Lipocine Announces Financial and Operational Results for the Second Quarter of 2015

SALT LAKE CITY, Aug. 11, 2015 (GLOBE NEWSWIRE) --Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced financial results for the quarter ended June 30, 2015, as well as recent operational highlights.

Quarterly and Recent Highlights

- Delivered top-line 52-week safety results from its Study of Oral Androgen Replacement cardiac ("SOAR") pivotal Phase 3 clinical study (http://clinicaltrials.gov/show/NCT02081300) evaluating efficacy and safety of LPCN 1021, an oral testosterone product candidate, in hypogonadal men with low testosterone. Overall, LPCN 1021 was well tolerated with no hepatic, cardiac, gastrointestinal or drug-related SAE's reported.
- Announced the successful completion of its labeling "food effect study" for LPCN 1021, which was conducted per the U.S. Food and Drug Administration ("FDA") requirement for submitting the New Drug Application ("NDA") for LPCN 1021. The top-line results of the study indicated that bioavailability of testosterone from LPCN 1021 is not affected by changes in meal fat content.
- Announced its development plans for LPCN 1107, the company's oral hydroxyprogesterone caproate ("HPC") product candidate. Based on FDA Type C written feedback, Lipocine intends to conduct a multiple-dose pharmacokinetic ("PK") dose selection study in pregnant women. The PK dose selection study is planned to commence in the fourth quarter of 2015.
- During the quarter, the FDA granted Lipocine orphan drug designation for LPCN 1107.
- Completed an underwritten public offering of 5,347,500 shares of its common stock at $6.50 per share for gross proceeds of $34.8 million. Lipocine received net proceeds of approximately $32.4 million, after deducting the underwriters' discounts and other estimated offering expenses.
- Presented additional data from its ongoing SOAR pivotal Phase 3 clinical study evaluating efficacy and safety of LPCN 1021 at both the American Urological Association Annual Meeting and the American Society of Andrology 40th Annual Conference.
- Appointed Jyrki Mattila, M.D., Ph.D., M.B.A to the newly created position of Executive Vice President and Chief Business Officer. In this role, Dr. Mattila will oversee business development and commercialization efforts for the Company.

"The highlight of the quarter was the announcement of the positive 52-week safety data from our Phase 3 study of LPCN 1021. Combined with successful completion of the food effect study, we are well-positioned to file our NDA in the second half of 2015" said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "In addition, the recent completion of our public offering in the quarter has allowed us to accelerate the development of both LPCN 1111 and LPCN 1107 and ensure sufficient capital for on-going pre-commercial activities with LPCN 1021."

Second Quarter 2015 Financial Results

Lipocine reported a net loss of $4.2 million, or $0.26 per diluted share, for the second quarter of 2015, compared with a net loss of $7.0 million, or $0.55 per diluted share, for the second quarter of 2014.

For the second quarter of 2015, research and development expenses were $3.2 million, compared with $6.0 million for the second quarter of 2014. The decrease was largely attributable to decreased external service provider costs related to clinical research and contract manufacturing costs.

For the second quarter of 2015, general and administrative expenses were $1.1 million, compared with $1.0 million for the same period in 2014. The slight increase was primarily due to increased personnel costs, partially offset by a decrease in professional fees and other.

As of June 30, 2015, Lipocine had cash, cash equivalents, and marketable investment securities of $53.4 million, compared with cash and cash equivalents of $27.7 million as of December 31, 2014.

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 with orphan drug designation, 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, product development and commercialization efforts and the projected timing of regulatory filings. 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'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)

	Three Months Ending June 30,		Six Months Ending June 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	$ 3,161,908	$ 5,973,829	$ 5,080,603	$ 9,342,829
General and administrative	1,115,835	1,035,733	2,171,379	2,959,356
Total operating expenses	4,277,743	7,009,562	7,251,982	12,302,185
Operating loss	(4,277,743)	(7,009,562)	(7,251,982)	(12,302,185)
Other income, net	31,297	37,935	49,930	63,401
Loss before income tax expense	(4,246,446)	(6,971,627)	(7,202,052)	(12,238,784)
Income tax expense	--	--	(200)	--
Net loss	$ (4,246,446)	$ (6,971,627)	$ (7,202,252)	$ (12,238,784)
Basic loss per share attributable to common stock	$ (0.26)	$ (0.55)	$ (0.49)	$ (0.96)
Weighted average common shares outstanding, basic	16,496,239	12,770,391	14,667,943	12,749,355
Diluted loss per share attributable to common stock	$ (0.26)	$ (0.55)	$ (0.49)	$ (0.96)
Weighted average common shares outstanding, diluted	16,496,239	12,770,391	14,667,943	12,749,355
Comprehensive loss:				
Net loss	$ (4,246,446)	$ (6,971,627)	$ (7,202,252)	$ (12,238,784)
Unrealized net loss on available-for-sale securities	(10,085)	--	(10,085)	--
Comprehensive loss	$ (4,256,531)	$ (6,971,627)	$ (7,212,337)	$ (12,238,784)

LIPOCINE INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets

(Unaudited)

	June 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 38,297,243	$ 27,666,055
Marketable investment securities	5,571,535	--
Accrued interest income	99,451	--
Prepaid and other current assets	181,275	229,912

Total current assets	44,149,504	27,895,967
Property and equipment, net of accumulated depreciation of$1,042,746 and $1,034,029, respectively	79,864	73,782
Long-term marketable investment securities	9,543,570	--
Other assets	23,753	23,753
Total assets	$ 53,796,691	$ 27,993,502
Current liabilities:		
Accounts payable	$ 398,817	$ 306,276
Accrued expenses	1,266,188	1,327,256
Total current liabilities	1,665,005	1,633,532
Total liabilities	1,665,005	1,633,532
Liabilities and Stockholders' Equity		
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; 18,205,740 and 12,800,382 issued and 18,200,030 and 12,794,672 outstanding	1,820	1,280
Additional paid-in capital	127,619,992	94,636,479
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(10,085)	--
Accumulated deficit	(75,439,329)	(68,237,077)
Total stockholders' equity	52,131,686	26,359,970
Total liabilities and stockholders' equity	$ 53,796,691	$ 27,993,502

CONTACT: Morgan Brown

Executive Vice President & Chief Financial Officer

Phone: (801) 994-7383

Email: mb@lipocine.com

John Woolford

Phone: (443) 213-0500

john.woolford@westwicke.com
