxyprogesterone caproate product indicated for the prevention of recurrent preterm birth, and is currently in Phase 1 testing.

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 expectations regarding clinical trials, the potential uses and benefits of Lipocine's product candidates, and product development and commercialization efforts. 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, 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'sfilings with the U.S. Securities and Exchange Commission (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 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.

LIPOCINE INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

Years Ending December 31, 2014 and 2013

	2014	2013
Operating expenses:		
Research and development	$ 15,479,446	$ 5,122,864
General and administrative	5,001,368	3,635,690
Reverse merger costs	--	1,011,630
Settlement for termination of certain rights in stock purchase agreement	--	913,446
Total operating expenses	20,480,814	10,683,630
Operating loss	(20,480,814)	(10,683,630)
Other income, net	108,338	38,476
Loss before income tax expense	(20,372,476)	(10,645,154)
Income tax benefit (expense)	(200)	55,048
Net loss	$ (20,372,676)	$ (10,590,106)
Basic loss per share attributable to common stock	$ (1.60)	$ (1.44)
Weighted average common shares outstanding, basic	12,766,295	7,363,076
Diluted loss per share attributable to common stock	$ (1.60)	$ (1.44)
Weighted average common shares outstanding, diluted	12,766,295	7,363,076
Comprehensive loss	$ (20,372,676)	$ (10,590,106)

LIPOCINE INC. AND SUBSIDIARIES

Consolidated Balance Sheets

December 31, 2014 and 2013

	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	$ 27,666,055	$ 45,263,698
Prepaid and other current assets	229,912	770,030
Total current assets	27,895,967	46,033,728
Property and equipment, net accumulated depreciation of $1,034,029 and $1,019,409, respectively	73,782	28,794
Other assets	23,753	45,000
Total assets	$ 27,993,502	$ 46,107,522
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 306,276	$ 1,027,021
Accrued expenses	1,327,256	256,754
Total current liabilities	1,633,532	1,283,775
Total liabilities	1,633,532	1,283,775
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $0.0001 per share, 10,000,000 shares authorized; zero issued and outstanding	--	--
Common stock, par value $0.0001 per share, 100,000,000 shares authorized; 12,800,382 and 12,668,393 issued and 12,794,672 and 12,668,393 outstanding	1,280	1,267

Additional paid-in capital	94,636,479	92,686,881
Treasury stock at cost, 5,710 and zero shares	(40,712)	--
Accumulated deficit	(68,237,077)	(47,864,401)
Total stockholders' equity	26,359,970	44,823,747
Total liabilities and stockholders' equity	$ 27,993,502	$ 46,107,522

https://ir.lipocine.com/Lipocine-Announces-Financial-and-Operational-Results-for-the-Full-Year-2014