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

SALT LAKE CITY, Nov. 12, 2015 (GLOBE NEWSWIRE) --Lipocine Inc. (NASDAQ:LPCN), a specialty pharmaceutical company, today announced financial results for the quarter ended September 30, 2015, as well as recent operational highlights.

Quarterly and Recent Highlights

- Submitted a 505(b)(2) New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for LPCN 1021, an oral testosterone product candidate for testosterone replacement therapy ("TRT") in adult males for conditions associated with a deficiency or absence of endogenous testosterone ("hypogonadism"). The filing is supported by results from Lipocine's Study of Oral Androgen Replacement ("SOAR") pivotal Phase 3 clinical study (http://clinicaltrials.gov/show/NCT02081300) evaluating efficacy and safety of LPCN 1021 in hypogonadal men with low testosterone.

- Announced first subject dosed in its multi-dose PK dose finding clinical study for LPCN 1107, the company's oral hydroxyprogesterone caproate ("HPC") product candidate, being developed as a potential therapy for the prevention of pre-term birth ("PTB"). The primary objective of the study will be to study pharmacokinetics over an extended period of time with multiple dose strengths of oral administration of LPCN 1107 in pregnant women.

- Announced the acceptance of the NDA for LPCN 1021 by the FDA. The FDA has assigned a Prescription Drug User Fee Act ("PDUFA") action date of June 28, 2016, for completion of the review of the NDA for LPCN 1021. Additionally the 74-day filing communication letter did not mention a need to convene an Advisory Committee for advice on the NDA for LPCN 1021.

"The highlight of the quarter was the filing of our NDA for LPCN 1021, a significant milestone for the company. We remain focused on bringing this oral testosterone replacement product candidate to patients, which we believe has the potential both to improve the ease of use compared to the available formulations, including topical gels and injections, and to overcome inadvertent testosterone transference risk to children and partners," said Dr. Mahesh Patel, President and CEO of Lipocine Inc. "In addition, we made significant progress on the development of LPCN 1107, one of our novel pipeline products."

Third Quarter 2015 Financial Results

Lipocine reported a net loss of $6.4 million, or $0.35 per diluted share, for the third quarter of 2015, compared with a net loss of $4.1 million, or $0.32 per diluted share, for the third quarter of 2014.

For the third quarter of 2015, research and development expenses were $4.7 million, compared with $3.2 million for the third quarter of 2014. The increase was largely attributable to a one-time payment of $2.3 million to the FDA for the NDA filing, partially offset by decreased clinical research, consultant and manufacturing costs related as Phase 3 study for LPCN 1021 was completed.

For the third quarter of 2015, general and administrative expenses were $1.7 million, compared with $872,000 for the same period in 2014. The increase was primarily due to increased personnel costs and costs related to market research and pre-commercialization activities.

As of September 30, 2015, Lipocine had cash, cash equivalents, and marketable investment securities of $47.8 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. LPCN 1021 demonstrated positive efficacy and safety results in Phase 3 testing, is targeted for testosterone replacement therapy and has a NDA under review with the FDA. Additional pipeline candidates include LPCN 1111, a next generation oral testosterone replacement 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, that 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 and actions. 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.

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LIPOCINE INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ending September 30,		Nine Months Ending September 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	$ 4,733,889	$ 3,246,526	$ 9,814,492	$ 12,589,355
General and administrative	1,700,099	871,825	3,871,478	3,831,181
Total operating expenses	6,433,988	4,118,351	13,685,970	16,420,536
Operating loss	(6,433,988)	(4,118,351)	(13,685,970)	(16,420,536)
Other income, net	61,560	24,299	111,490	87,700
Loss before income tax expense	(6,372,428)	(4,094,052)	(13,574,480)	(16,332,836)
Income tax expense	-	-	(200)	-
Net loss	$ (6,372,428)	$ (4,094,052)	$ (13,574,680)	$ (16,332,836)
Basic loss per share attributable to common stock	$ (0.35)	$ (0.32)	$ (0.86)	$ (1.28)
Weighted average common shares outstanding, basic	18,238,632	12,775,324	15,871,252	12,757,144
Diluted loss per share attributable to common stock	$ (0.35)	$ (0.32)	$ (0.86)	$ (1.28)
Weighted average common shares outstanding, diluted	18,238,632	12,775,324	15,871,252	12,757,144
Comprehensive loss:				
Net loss	$ (6,372,428)	$ (4,094,052)	$ (13,574,680)	$ (16,332,836)
Unrealized gain on available-for-sale securities	15,887	-	5,802	-
Comprehensive loss	$ (6,356,541)	$ (4,094,052)	$ (13,568,878)	$ (16,332,836)

LIPOCINE INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(Unaudited)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 23,925,531	$ 27,666,055
Marketable investment securities	17,868,989	-
Accrued interest income	146,844	-
Prepaid and other current assets	347,755	229,912
Total current assets	42,289,119	27,895,967

Property and equipment, net of accumulated depreciation of $1,053,595 and $1,034,029, respectively	82,906	73,782
Long-term marketable investment securities	6,032,439	-
Other assets	23,753	23,753
Total assets	$ 48,428,217	$ 27,993,502
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 456,830	$ 306,276
Accrued expenses	1,722,146	1,327,256
Total current liabilities	2,178,976	1,633,532
Total liabilities	2,178,976	1,633,532
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; 18,249,456 and 12,800,382 issued and 18,243,746 and 12,794,672 outstanding	1,825	1,280
Additional paid-in capital	128,094,083	94,636,479
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive income	5,802	-
Accumulated deficit	(81,811,757)	(68,237,077)
Total stockholders' equity	46,249,241	26,359,970
Total liabilities and stockholders' equity	$ 48,428,217	$ 27,993,502

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https://ir.lipocine.com/Lipocine-Announces-Financial-and-Operational-Results-for-the-Third-Quarter-of-2015