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

SALT LAKE CITY, Aug. 13, 2014 (GLOBE NEWSWIRE) -- Lipocine Inc. (Nasdaq:LPCN), a specialty pharmaceutical company, today announced financial results for the quarter ended June 30, 2014, as well as recent operational highlights.

Quarterly and Recent Highlights

- Lipocine 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.
- The United States Patent and Trademark Office (USPTO) issued U.S. Patent number 8,778,922, entitled "Steroidal Compositions." This patent relates to pharmaceutical compositions having testosterone undecanoate. The patent is expected to provide protection through January 2029 for LPCN 1021.
- The first patient was dosed in a Phase 2a clinical study of LPCN 1111, a novel ester prodrug of testosterone, in hypogonadal males. The primary objectives of the study will be to determine safety, tolerability, single and steady state pharmacokinetics of testosterone following oral administration of LPCN 1111. Top-line results from this study are expected in the second half of 2014.
- Lipocine successfully completed a Phase 1 study of LPCN 1107, the company's oral hydroxyprogesterone caproate (HPC) product candidate. 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 was added to the Russell Microcap Index when Russell Investments reconstituted its comprehensive set of U.S. and global equity indices on June 27, 2014.

"Lipocine continues to make significant progress across our entire pipeline, achieving milestones in all of our programs in the last few months. Our next key milestone will be the top-line results from our SOAR trial for LPCN 1021 in the third quarter," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "We continue to believe a significant potential demand exists for a convenient, orally available testosterone replacement therapy. In addition, we believe that the safety of testosterone replacement continues to be reinforced, including the recent FDA response to a citizen's petition on the issue."

Second Quarter 2014 Financial Results

Research and development expenses were $6.0 million in the second quarter of 2014, compared with $0.4 million in the second quarter of 2013. The increase was largely attributable to costs associated with development of product candidates, primarily LPCN 1021. General and administrative expenses were $1.0 million in the second 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 $7.0 million, or $0.55 per diluted share, for the second quarter of 2014, compared with a net loss of $1.4 million, or $0.31 per diluted share, for the second quarter of 2013.

As of June 30, 2014, Lipocine had cash and cash equivalents of $34.2 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, 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 such forward-looking statements include statements that are not historical facts relating to an expectation that top-line efficacy data for our LPCN 1021 pivotal Phase 3 clinical study will be available in the third quarter of 2014 and an anticipation of our NDA filing in the second half of 2015; an expectation regarding patent protection for LPCN 1021 through January 2029; expectations relating to top-line results from our LPCN 1111 Phase 2a clinical study in the second half of 2014; statements regarding the potential uses and benefits of Lipocine's product candidates and statements regarding our product development efforts. Investors are cautioned that all such forward-looking statements may not be realized and are subject to and involve risks and uncertainties, including, without limitation, the risks 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, its Quarterly Reports on Form 10-Q and other 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.

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	Three Months Ending June 30,		Six Months Ending June 30,	
	2014	2013	2014	2013
Operating expenses:				
Research and development	$ 5,973,829	$ 443,857	$ 9,342,829	$ 1,088,967
General and administrative	1,035,733	712,627	2,959,356	1,419,663
Reverse merger costs	--	216,728	--	216,728
Total operating expenses	7,009,562	1,373,212	12,302,185	2,725,358
Operating loss	(7,009,562)	(1,373,212)	(12,302,185)	(2,725,358)
Other income, net	37,935	687	63,401	1,211
Loss before income tax expense	(6,971,627)	(1,372,525)	(12,238,784)	(2,724,147)
Income tax expense	--	(182)	--	(294)
Net loss	$ (6,971,627)	$ (1,372,707)	$ (12,238,784)	$ (2,724,441)
Basic loss per share attributable to common stock	$ (0.55)	$ (0.31)	$ (0.96)	$ (0.61)
Weighted average common shares outstanding, basic	12,770,391	4,455,790	12,749,355	4,455,790
Diluted loss per share attributable to common stock	$ (0.55)	$ (0.31)	$ (0.96)	$ (0.61)
Weighted average common shares outstanding, diluted	12,770,391	4,455,790	12,749,355	4,455,790
Comprehensive loss	$ (6,971,627)	$ (1,372,707)	$ (12,238,784)	$ (2,724,441)

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets

(Unaudited)

	June 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 34,164,006	$ 45,263,698
Prepaid and other current assets	1,273,163	770,030
Total current assets	35,437,169	46,033,728
Property and equipment, net accumulated depreciation of $1,025,467 and $1,019,409, respectively	24,602	28,794
Other assets	23,753	45,000
Total assets	$ 35,485,524	$ 46,107,522
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 641,801	$ 1,027,021
Accrued expenses	1,028,570	256,754
Total current liabilities	1,670,371	1,283,775
Total liabilities	1,670,371	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; 12,780,382 and 12,668,393 issued and 12,774,672 and 12,668,393 outstanding	1,278	1,267
Additional paid-in capital	93,957,772	92,686,881
Treasury stock at cost, 5,710 and zero shares	(40,712)	--
Accumulated deficit	(60,103,185)	(47,864,401)
Total stockholders' equity	33,815,153	44,823,747
Total liabilities and stockholders' equity	$ 35,485,524	$ 46,107,522

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