

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

SALT LAKE CITY, Nov. 10, 2014 (GLOBE NEWSWIRE) -- [Lipocine Inc.](#) (Nasdaq:LPCN), a specialty pharmaceutical company, today announced financial results for the quarter ended September 30, 2014, as well as recent operational highlights.

Quarterly and Recent Highlights

- LPCN 1021 demonstrated positive top-line efficacy results in the 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 replacement therapy product candidate, in hypogonadal men with low testosterone ("Low T"). Overall, the study demonstrated positive results with respect to the trial's primary efficacy endpoint with no serious adverse events. Lipocine continues to expect to file a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") in the second half of 2015.
- 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 in the first quarter of 2015 with the objective of determining the optimal once daily dosing regimen of LPCN 1111.
- The first patient was dosed in a Phase 1 study in pregnant women of LPCN 1107, an oral hydroxyprogesterone caproate ("HPC") product candidate indicated for the prevention of recurrent preterm birth. The primary objectives of the study will be to determine safety, tolerability and pharmacokinetics of oral administration of LPCN 1107 in pregnant subjects. Top-line results from this study are expected in the first quarter of 2015.

"The highlight of the quarter were the positive top-line efficacy results from our SOAR trial for LPCN 1021," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "Based on the data, we continue to believe that LPCN 1021 represents a significant opportunity, given the product's profile to-date and the need for a convenient, orally available testosterone replacement therapy."

Third Quarter 2014 Financial Results

Research and development expenses were \$3.2 million in the third quarter of 2014, compared with \$1.6 million in the third quarter of 2013. The increase was largely attributable to costs associated with development of product candidates, primarily LPCN 1021, partially offset by a reduction in manufacturing and drug purchase costs. General and administrative expenses were \$872,000 in the third quarter of 2014, compared with \$1.2 million for the same period in 2013. The decrease was primarily the result of higher professional fees associated with preparing to be a public company in 2013.

Lipocine reported a net loss of \$4.1 million, or \$0.32 per diluted share, for the third quarter of 2014, compared with a net loss of \$3.5 million, or \$0.39 per diluted share, for the third quarter of 2013.

As of September 30, 2014, Lipocine had cash and cash equivalents of \$31.7 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, 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 includes 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 efforts. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks related to products, product benefits, clinical and regulatory expectations and plans, the receipt of regulatory approvals, pre-clinical and clinical development timelines, the results of clinical trials, patient acceptance of Lipocine's products, the manufacturing and commercialization of Lipocine's products, anticipated financial performance, future revenues or earnings, business prospects, projected ventures, new products and services, anticipated market performance, future expectations for liquidity and capital resources needs, 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 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

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

<u>Three Months Ending September 30,</u>		<u>Nine Months Ending September 30,</u>	
<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>

Operating expenses:				
Research and development	\$ 3,246,526	\$ 1,568,969	\$ 12,589,355	\$ 2,657,936
General and administrative	871,825	1,181,894	3,831,181	2,601,557
Reverse merger costs	--	794,902	--	1,011,630
Total operating expenses	<u>4,118,351</u>	<u>3,545,765</u>	<u>16,420,536</u>	<u>6,271,123</u>
Operating loss	(4,118,351)	(3,545,765)	(16,420,536)	(6,271,123)
Other income, net	24,299	15,084	87,700	16,295
Loss before income tax expense	<u>(4,094,052)</u>	<u>(3,530,681)</u>	<u>(16,332,836)</u>	<u>(6,254,828)</u>
Income tax benefit	--	55,342	--	55,048
Net loss	<u>\$ (4,094,052)</u>	<u>\$ (3,475,339)</u>	<u>\$ (16,332,836)</u>	<u>\$ (6,199,780)</u>
Basic loss per share attributable to common stock	<u>\$ (0.32)</u>	<u>\$ (0.39)</u>	<u>\$ (1.28)</u>	<u>\$ (1.04)</u>
Weighted average common shares outstanding, basic	<u>12,775,324</u>	<u>8,914,666</u>	<u>12,757,144</u>	<u>5,958,415</u>
Diluted loss per share attributable to common stock	<u>\$ (0.32)</u>	<u>\$ (0.39)</u>	<u>\$ (1.28)</u>	<u>\$ (1.04)</u>
Weighted average common shares outstanding, diluted	<u>12,775,324</u>	<u>8,914,666</u>	<u>12,757,144</u>	<u>5,958,415</u>
Comprehensive loss	<u>\$ (4,094,052)</u>	<u>\$ (3,475,339)</u>	<u>\$ (16,332,836)</u>	<u>\$ (6,199,780)</u>

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets (Unaudited)

	September 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 31,667,417	\$ 45,263,698
Prepaid and other current assets	285,916	770,030
Total current assets	<u>31,953,333</u>	<u>46,033,728</u>
Property and equipment, net accumulated depreciation of \$1,028,796 and \$1,019,409, respectively	40,687	28,794
Other assets	23,753	45,000
Total assets	<u>\$ 32,017,773</u>	<u>\$ 46,107,522</u>

Liabilities and Stockholders' Equity

Current liabilities:		
Accounts payable	\$ 399,113	\$ 1,027,021
Accrued expenses	1,657,788	256,754
Total current liabilities	<u>2,056,901</u>	<u>1,283,775</u>
Total liabilities	<u>2,056,901</u>	<u>1,283,775</u>

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; 12,784,382 and 12,668,393 issued and 12,778,672 and 12,668,393 outstanding	1,278	1,267
Additional paid-in capital	94,197,543	92,686,881
Treasury stock at cost, 5,710 and zero shares	(40,712)	--
Accumulated deficit	(64,197,237)	(47,864,401)
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Total stockholders' equity	29,960,872	44,823,747
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Total liabilities and stockholders' equity	<u>\$ 32,017,773</u>	<u>\$ 46,107,522</u>

<https://ir.lipocine.com/Lipocine-Announces-Financial-and-Operational-Results-for-the-Third-Quarter-of-2014>